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OBVIOUSNESS GUIDANCE AT THE PTO

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INTRODUCTION

The doctrine of obviousness dictates that an invention is patentable only if it is "nonobvious to a person having ordinary skill in the art."[1] This doctrine has the function of balancing the social cost of an exclusive patent right with the contribution that a technological invention brings to society.

The obviousness determination is notoriously indeterminate[2] and is prone to two types of errors. Type II errors, also known as false negatives, refer to granted patents that are actually invalid.[3] These so-called "bad patents" have long been at the center of public discussion.[4] They create deadweight loss and impose various

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[1] 35 U.S.C. § 103 (2013).

[2] *E.g.*, Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57 (2008). For further references, see *infra* notes 24-28.

[3] *See* RONALD E. WALPOLE ET AL., PROBABILITY AND STATISTICS FOR ENGINEERS AND SCIENTISTS 342 (Sally Yagan et al. eds., 8th ed. 2007) ("Nonrejection of the null hypothesis when it is false is called a type II error.").

[4] E.g., FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5-7 (2003) (arguing that questionable patents deter and raise the cost of innovation, and increase defensive patenting and licensing complications); NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 81-82 (Stephen A. Merrill et al. eds. 2004), http://www.nap.edu/catalog/10976/a-patent-system-for-the-21st-century (finding that obviousness standard is too low in granted patents, especially in fields of business method patents and gene sequence patents); John F. Luman III & Christopher L. Dodson, *No Longer a Myth, the Emergence of the Patent Toll*, 18 INTELL. PROP. & TECH. L.J. 12, 13 (2006), https://quote.ucsd.edu/jskrentny/files/2014/08/LumanDodsonPatentTrolls.pdf ("many software patents simply cover inventions that were obvious at the time of the patent application"); Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 1026 (raising the criticism that many software patents simply cover inventions that were obvious); David Balto, *Stop Bad Patents Before They Become Problems*, U.S. NEWS, Sept. 5, 2013 (reporting on a campaign to bring attention to patent trolls); Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613 (2015) (detailing empirical study confirming that the USPTO is biased in favor of granting patents that are invalid); Jay P. Kesan & Andres A. Gallo, *Why "Bad" Patents Survive in the Market and How Should We Change? The Private and Social Costs of Patents*, 55 EMORY L.J. 61 (2006); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305 (2001); Adam B. Jaffe & Josh Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress*, 6 INNOVATION POL'Y & ECON. 27, 29-31 (2006) (arguing that recent changes in the patent system have resulted in increased litigation and a greater threat of litigation, creating a net social loss); Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*,

costs to society,[5] inflating the market price for products that embody patented inventions, hindering downstream research in areas fraught with substandard patents,[6] and diverting resources to acquire, enforce, maintain, and defend against these substandard patents.[7] Bad patents also contribute to the "patent troll" phenomenon, permitting patent holders to abuse the system by threatening lawsuits with their amassed portfolio of dubious or trivial patents.[8]

On the other hand, Type I errors are patent rejections that should have been granted. Type I errors receive relatively less attention,[9] but are nonetheless important; they reduce incentives in research and development activities, and eventually undermine the patent system's goal of promoting the progress of useful arts.

Errors can occur at both the agency level and the court level. The U.S. patent regime functions in a tiered system. First, in a process called patent prosecution, the applicant files a patent application with the United States Patent and Trademark Office (PTO), which examines the application and makes the decision to grant or reject a patent.[10] Later, a small proportion of granted patents will become the

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40 HOUS. L. REV. 1219, 1227-35 (2004) (discussing the social costs of low quality patents); T. R. Beard et al., *Quantifying the Cost of Substandard Patents: Some Preliminary Evidence*, 12 YALE J.L. & TECH. 240 (2010).

[5] Beard et al., *supra* note 4 (finding that the economic losses resulting from the grant of substandard patents can reach $21 billion per year by deterring valid research with an additional deadweight loss from litigation and administrative costs of $4.5 billion annually).

[6] *See* Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 17 J. ECON. PERSP. 131, 147 (2002) (noting the negative consequences of lowering the standard for nonobviousness and granting more questionable patents).

[7] *See, e.g.*, Bloomberg West, *TV News Archive*, BLOOMBERG (May 23, 2014, 11:41 PM), https://archive.org/details/BLOOMBERG_20140524_030000_Bloomberg_West?q=4700+3000+patent+troll - start/2516/end/2576 ("Of 4700 patent suits filed in 2012, 3000 were filed by patent trolls"); Balto, *supra* note 4 ("Patents trolls are targeting retailers as easy targets for quick money over questionable patents covering things like Wi-Fi and website features.").

[8] *E.g.*, T.J. Chiang, *What is a Troll Patent and Why are They Bad?*, PATENTLY-O, (Mar. 6, 2009), http://patentlyo.com/patent/2009/03/what-is-a-troll-patent-and-why-are-they-bad.html; Mark A. Lemley & Doug Lichtman, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 48 (2007) ("Sadly, a large and growing number of 'patent trolls' today play this exact strategy, using patents on obvious inventions quite literally to tax legitimate business activity.").

[9] Ron. D. Katznelson, *Patent Reforms Must Focus on the U.S. Patent Office*, MED. INNOVATION & BUS. 77, 78 (2010) ("Allowance errors receive more attention because they are more visible …. Costs of rejection errors are less visible, but no less real.").

[10] 35 U.S.C. § 141(d) (2012) (stating that an applicant of a rejected application have the opportunity to appeal within the agency to the Patent Trial and Appeal Board, appeal to the Federal Circuit); or 35 U.S.C. § 145 (2012) (stating that an applicant dissatisfied with the

subject of patent infringement disputes, and the potential infringer can opt to challenge the validity of the patent either in a federal district court[11] or at the Patent Trial and Appeal Board of the PTO.[12]

This note aims to explore errors at the level of patent prosecution at the PTO.[13] Patent prosecution produces false positives and false negatives and in overall results in a standard of obviousness that is less stringent than at the courts.[14] Some of these errors may never be corrected, such as the final rejection of an otherwise valid patent, or when an alleged infringer takes a license for a patent that is actually obvious. Even when some errors are eventually corrected in litigation, such as when a court invalidates a patent for obviousness, the patent has already been in force for years, imposing significant social costs.[15] Further, these dubious patent grants create *de facto* rights and benefits, setting expectations for future market activities in acquiring, prosecuting, and maintaining patents.

This note proposes that the PTO should proactively promulgate obviousness guidance under its nonlegislative rulemaking authority to elucidate its policy position on obviousness issues long before the court can weigh in. Doing so would

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decision of the Patent Trial and Appeal Board in an appeal may file a civil challenge in the U.S. District Court for the Eastern District of Virginia).

[11] 28 U.S.C. § 1338 (2011) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents…").

[12] *E.g.,* 35 U.S.C. § 311 (2012) ("[A] person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent."); 35 U.S.C. § 321 (2012) ("[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.").

[13] While cognizant of a lively normative debate of the optimal standard of obviousness at the court level, this note does not address this question. Instead, this note hopes to take the court's legal resolution as a given baseline, and analyze the PTO's prosecution errors and biases in relation to the baseline. This is admittedly a partial approach, because my proposal to fix the prosecution bias will affect substantive patent policy, which the courts will later take into consideration when adjudicating validity of granted patents. In other words, the baseline is not exogenous, but rather endogenous to prosecution results.

[14] *See infra* Part I.B. *But see* Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 101, 123-24 (2008) (finding that the USPTO is not a rubber stamp but actually rejects a nontrivial amount of applications and that disparities between industries in how they experience patent prosecution may not reflect conventional wisdom about cross-field differences in examination rigor).

[15] See text and citation associated with *supra* note 4. *Cf.* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 N.W. U. L. REV. 1495, 1502 (2001) (arguing that it may not be cost effective to strengthen patent examination and reduce patents of poor quality because the value of many patents do not depend on their validity).

increase the determinateness of the obviousness doctrine, produce more uniform results in patent prosecution across the PTO, and reduce the level of uncertainty in patent prosecution. Such guidance will also reduce both types of errors and mitigate the problem of a lowered obviousness standard in patent prosecution.

Emerging technology is a particularly apt field for such obviousness guidance. Obviousness in the emerging field of technology suffers the most from doctrinal indeterminateness and bias because legal guidance is the most lacking. It takes time for judicial opinions to catch up with new technology. The PTO, in contrast, can identify emerging technology at a much earlier time than the courts, and thus is at a good position to consider patent policy for emerging technology.

Part I of this note provides the background on the two types of errors inherent in the PTO's decision-making on the obviousness issue. The errors arise from the indeterminate nature of the obviousness doctrine itself, as well as from the patent prosecution procedures at the PTO. The problem is especially salient in areas of emerging technology, where legal guidance and precedents are most lacking.

Part II describes the PTO's authority, particularly its authority to make nonlegislative rules in the form of guidance documents. Although the PTO lacks authority to make legislative rules on substantive patent law, it can still make nonlegislative rules. The PTO has exercised this nonlegislative rulemaking authority at many occasions and promulgated a large number of guidance documents.[16] These guidance documents have not only restated changes in the law that Congress or the courts had already effectuated, but have also provided the PTO's own interpretation of the law and announced its policy position on substantive issues.[17] Still, these previous uses of guidelines have been somewhat backward looking, announcing substantive policies for new technologies long after their advent and usually not until a societal consensus on the policy issue has started to emerge. Forward-looking substantive guidance on obviousness can help improve the determinateness of the obviousness doctrine and counter the effects of bias in patent prosecution.

Part III describes in detail how the PTO should adopt obviousness guidelines in fields of emerging technology. One particular proposal is for the PTO to announce examples of inventions in an emerging field that are deemed obvious, rather than examples of nonobvious, patentable inventions. Part IV argues that obviousness guidelines are feasible under the current regime of institutional

[16] *See infra* Part II.
[17] *See infra* Part II.

authority and will withstand judicial challenges. Part V analyzes the costs and benefits of the proposed obviousness guideline.

I
OBVIOUSNESS ERRORS IN PATENT PROSECUTION

The PTO carries the formidable duty of examining and granting patents.[18] Its vast examiner corps[19] examines and grants over 300,000 patents each year.[20] These patents are at the core of the intellectual property scheme and are highly valued by companies and research institutions. During the examination process, the examiner (an employee of the PTO) and the patent applicant (or her legal representation) engage in a series of back-and-forth oral and written negotiations over whether or not the application meets the standard of obviousness, among other requirements. It takes twenty-seven months, on average, to reach a final disposition on a patent application.[21]

The PTO has often been criticized for granting obvious patents,[22] but errors are often the result of an inadequate system.[23] The highly indeterminate nature of

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[18] 35 U.S.C. § 2(b)(8)-(13) (2012) (enumerating the various statutory duties of the PTO in advising the President, other executive branches, and congressional committees on intellectual-property-related policy issues).

[19] USPTO, 2014 PERFORMANCE AND ACCOUNTABILITY REPORT 11 (2015), http://www.uspto.gov/about/stratplan/ar/USPTOFY2014PAR.pdf (stating that the PTO employs 9,302 patent examiners as of the end of fiscal year 2014).

[20] *Id.* at 143 (579,782 utility patent applications were filed and 303,931 of them were issued in 2014 alone).

[21] *Id.* at 2 (the average total patent pendency in 2014 was 27.4 months).

[22] *E.g.*, Jaffe & Lerner, *supra* note 4, 32-35, 75, 119-23, 145-49 (criticizing PTO for granting patents on obvious inventions and identifying the realities of the innovation and patenting process); John H. Barton, *Non-Obviousness*, 43 IDEA 475, 477-78 (2003) (arguing that the nonobviousness standard applied by PTO and courts today is not as strict as that articulated by Supreme Court in *Graham*); Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 2 (2007) (noting that "[a]cademics, business leaders, and government officials have all expressed concern that too many patents are issued for [obvious] inventions" (internal quotations omitted)); Carl Shapiro, *Symposium on Ideas into Action: Implementing Reform of the Patent System: Economic Analysis and Critique*, 19 BERKELEY TECH. L.J. 1017, 1018 (2004) (noting that complaints regarding the PTO "typically allege that the [PTO] issues too many questionable patents" including those that were "obvious at the time the patent application was filed").

[23] DONALD A. NORMAN, THE DESIGN OF EVERYDAY THINGS 180-84 (2013) (describing the framework for rules-based mistakes people make in a poorly designed system).

the obviousness doctrine, as well as the procedural characteristics of patent prosecution at the PTO, both give rise to type I and type II errors.

A. Errors Arising from the Indeterminateness of Obviousness

The obviousness inquiry has been described as standard-like,[24] fact-specific,[25] flexible,[26] hard to apply,[27] and indeterminate.[28] What exactly do these terms mean? Consider two proposed rules on traffic safety: Rule A holds that one shall not drive above fifty miles per hour, and Rule B holds that one shall not drive at an unreasonably dangerous speed. People generally agree on what "fifty miles per hour" means, but reasonable minds can differ on what counts as an "unreasonably dangerous speed." The standard of obviousness is akin to the standard of reasonableness; reasonable minds can differ on whether or not an invention is obvious because there lacks a shared understanding of what obvious means.[29] The indeterminateness of the obviousness evaluation stems from this want of a larger core of shared understanding.[30]

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[24] Michael Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1774-75 (2011) ("[A] pure standard is optimal [for the obviousness doctrine]"). For more general discussions of rules and standards in patent law, *see* John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003); Rochelle Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 8-10 (1989) (discussing the "precision" of legal rules and standards).

[25] Pfizer Inc. v. Teva Pharmaceuticals USA, Inc., 803 F. Supp. 2d 409, 441 (E.D. Va. 2011) ("Overall, the court must keep in mind that obviousness is a fact-specific inquiry …."); Jonathan Darrow, *The Patentability of Enantiomers*, 2007 STAN. TECH. L. REV. 2, 8 (2007) ("[O]bviousness is a fact-specific inquiry.").

[26] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007) ("Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach ....").

[27] Gene Quinn, *When is an Invention Obvious?*, IPWATCHDOG.COM (Feb. 1, 2014), http://www.ipwatchdog.com/2014/02/01/when-is-an-invention-obvious/id=47709/ ("[T]he application of these factors or considerations [of the obviousness inquiry] is exceptionally difficult.").

[28] Mandel, *supra* note 2, at 57 ("[T]he nonobviousness standard … is indeterminate.").

[29] Mandel, *supra* note 2, at 92-95 (arguing that the obviousness doctrine is more indeterminate than the negligence doctrine in torts, and is at a similar level of indeterminacy with the doctrine of obscenity, as in a "you know it when you see it" standard).

[30] *Id.* at 91; Joseph Singer, *The Player and the Cards: Nihilism and Legal Theory*, 94 YALE L.J. 1, 6-7 (1984) (commenting on the problem of legal reasoning being indeterminate and thus on a social level questioning the possibility of setting up a legal system based on the rule of law).

The black letter law of obviousness, as set out in section 103 of the Patent Act, provides that a patent may not be obtained on an invention

> If the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claimed invention pertains.[31]

To decide whether or not an invention is obvious, the decision maker—a judge, a jury, a patent examiner, or an administrative patent judge at the PTAB—makes three antecedent findings of fact: the scope and content of the prior art, the difference between the claimed invention and the prior art, and the level of ordinary skill in the art. Based on these three factors, the decision maker reaches a *prima facie* decision on whether or not the difference between the claimed invention and the prior art is obvious to persons having ordinary skill in the art.[32]

After making this *prima facie* decision, the decision maker may take into account so-called secondary considerations to make the final determination of obviousness. All but one secondary consideration are evidence of circumstances before, around, or after the invention that tend to show that the invention is not obvious.[33] Examples of such secondary considerations include evidence that other people have tried to make the invention and failed,[34] or the product implementing the invention has been a commercial success.[35]

Despite these detailed rules and factual findings to guide and structure the obviousness inquiry, the ultimate question of obviousness is, unfortunately, still largely indeterminate. "Obvious" is a subjective term. People with different knowledge bases and creative backgrounds may find an invention obvious or not obvious, yet still be within the reasonable range of judgment. On the one hand, a patent examiner may wrongly grant obvious patents because she likely has lower than ordinary skill in the art. For example, she may not be aware of knowledge that

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[31] 35 U.S.C. § 103 (2012).

[32] Graham v. John Deer Co., 383 U.S. 1, 17 (1966).

[33] The exception is simultaneous invention, which tends to show that the invention is obvious.

[34] In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation, 676 F.3d 1063, 1081-83 (Fed. Cir. 2012).

[35] Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1376-77 (Fed. Cir. 2005).

is commonly known among people of ordinary skill in the art.[36] On the other hand, the patent examiner may wrongly reject nonobvious patents due to hindsight bias. The examiner often evaluates obviousness of an invention long after the invention has been made, and may find innovative inventions obvious because the solution has already been revealed.[37]

In light of the difficulties in making the *prima facie* obviousness decision, the courts have developed a series of secondary considerations, also known as objective indicia of nonobviousness, to help with the application of the obviousness doctrine. Secondary considerations are factual circumstances that often serve as evidence that the invention was not obvious. These secondary considerations reduce obviousness to an issue of fact-finding based on circumstantial evidence, which the judiciary is accustomed to doing—the most famous example probably being the standard of reasonable care in determining negligence. However, for three reasons explained by Professor Mandel, the obviousness test is more indeterminate than a reasonableness test in negligence. First, negligence is significantly defined by the Hand formula, which provides decision makers with helpful context that is lacking in the obviousness determination. Second, judicial precedents help inform the standard of negligence, but usually do not exist for obviousness determinations. Third, lay decision makers are much more familiar with the perspective of an ordinary reasonable person than that of a technical expert.[38] Furthermore, the Federal Circuit is currently divided on the question of how much weight to afford secondary considerations relative to the *prima facie* obviousness decision. Some panels of the Federal Circuit have held that secondary considerations only come after a *prima facie* determination of obviousness; other panels have placed more weight on secondary considerations.[39]

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[36] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419-21 (2007) (requiring decision makers to take into consideration implicit knowledge shared among persons having ordinary skill in the art even though it is not explicit laid out in prior art documents and rejecting a formalistic conception of that knowledge).

[37] Courts have repeatedly cautioned against hindsight bias. For empirical demonstration of hindsight bias. *See, e.g.*, Gregory Mandel, *Another Missed Opportunity: The Supreme Court's Failure to Define Non-Obvious or Combat Hindsight Bias in* KSR v. Teleflex, 12 LEWIS & CLARK L. REV. 323, 340-42 (2008); Gregory N. Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Bias Issue Before the Supreme Court in* KSR v. Teleflex, 9 YALE J.L. & TECH. 1, 18-20 (2007); Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1411-14 (2006) [Hereinafter *Patently Non-Obvious*].

[38] Mandel, *supra* note 2, at 93–94.

[39] *Compare* Alco Standard Corp. v. Tennessee Valley Authority, 808 F.2d 1490, 1504-09 (Fed. Cir. 1986) (Rich, J., dissenting) ("[O]nly commercial success relied on here or below

Judicial definitions add to the shared understanding of obviousness, but they do not make the obviousness doctrine much less indeterminate. The Supreme Court has rejected a rigid application of obviousness in favor of an "expansive and flexible approach."[40] For a long time the Federal Circuit has experimented with a "teaching, suggestion, motivation" test (TSM), which finds an invention nonobvious over prior art references unless there is explicit prior art that teaches, suggests, or provides motivation to combine prior art references. In *KSR v. Teleflex*, the Federal Circuit applied the TSM test and found an invention nonobvious, and thus patentable, when the challenger could not point to a specific piece of prior art evidence that supplied the specific teaching, suggestion or motivation underlying the work. However, the Supreme Court rejected this TSM test when it was applied as a "rigid and mandatory formula," and held that a person having ordinary skill in the art does not necessarily have to be taught or motivated by "published articles and the explicit content of issued patents," but may be motivated by common sense, market demand, or design trend.[41]

Various other judicially developed subtests of obviousness add to the shared understanding of obviousness, but these subtests still leave considerable space for individual discretion. For example, when analyzing new chemical compounds, the Federal Circuit often starts from a "lead compound" and asks whether or not it is obvious to apply certain chemical processes to modify part of its structure.[42] The lead compound approach adds to the meaning of obviousness in the area of chemical compounds, and improves the consistency of the decision making process. However, the doctrine still remains largely indeterminate because the question remains whether or not a certain modification process is obvious to person having ordinary skill in the art.

Judicial precedents of obviousness may shed light on the substantive standard of obviousness and provide some consistency, but their effects have been limited. In a string of cases including *KSR v. Teleflex*,[43] *Leapfrog Enterprises, Inc.*

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cannot be attributed to Smith's invention as disclosed in his patent but must have been due primarily to other factors.") *with* Arkie Lures v. Gene Larew Tackle, Inc., 119 F.3d 953 (Fed. Cir. 1997) ("The district court's statement that 'secondary considerations are just that – secondary,' suggests a misconception of the role of these considerations in determination of the ultimate question.").

[40] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 401 (2007).

[41] *Id.*, at 402.

[42] *E.g.*, Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 555 Fed. Appx. 961 (Fed. Cir. 2014); Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 752 F.3d 967 (Fed. Cir. 2014).

[43] *KSR*, 550 U.S. 401.

v. Fisher-Price, Inc.,[44] and *Muniauction. Inc. v. Thomson Corp.*,[45] the courts evaluated inventions that merely updated pre-existing products—a gas pedal for vehicles, a children's learning toy, and municipal bond auctions—with electronics and computer technology, and found them all obvious. These opinions act as the baseline for thousands of other "mere updating" patents, and, to a large extent, render these patents invalid. However, the effect of judicial precedents is limited for two reasons. As courts have also repeatedly held, an obviousness analysis involves a contextual analysis of all the complex and technical facts and does not turn on a single subtest. Even if an invention merely updates a preexisting product and is found *prima facie* obvious, the court may still decide that the invention is not obvious based on evidence of secondary considerations. The question of obviousness defies a rigid definition. Courts strive to conserve the flexible nature of the question, making it a case-by-case determination, and have repeatedly rejected rigid applications of *per se* rules of obviousness.[46]

Understanding the purpose of the obviousness doctrine adds to a shared understanding of the doctrine, but it does not help decision makers determine obviousness with consistency. The obviousness doctrine reflects a utilitarian goal of awarding patents only when necessary to induce innovation. Hence, an invention should be found nonobvious if it, when viewed prospectively, has a low probability of success.[47] Yet, determining whether or not a technical advance is likely to succeed is not much easier than determining obviousness itself.

The indeterminate nature of the obviousness doctrine makes it hard to apply in a consistent way, resulting in two types of errors: granting obvious patents, or rejecting nonobvious inventions. Although one might think such errors are harmless when they cancel one another out and overall produce a standard of obviousness at the right level, the indeterminateness may exacerbate existing

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[44] 485 F.3d 1157 (Fed. Cir. 2007).

[45] 532 F.3d 1318 (Fed. Cir. 2008).

[46] *E.g., In re* Brouwer, 77 F.3d 422, 425 (Fed. Cir. 1996) ("The test of obviousness … requires that one compare the claim's 'subject matter as a whole' with the prior art"); *In re* Ochiai, 71 F.3d at 1565, 1572 ("[Obviousness] requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another per se rule"); *In re* Baird, 16 F.3d 380, 382, (Fed. Cir. 1994) (rejecting a *per se* rule).

[47] Mandel, *supra* note 2; Robert Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 2 (1992) (stating that the non-obvious requirement "seeks to reward inventions that, viewed prospectively, have a low probability of success."); Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547 (2008) (stating that obviousness should be judged based on whether research project "would be easy or difficult (likely or unlikely to succeed)").

biases that are inherent in the system. For example, when the prospective of receiving a patent as a reward for a research investment becomes more uncertain, risk-averse investors may decide not to finance research and development. This may disproportionately push small firms and individual inventors away from innovative activities. The indeterminateness of the obviousness doctrine may also lead to too many patent grants. Because the number of trivial advances in technology outbalances revolutionary ones, the obviousness doctrine may give rise to more instances of false positives than false negatives.[48] Further, there are generally greater incentives for a patent owner to appeal a wrongly rejected invention than for third parties to challenge a wrongly granted patent. Therefore, false negatives will be corrected while false positives may remain, resulting in too many obvious patents.[49]

For emerging areas of technology, the obviousness inquiry is even more indeterminate.[50] An emerging area of technology is in its initial development stage, meaning that relatively fewer patents have been filed and examined in this field. The general obviousness standard applies to patent applications in emerging areas, but there is little precedent, if any, showing exactly how the obviousness standard is to be applied in the new area. Examiners have limited experience with the technology and patent policy in the new area, making it all the more challenging to apply the obviousness standard consistently.[51]

Emerging technology may further bias the examiner towards lowering the standard of obviousness. An emerging area of technology may be experiencing a rapid growth, resulting in a quickly evolving ordinary skill for active workers in the field. Much of the knowledge may not be reflected in prior art documents, but

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[48] Mandel, *supra* note 2, at 89-108 (making the same argument).

[49] Joseph Farrel & 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 (2004).

[50] FTC, *supra* note 4, at 41 ("The PTO recognized that applying patentability criteria to emerging technologies may be difficult or, at minimum, might differ from their application to more established subject matter, and that more senior examiners could assist with the tough judgment calls that ensue.").

[51] FTC, *Hearing on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy 101*, (Feb. 6, 2002), https://www.ftc.gov/sites/default/files/documents/public_events/competition-ip-law-policy-knowledge-based-economy-hearings/020206ftc.pdf (testimony of Richard Levin, President of Yale University) ("Almost by definition new areas of technology lack well-developed bodies of prior art in earlier patents and in the published literature. This makes it difficult for patent examiners to determine whether a claim meets the required test of … obviousness.").

exists only as implicit knowledge among active workers. It is less likely that an examiner would be in possession of the implicit knowledge in the field. These factors further contribute to the examiner's lack of knowledge,[52] and likely lend to an even lower standard of obviousness.

B. Errors Arising from a Biased PTO's Prosecution Practice

Patent examination is an *ex parte* negotiation between an examiner and the patent applicant. An examiner either allows the patent, or rejects it and explains why it is not patentable. If the examiner rejects a patent, the applicant can argue against it or amend the claims to seek a patent with a narrower scope. The examiner can again grant or reject the patent. This second rejection is usually called a final rejection, but the applicant has an opportunity to amend the claims again, seek an interview with the examiner to persuade her in person, file a continuation, or appeal.[53] It takes on average twenty-seven months for a patent to be disposed.

Patent prosecution serves as a coarse filter to winnow out applications that are obviously invalid. An examiner spends, on average, only about seventeen hours on each patent.[54] The standard of obviousness is likely to be lowered in patent prosecution for reasons such as lack of information, asymmetric incentives to challenge grants and rejections, asymmetric numbers of obvious and nonobvious applications, budgetary incentives, and examiner count incentives.

Examiners' lack of information about prior art lowers the standard of obviousness. Although the examiner conducts the search from an impressive source of prior art, she is not expected to uncover all the relevant prior art, which could include not only documented literature, but also actual products that were used, on sale, offered for sale, or otherwise known to the public. Thus, the examiner may incorrectly conclude that an invention is not obvious because she

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[52] Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 415 (2011) ("[T]he Agency lacks either a staff with significant knowledge in this technology or the resources necessary to review patent applications in [an] emerging field.").

[53] Mark A. Lemley & Bhaven Sampat, *Examining Patent Examinations*, 2010 STAN. TECH. L. REV. 2, 3 (2009).

[54] Gene Quinn, *High Value Patents—Where Strength Meets Quality*, IPWATCHDOG.COM (Dec. 11, 2014), http://www.ipwatchdog.com/2014/12/11/high-value-patents-where-strength-meets-quality/id=52569/ ("It is unrealistic to expect an examiner to thoroughly review an average of nearly 50 references per patent in the 16 to 17 hours an examiner can spend per patent while processing the necessary number of patent applications." (quoting Stephen Kunin, former Deputy Commissioner for Patent Examination Policy at the USPTO)).

had knowledge of an incomplete set of prior art. The PTO has implemented initiatives to mitigate its lack of information and improve the quality of its work product.[55] The "peer-to-patent" pilot programs, for example, allow third parties to submit prior art to help examiners make obviousness and novelty determinations.[56] Though the pilot programs have proven successful in providing needed information to examiners,[57] they do not promise to eliminate all the problems with lack of information, and it remains to be seen how the PTO can successfully implement them on a larger scale.[58]

Because a patent owner often has a greater incentive to appeal an erroneous rejection than third parties to challenge an erroneous grant,[59] erroneous rejections are more likely to be corrected than erroneous grants. This further contributes to a lowered standard of obviousness in patent prosecution.

The PTO's limited budget and its objective of achieving prosecution efficiency may also create bias towards granting patents.[60] To begin with, patent rejections can be directly appealed in the courts, and judicial review is costly to the

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[55] *E.g.*, USPTO, *USPTO Launches Second Peer to Patent Pilot in Collaboration with New York Law School*, http://www.uspto.gov/about-us/news-updates/uspto-launches-second-peer-patent-pilot-collaboration-new-york-law-school; USPTO, *Prioritized Patent Examination Program*, http://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program (explaining that the program gives prioritization and resources to the examination of certain patents upon payment of fees).

[56] USPTO, *USPTO Launches Second Peer to Patent Pilot in Collaboration with New York Law School*, http://www.uspto.gov/about-us/news-updates/uspto-launches-second-peer-patent-pilot-collaboration-new-york-law-school.

[57] *See* Daniel R. Bestor & Eric Hamp, *Peer to Patent: A Cure for Our Ailing Patent Examination System*, 9 NW. J. TECH. & INTELL. PROP. 16 (2010); Christopher Wong & Joseph Merante, *Peer-to-Patent Year One Potential for Implementation in Various Fields of Art Including Biotechnology*, ABA SCITECH LAW, 26, 28 (2008).

[58] *See* Erika Morphy, *New Web Site May Sooth Patent Process*, TECHNEWSWORLD (Mar. 6, 2007), http://www.technewsworld.com/story/software/56129.html?wlc=1294697010 ("The new system also favors large companies that routinely submit patent applications for approval. These firms can maintain staff to monitor the new system and research prior art to shoot down the applications.").

[59] Farrel & Merges, *supra* note 49, at 948-60.

[60] In the 2014 Performance & Accountability Report, the PTO listed as its first goal to optimize patent quality and timeliness. It reported accomplishing providing timely examination of patent applications and reducing backlog of requests for continued examination (RCEs) and patent pendency. USPTO, *supra* note 19, at 41, 46.

agency,[61] so the PTO may be biased towards granting patents to avoid costly judicial review.[62] The pressure on the PTO to reduce its huge backlog may incentivize examiners to reach a final resolution on a patent application. Because the prosecution procedure allows a disappointed applicant to keep her patent alive by keeping filing continuations, the PTO may be incentivized to grant rather than reject borderline patents to reduce the backlog.[63]

Because the PTO is largely self-funded by user fees,[64] it may be incentivized to grant patents so that it can collect issuance fees and maintenance fees. The PTO collects three types of fees from applicants: examination fees that are paid when a patent application is filed, an issuance fee that is paid when a patent is granted, and a maintenance fee that is paid annually permitting the patent to remain enforceable. The examination fees do not cover the actual cost incurred for the PTO to conduct a patent examination. The average cost to examine a patent is about $4,000.[65] The examination fees are only $1,600 for large corporations, and even less for small entities and micro entities.[66] Therefore, the PTO relies on issuance fees and maintenance fees, which are granted only in the event that a patent is allowed.[67] The budgetary concerns may incentivize the PTO, as a whole, to favor patent applicants and over grant patents.[68] This hypothesis is also corroborated in an empirical study, which found that there is a higher allowance rate for patents on

[61] For a third party challenging the validity of a granted patent in courts, the PTO is almost never a party. Wasserman, *supra* note 52, at 406.

[62] *Id.* at 400-417.

[63] *Id.* at 415 ("The backlog of patent applications is a pressing issue to the Agency; the PTO may hope that taking a restrictive stance on patentability standards will result in the filing of fewer patent applications."); *see also* Adam B. Jaffe & Josh Lerner, *supra* note 4, at 136 (2004) (arguing that the current court system incentivizes examiners to "go easy" on applicants and allow their patents).

[64] The PTO has been funded by user fees since 1990. *See* Omnibus Reconciliation Act of 1990, Pub. L. No. 101-508, § 10101, 1990 U.S.C.C.A.N. (104 Stat. 1388), 1388-91.

[65] USPTO, *supra* note 19, at 53 (reporting that total cost per patent production unit was $3,940 in FY 2014).

[66] 37 C.F.R. § 1.16 (2015) (for a utility patent, the basic filing fee is $280, the patent search fee is $600, and the patent examination fee is $720).

[67] 37 C.F.R. § 1.18 (2015); 37 C.F.R. § 1.20 (2015). Wasserman made this exact argument in 2011, *supra* note 52, at 407-09. Although since then fees that the PTO charges patent applicants and patentees have gone up, her conclusion still holds true under today's fee schedule.

[68] Wasserman, *supra* note 52, at 407-15 (arguing that the PTO may favor patent applicants at the expense of the general public under budgetary incentives); Frakes & Wasserman, *supra* note 4 (providing empirical support for the same argument).

technologies with high renewal rates and those filed by large entities, which are the types of patents that earn the most revenue for the PTO.[69]

The PTO's various internal administrative mechanisms translate agency-level biases and preferences into individual applications. These mechanisms, including guidance documents, PTAB decisions, and the Patent Examiner Count System, create systematic bias towards a less stringent standard of obviousness.

Individual examiners' idiosyncrasies may further complicate the result. Specifically, a recent study hypothesized two behavioral patterns that emerge among examiners and lead to bifurcated results in patent prosecution.[70] The Patent Examiner Count System awards examiners "counts," which are used to appraise examiner performance. The Count System awards counts for office actions based on the merits. It also awards counts for disposals of a patent, which include allowance and abandonment of a patent. As a result, an experienced examiner may be incentivized to work quickly to dispose every patent application, getting two points for each application—one for the first office action, and one for the allowance. A junior examiner, who is less experienced and whose work is under more scrutiny, may also take a completely opposite response. She may be incentivized to hold a high patentability standard and continually reject a patent. This could turn an application into a continued source of counts if the applicant is pressed into filing requests for continued examinations (RCEs) and continuations, because the examiner gets counts for a first office action based on the merits, responses to every RCE filed, the first office action in every continuation filed, and allowance or abandonment of the applications.[71] Empirical studies of the PTO's allowance data corroborate this hypothesis, showing that senior examiners take less time on average to prosecute patents to allowance, and have a higher allowance rate than junior examiners.[72] The distinct examiner mentalities are less problematic for a more rule-like doctrine such as novelty, which leaves less space for individual decision maker's discretion, but are more salient in the highly indeterminate doctrine of obviousness, which is highly dependent on the subjective judgment of

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[69] *See* Michael Frakes & Melissa Wasserman, *Does Agency Funding Affect Decision Making?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67 (2014) (detailing an empirical study that supports the hypothesis that the PTO's fee structure incentivizes the agency to over grant patents).

[70] Shine Tu, *Luck/Unluck of the Draw: An Empirical Study of Examiner Allowance Rates*, 2012 STAN. TECH. L. REV. 10 (2012).

[71] Tu, *supra* note 70, at 24.

[72] *E.g.*, Mark A. Lemley & Bhaven N. Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. & STAT. 817, 821-22 (2012). *See also* Tu, *supra* note 70, at 81.

the decision maker, leading to bifurcated prosecution results based on the luck of the applicant.

II
THE PTO'S BOUNDED AUTHORITY

The obviousness question is ambiguous and indeterminate, leaving a large margin of uncertainty to the examiners to exercise their independent judgment with little guidance. The PTO prosecution practice is set up in a way so that borderline patents are more likely to be granted rather than rejected, for reasons including lack of information, asymmetric incentives to challenge grants and rejections, asymmetric numbers of obvious and nonobvious applications, budgetary incentives, and examiner count incentives. These factors contribute to the perceived phenomena of lowered patents quality.

In the height of societal discontent over bad patents and patent trolls, the courts came to the rescue. The Supreme Court granted certiorari in *KSR v. Teleflex*, found the particular invention obvious and invalid, and announced generally applicable rules in an effort to raise the obviousness standard. The Court rejected the rigid application of the TSM test, and articulated that an invention that merely combines two prior art teachings and yields predictable results is obvious.[73]

As much as the new test seemed a blessing to the then-rampant patent quality problems, it came years after the patents were granted, and the damage was already done in the interim.[74] Why did the test not emerge earlier? It provided more certainty to the obviousness doctrine, especially for emerging technologies, where it is particularly indeterminate how the obviousness doctrine applies and little is known about the level of ordinary skills. It also provided more guidance to the examiner and mitigated inherent biases in the prosecution procedure.

The reason why the test did not emerge earlier is that this is the way that the judiciary works. A court adjudicates the case before it, and only makes rules incidentally when the right case has been brought to it. It has limited means of collecting information that is necessary for rulemaking. A court only has the information that comes before it: factual circumstances of a case, legal arguments made by parties to the case, sometimes *amici* briefs and the court's own research. Overall, a court makes law *ex post*, after the facts have arisen and matured, rather than announcing a general policy from the start.

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[73] *KSR*, 550 U.S. at 416.

[74] The patent involved in KSR v. Teleflex, US Patent No. 6,237,565 was filed in 2000 and granted in 2001, six years before the Supreme Court invalidated it.

On the other hand, the PTO refrains from making rules because its hands are bound. Under administrative law, the PTO has three potential ways of making substantive rules: informal rulemaking (which is a form of legislative rulemaking) under §553 of the Administrative Procedure Act, nonlegislative rulemaking under the exceptions in §553(b)(3)(A), and announcing rules in adjudications. However, the PTO lacks authority to make legislative rules, and its ability to make nonlegislative rules and conduct adjudications is also subject to limitations.

A. The PTO's Power and Authority

The PTO lacks authority to use informal rulemaking to make substantive rules. As an executive agency, the PTO must act within its congressionally delegated authority. The Patent Act authorizes the PTO to "establish regulations . . . to govern the *conduct of proceedings* in the [PTO]."[75] The Federal Circuit interpreted this statutory language to mean a delegated authority to make *procedural* rules about its proceedings, but not *substantive* rules on patent policy.[76] Thus the PTO is stripped of one of the most powerful agency tools, informal rulemaking (a type of legislative rulemaking), to provide its interpretation of substantive patentability standard.

Because the agency does not hold the power in saying what the law is, its many actions will not receive *Chevron* deference, a high level of deference that courts give to executive agencies' interpretation of statutory language.[77] The PTO only has the statutorily granted authority to issue procedural rules governing patent examination at the PTO, but not substantive rules regarding patentability issues such as obviousness.[78]

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[75] 35 U.S.C. § 2(b)(2) (emphasis added) ("The Office . . . may establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office[,] . . . shall facilitate and expedite the processing of patent applications[,] [and] . . . may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office.").

[76] Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (rejecting PTO's claim for *Chevron* deference in its Final Determination, which interprets Hatch-Waxman Act and Uruguay Round Agreement Acts as limiting the length of potential patent term extensions for patents granted prior to June 8, 1995); *see generally*, Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. 831, 841-53 (2012).

[77] *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[78] Merck & Co. v. Kessler, 80 F.3d at 1549 (denying *Chevron* deference to a PTO construction of a patent term extension statute on the ground that "Congress has not vested the Commissioner with any general substantive rulemaking power") (interpreting 35 U.S.C.

It is abnormal in the modern world of expanding executive power that the PTO, an enormous agency commanding over 12,000 employees and charged with the crucial task of examining and granting patents,[79] does not have the authority to make substantive rules. This lack of authority is often attributed to the idiosyncratic power balance in the patent area.[80] Congress established the Federal Circuit as a specialized federal appellate court that has exclusive subject matter jurisdiction on all patent cases. This special court has much experience and expertise in patent policy, and thus retains for itself the authority to interpret the Patent Act and decide substantive patent policy.

Though the PTO can still make rules under its nonlegislative rulemaking authority, this power has been exercised cautiously. Most nonlegislative rules closely follow the language of legislative or judicially made laws. The constrained budget, huge backlog, and criticism on patent quality all push the PTO to avoid aggressive policy positions that may lead to costly litigation when challenged, and focus its limited budget and resources on providing efficient and high quality work on patent prosecution. Compared to other modern executive agencies, the PTO is usually seen as a "weak" government agency that passively follows the Federal Circuit's legal determinations and substantive policy directions, rather than actively engaging in patent policy making.[81]

Congress reoriented the power division in 2011 when it passed the America Invents Act, which established various post grant review proceedings before the

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2(b)(1)(A)). Obviousness is treated as a question of law and reviewed *de novo*. *Comment Note*, *supra* note 26 (citing In re NTP, Inc., 654 F.3d 1279, 99 U.S.P.Q.2d 1481 (Fed. Cir. 2011)). The line between substantive and procedural rules is blurry, though. And procedural initiatives do affect substantive rights. Programs such as peer to patent and software partnership seek to improve patent quality by expanding the prior art basis for patent examination; fast track patent examination program expedites the issuance of a patent, effectively extending the term of monopoly for a fee.

[79] USPTO, *supra* note 19, at 11.

[80] Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 2001-02 (2013) (arguing that the role of the Federal Circuit constrains the PTO's executive authority in patent policy). *See generally* Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. 595 (2012) (describing the idiosyncratic power balance between the Federal Circuit and the PTO, and arguing that the America Invents Act of 2011 would bring significant disrupt to the existing power balance).

[81] John M. Golden, *The USPTO's Soft Power: Who Needs Chevron Deference?*, 66 SMU L. REV. 541, 541 (2003) ("[I]n terms of recognized power to speak on substantive questions of law, the USPTO can seem an institutional mite.").

Patent Trial and Appeal Board.[82] These AIA proceedings presented a new, and likely more desirable venue for a member of the public to challenge the validity of a patent.[83] They are faster and less expensive than court litigation.[84] The proceedings are also more favorable to the petitioner; the patent does not receive the presumption of validity, so the challenger only needs to prove invalidity by a preponderance of the evidence, rather than the clear and convincing standard required at court. The public has welcomed the advent of AIA proceedings. From September 2012 to March 2015, 1641 *inter partes* review (IPR) decisions have been instituted.[85] The PTAB has also gone through an aggressive recruitment of administrative patent judges (APJs) to sit on the AIA proceedings.[86]

Most significantly, the AIA granted the PTO the authority to make rules "establishing and governing" AIA proceedings,[87] and the PTO opted for formal adjudication. A panel of three APJs conducts the proceedings in an adversarial fashion. The adjudications allow limited discovery, afford an opportunity for presenting oral arguments, and forbid *ex parte* communications. Scholars have suggested that because Congress delegated the authority to conduct formal adjudications to the PTO, these adjudications should receive *Chevron* deference.[88] This would be a significant power shift because the PTO would be able to make

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[82] For example, *inter partes* review (IPR) was established under 35 U.S.C. § 311-319, and post-grant review proceedings under 35 U.S.C. § 321-29. (2012)

[83] Anyone but the patent owner can file for an IPR. 35 U.S.C. § 312.

[84] Gene Quinn, *How to Protect Your Patent from Post Grant Proceedings*, IP WATCHDOG (Sept. 21, 2014), http://www.ipwatchdog.com/2014/09/21/how-to-protect-your-patent-from-post-grant-proceedings-2/id=51333/ (pointing out that an IPR typically lasts for a year from the time of institution, and a party spends about $300,000 on it).

[85] USPTO, *AIA Progress* (2015), http://www.uspto.gov/sites/default/files/documents/032615_aia_stat_graph.pdf (showing 2994 petitions have been filed).

[86] USPTO, 2013 PERFORMANCE AND ACCOUNTABILITY REPORT 23 (2014), http://www.uspto.gov/about/stratplan/ar/USPTOFY2013PAR.pdf (identifying "continued aggressive hiring of new [administrative patent] judges"); USPTO, 2012 PERFORMANCE AND ACCOUNTABILITY REPORT 3 (2013), http://www.uspto.gov/sites/default/files/about/stratplan/ar/USPTOFY2012PAR.pdf ("the PTAB boasts of dozens of new administrative patent judges hired from the top echelon of the U.S. intellectual property community"). The PTO hired 61 administrative patent judges in 2014 and 46 more in 2015. USPTO, *supra* note 19, at 55; USPTO, 2015 PERFORMANCE AND ACCOUNTABILITY REPORT 70 (2016), http://www.uspto.gov/sites/default/files/documents/USPTOFY15PAR.pdf.

[87] 35 U.S.C. §§ 316-26.

[88] Wasserman, *supra* note 80 (interpreting the AIA as anointing the PTO as the primary interpreter of core patentability standards, and arguing that courts should afford Chevron deference to PTO adjudication in AIA proceedings).

binding substantive patent rules in AIA proceedings. Yet it is questionable that Congress intended such a significant power shift without clearly indicating it.[89]

Regardless of the highly important question of *Chevron* deference, the AIA sends a clear message that patent quality needs improvement, and the PTO should step up to take action. In a recent paper, Professor Gold highlighted the PTO's soft power, and raised a potentially overlooked point that the PTO already has significant influence over substantive patent policy.[90] He pointed to the successful example of the PTO's utility guideline, and argued that the PTO can influence substantive patent law through nonlegislative rulemaking power by adopting guidance documents.

Following this line of inquiry, this note argues that the PTO can and should make nonlegislative rules on obviousness. The remainder of this section provides a detailed review of the PTO's previous use of nonlegislative rulemaking, supporting the argument that it is within the PTO's power to extend this authority to obviousness guidance.

B. The PTO's Previous Practice of Adopting Guidance

Guidance documents are an indispensable part of the PTO's examination practice. They provide instructions to over 9,000 examiners and the general public on the nuts and bolts of patent examination. The contents of guidance documents include distilling the basis of law from complicated and often contradictory case law, detailing steps and providing flow charts for analyzing the patentability of an invention, and offering form paragraphs for drafting an office action. The PTO routinely provides guidance in the forms of the Manual of Patent Examination Procedures, guidelines,[91] examples,[92] training materials,[93] and forums.[94]

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[89] *See also* Golden, *supra* note 81, at 545 (expressing "skeptic[ism] that the AIA has worked such a sea change through implicit, rather than express, provision").

[90] Wassermann, *supra* note 52, at 383.

[91] *E.g.*, Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007) [hereinafter 2007 Obviousness Guidelines].

[92] *E.g.*, USPTO, NATURE BASED PRODUCTS EXAMPLES (2014) [hereinafter USPTO, NATURE BASED PRODUCTS], http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf; USPTO, EXAMPLES: ABSTRACT IDEAS (2015) [hereinafter USPTO, ABSTRACT IDEAS], http://www.uspto.gov/patents/law/exam/abstract_idea_examples.pdf.

[93] *E.g.*, USPTO, ANALYZING NATURE BASED PRODUCTS (2015) [hereinafter USPTO, ANALYZING NATURE BASED PRODUCTS], http://www.uspto.gov/sites/default/files/documents/101%20JE%20training%20Nature-Based%20Products%20Module.pdf.

The agency promulgates guidance documents under its inherent authority to make nonlegislative rules.[95] In contrast to legislative rulemaking (also known notice-and-comment rulemaking), which exercises congressionally delegated lawmaking power, nonlegislative rulemaking does not exercise delegated law making power, and is not binding on the public.[96]

Nonetheless, nonlegislative rulemaking is a powerful tool for regulatory agencies to convey information to regulated entities,[97] without the procedures of a notice-and-comment rulemaking.[98] Under administrative law doctrines, nonlegislative rulemaking that affects substantive policy must fall under the one of two exceptions: interpretative rules or policy statements.[99] An interpretative rule provides the agency's interpretation regarding ambiguity in preexisting law. In theory, an interpretative rule does not make new law. When a nonlegislative rule goes beyond a fair interpretation of existing law, it is not an interpretative rule.[100]

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[94] *See* USPTO, *Subject Matter Eligibility Forum Agenda* (Jan. 21, 2015) [hereinafter USPTO, *Subject Matter Eligibility*], http://www.uspto.gov/patents/law/exam/forum_agenda_20150121.pdf.

[95] Golden, *supra* note 81, at 544; Metro. Sch. Dist. of Wayne Twp. v. Davila, 969 F.2d 485, 490 (7th Cir. 1992) ("All agencies charged with enforcing and administering a statute have inherent authority to issue interpretive rules informing the public of the procedures and standards [they] intend[ ] to apply in exercising [their] discretion." (citations and internal quotation marks omitted)); 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.2, at 306 (4th ed. 2002) ("Any agency has the inherent power to issue an interpretative rule, a policy statement, or a procedural rule to implement a statute it administers."); Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 1004 (1992) (contending that "once Congress has delegated authority to executive actors under law, the executive agencies must determine what the law means, and need not await a further delegation of interpretative authority from Congress to do so."). *But cf*. Jonathan R. Siegel, *The REINS Act and the Struggle to Control Agency Rulemaking*, 16 N.Y.U. J. LEGIS. & PUB. POL'Y 131, 159 (2013) (suggesting that Congress could explicitly abrogate otherwise inherent authority to issue interpretive rules).

[96] Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 383 (1985).

[97] Stuart Shapiro, *Executive Discretion and the Rule of Law: Agency Oversight as "Whac-a-Mole": The Challenge of Restricting Agency Use of Nonlegislative Rules*, 37 HARVARD J.L. & PUB. POL'Y 523, 526 (2014) ("Many of these [nonlegislative] policymaking approaches can be characterized as the movement of information from agency managers to other parties.").

[98] 5 U.S.C. § 553(b)(3)(A), (d)(2) (2011).

[99] 5 U.S.C. § 553(b)(3)(A); Robert A. Anthony, *Interpretative Rules, Policy Statements, Guidances, Manuals, and the Like – Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1323 (1992).

[100] *See* Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 ADMIN. L. REV. 547, 568 (2000).

On the other hand, a policy statement tentatively indicates how agency decision makers will exercise a discretionary power. To qualify as a policy statement the agency document must not bind the regulated entity definitively.[101]

The obviousness standard likely constitutes a policy statement, and may also qualify as an interpretive rule. A policy statement allows the PTO to tentatively indicate how examiners will exercise a discretionary power. In other words, it should preserve the discretionary power for the patent examiners to decide the nonobviousness of each patent application based on the entirety of the facts presented. It announces new law that is tentative and not binding.

PTO has traditionally seen its own role as truthfully applying the substantive patent law as determined by Congress and interpreted by the court. It has carefully avoided the outer boundaries of its authority to avoid legal challenges on its actions, which can be costly both financially and politically. The Federal Circuit may announce precedents that further limit the agency's authority, or disagree with the substance of the PTO policy position, decreasing the credibility and authority of the agency.

Hence, the vast majority of the PTO's promulgated guidance documents track changes of substantive law effectuated by Congress, the Supreme Court, or the Federal Circuit. The obviousness guidelines, promulgated in 2007 and 2010, are examples of guidance documents that merely restate the law without adding much to it. The PTO promulgated the 2007 Obviousness Guideline,[102] in response to *KSR v. Teleflex*,[103] restating the holding of *KSR* and instructing patent examiners to apply seven rationales of obviousness. These rationales were taken from previous Federal Circuit and PTAB case law that are consistent with *KSR*.[104] Three years later, the PTO promulgated the 2010 Obviousness Guideline, restating new developments and interpretations of the Federal Circuit's obviousness doctrine from 2007.[105]

However, the PTO has done more than merely restate the law. Substantive policy making is an inherent component of the PTO's day-to-day function.[106] The

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[101] Asimow, *supra* note 96.

[102] 2007 Obviousness Guidelines, *supra* note 91.

[103] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[104] *See* 2007 Obviousness Guidelines, *supra* note 91, at 57,526-27, 29.

[105] *See* Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53,643 (Sep. 1, 2010).

[106] *See* Golden, *supra* note 81, at 543-44 (arguing that the task of patent examination requires the PTO to address patentability questions and thus to "provide answers to substantive questions of patent law") (internal citation omitted); Wasserman, *supra* note 52, at 388-89 ("On a daily

examiners have to make decisions regarding each patent application, including applying the standard of obviousness to the invention. The indeterminateness of the obviousness doctrine means that the decision necessarily involves individual judgment of each examiner. This is especially true in emerging areas of technology, where established definitions of obviousness or legal precedents provide little guidance on the substantive standard. The PTO must make the important determination of obviousness for each patent application. Although the validity of granted patents may later be challenged, the PTO takes a first cut at substantive patent policy, and create *de facto* rights and set expectation for the patentability standards.

The PTO has, from time to time, promulgated guidelines providing its own interpretation of law—in a way "making" law because it adds new content to the previous, unclarified law. These interpretations are in response to new statutes, new judicial opinions, and new facts such as the emergence of new technology. The rest of this section describes the PTO's two different types of such nonlegislative rulemaking: (1) interpretation in response to new changes of law; and (2) guidance as to patentability of inventions in a particular field of technology.

1. Interpretation in Response to Legislative or Judicial Change in Law

In response to three Supreme Court cases on patentable subject matter,[107] the PTO promulgated a series of guidance documents in the forms of guidelines,[108] examples,[109] training materials,[110] and forum presentations at major patent law

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basis, the PTO must make difficult substantive decisions on issues … such as … standards for nonobviousness.").

[107] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S.Ct. 2347, 2358-9 (2014), Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2120 (2013), and Mayo Collaborative Serv. v. Prometheus Labs., Inc.,132 S.Ct. 1289, 1305 (2012).

[108] *E.g.*, Memorandum, USPTO, Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappas* (July 27, 2010), http://www.uspto.gov/sites/default/files/patents/law/exam/bilski_guidance_27jul2010.pdf.

[109] *E.g.*, USPTO, Nature-Based Products, http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf (last visited Mar. 27, 2016); USPTO, Examples: Abstract Ideas, http://www.uspto.gov/patents/law/exam/abstract_idea_examples.pdf (last visited Mar. 27, 2016).

[110] *E.g.*, USPTO, Analyzing Nature Based Products, http://www.uspto.gov/sites/default/files/documents/101%20JE%20training%20Nature-Based%20Products%20Module.pdf (last visited Mar. 27, 2016).

firms.[111] Although a large part of the guidance documents have been devoted to restating the Supreme Court's new rulings and adjusting the PTO examination practice to reflect the changes in law, the PTO also provides its own interpretation of the law and supplements it with specific examples.

Nature-based products is a compelling example of the PTO providing interpretation of law. In 2013, the Supreme Court held in *Myriad* that isolated forms of naturally occurring DNA segments are not eligible for patent protection under 35 U.S.C. § 101.[112] In March 2014, the PTO promulgated a guidance (the March Guidance) to "address the impact of … Myriad" on the "long-standing rule against patents on naturally occurring things."[113] The March Guidance provided the PTO's own interpretation of *Myriad*, and established a three-step process for determining subject matter eligibility of a natural product, which ultimately turned on whether or not the claims as a whole recited something "significantly different" than the natural products.[114] The March Guidance also listed factors that weigh towards and against eligibility,[115] as well as concrete examples of various nature-based products that are or are not eligible subject matter.[116] These factors and examples are not from preexisting statutes or case law but are the PTO's own interpretation of laws.

2. Guidance in Response to Changes in Fact

The PTO has promulgated guidance documents not only to restate changes in the law and fill in legal gaps, but also to more proactively provide guidance in patentability standards regarding new development of facts, such as an emerging field of technology. Perhaps the most famous examples are the utility guidelines promulgated in 2009 and 2011.[117] The utility guidelines have probably been the

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[111] *See, e.g.*, USPTO, *Subject Matter Eligibility Forum*, http://www.uspto.gov/sites/default/files/documents/101%20JE%20training%20Nature-Based%20Products%20Module.pdf (last visited Mar. 27, 2016).

[112] *Myriad*, 133 S.Ct. 2107.

[113] Memorandum, USPTO, Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products 1 (Mar. 4, 2014) [hereinafter USPTO, *March Guidance*] (internal citation omitted), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

[114] *Id.*

[115] *Id.* at 4-5.

[116] *Id.*

[117] Examples of comments on the successful implementation of the utility guidance to effectuate policy changes include Burstein, *supra* note 24; Arti Rai, *Growing Pains in the Administrative State: The Patent Office's Trouble Quest for Managerial Control*, 157 U. PENN. L. REV. 2051, 2053-54 (2009); Golden, *supra* note 81.

PTO's most aggressive nonlegislative rulemaking to influence substantive patent policy. They were adopted in response to the emerging technology of gene sequencing and were used to reject patent applications on expressed sequence tags (ESTs).

The gene patent controversy started in the early 1990s when Craig Venter and the National Institute of Health (NIH) filed hundreds of patents on human gene sequences.[118] The patentability of gene sequence has been a topic of considerable debate. One specific issue was the patentability of a particular type of gene sequence known as expressed sequence tags (ESTs). An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is an important research tool and can be used as a probe to isolate the full cDNA sequences or as a marker to locate a particular gene on a chromosomal map,[119] but EST's practical benefit is limited to research purposes.[120] Professors Eisenberg and Merges, in an influential opinion letter published in 1995, concluded that patents on ESTs as research tools are undesirable because they discourage subsequent research.[121] They concluded that ESTs likely do not meet the utility requirement because they lack practical or specific utility,[122] and are also vulnerable to obviousness challenges.[123]

In 1999, the PTO promulgated a utility guideline,[124] which specifically rejected patentability for ESTs because of their lack of utility. The 1999 Utility Guideline interpreted utility as "at least one ... credible, specific, and substantial [utility]."[125] The guideline also provided a specific example, stating that a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered specific in the absence of an explicit DNA target

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[118] *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genes,* 11 GENOMICS & HUMAN GENETICS 383 (2010) (describing the early history of patents on gene sequences and ESTs).

[119] Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial DNA Sequences,* 23 AIPLA Q.J. 1, 18 (1995).

[120] *Id.* at 18.

[121] *Id.* at 52.

[122] *Id*. at 3-19.

[123] *Id.* at 52.

[124] USPTO, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS (1999) [hereinafter USPTO, UTILITY INTERIM GUIDELINES], http://www.uspto.gov/sites/default/files/web/menu/utility.pdf; Press Release, USPTO, USPTO Offers Training Materials for Interim Written Description and Utility Guidelines (Mar. 1, 2000), http://www.uspto.gov/news/pr/2000/00-15.jsp.

[125] USPTO, UTILITY INTERIM GUIDELINES, *supra* note 124, at 5.

disclosure; therefore, ESTs do not possess specific utility and are not patentable.[126] The PTO later reaffirmed this interpretation in its 2011 Utility Examination Guidelines.[127]

These utility guidelines were widely recognized as successful examples of PTO nonlegislative rulemaking, because the Federal Circuit later explicitly endorsed the PTO's position on patentability of ESTs. An inventor, Dane Fisher, filed a patent application on an EST gene sequence, which was rejected in 2004.[128] On appeal, the Federal Circuit not only affirmed the PTO's finding that Fisher's claim lacked specific and substantial utility,[129] but also explicitly acceded to the PTO's utility guidelines. It "[took] judicial notice" of the guidelines, and stated that the PTO's standards "comport with this court's interpretation."[130] The Federal Circuit also noted that the example in the utility guidelines "is applicable to the facts here," and that the MPEP "particularly explains that [an EST claim] directed to be useful as 'gene probe' or 'chromosome market,' as is the case here, fails to satisfy the specific utility requirement."[131]

Compared with other guidelines that merely restate or interpret case law, the utility guidelines are more forward-looking. They were adopted proactively, at a time when the patentability policy for the emerging technology of ESTs was not completely settled.

The utility guidelines, however, also take on a somewhat backward-looking approach. The gene patent controversy first started at the beginning of the 1990s, public awareness on gene sequencing soared in the mid-1990s, and Professors Eisenberg and Merge's opinion letter was published in 1995, all long before the utility guidelines were adopted in 1999 and 2001. The utility guidelines were more likely codifying the emerging public consensus on EST patentability, rather than the PTO's effort to actively lead and shape the policy.

The PTO's cautious use of guidance documents reflects the agency's modest assessment of its institutional role in the patent regime; it does not seem keen on providing direct input to shape substantive patent policy. The PTO appears to

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[126] *Id.*
[127] Utility Examination Guidelines, 66 Fed. Reg. 1,092 (Jan. 5, 2001).
[128] *See generally ex parte* Fisher, 72 USPQ.2d 1020 (B.P.A.I. 2004).
[129] *In re* Fisher, 421 F.3d 1365, 1369-70 (Fed. Cir. 2005).
[130] *Id.* at 1372.
[131] *Id.* at 1372-73.

perceive its major task as examining patents efficiently,[132] and with high quality.[133] With regard to policymaking, the PTO views itself as a modest part of a bigger executive mechanism. It focuses on providing information to the executive and legislative branches to facilitate policymaking,[134] rather than proactively shaping substantive policy through its examination practice.

Patent examination is not a mechanical task of merely following the law, however. Especially for questions of obviousness, examiners continually confront new facts, new inventions, and must determine the bounds of the law with each patent application. When the PTO deems a patent nonobvious, it necessarily provides its own interpretation of substantive patent law, making substantive policy determinations. The PTO could leave the highly indeterminate obviousness question to each examiner's individual judgment and passively wait for the judiciary to review and make the ultimate legal determination. Alternatively, the PTO can provide internal training to examiners to standardize prosecution practice, improve consistency and reduce errors. Ideally, the PTO would make its guidelines known to the public to further reduce regulatory cost.[135]

The remainder of this note proposes and analyzes a more forward-looking use of PTO guidance on the doctrine of obviousness in areas of emerging technology. This approach would convey the PTO's policy position to examiners and the public at an earlier time, reducing both type I and type II errors in obviousness determinations, and reducing the structural bias towards a lowered obviousness standard in the PTO's examination procedures.

III
A PROPOSAL FOR OBVIOUSNESS GUIDANCE

The PTO should promulgate forward-looking obviousness guidelines. A particularly good example would be in an emerging area of technology, before a societal consensus is formed over the optimal policy on the emerging technology. Thus, the PTO could provide instructions to examiners and the public about how it

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[132] It measures efficiency with patent pendency, budgetary expense, and backlog reduction. *See* USPTO, *supra* note 19, at 44-56.

[133] It measures patent quality through reviews of written work product by supervisory examiners and the PTO's customers. *See* USPTO, *Patent Quality Assurance*, http://www.uspto.gov/patent/laws-and-regulations/examination-policy/patent-quality-assurance (last visited Mar. 22, 2016).

[134] *See generally* USPTO, *supra* note 19.

[135] *See infra* Part V.

would determine the obviousness of inventions in a new field of technology. Such instructions would reduce uncertainty and inconsistency in the PTO's examination practice. They would also enable the PTO to play a more active role in the U.S. patent policy regime and to use its expertise and unique position to impact patent policy in a more proactive and affirmative way.

The obviousness guideline would meet the following three conditions. First, it should provide more consistency and reduce indeterminateness in the application of the obviousness doctrine. Second, the guidance should be made within the PTO's authority of nonlegislative rulemaking. Third, the benefits of implementing the guidance should outweigh the costs. Though the discussions in Part III take into consideration all three conditions, the second and third conditions will be further elaborated in Parts IV and V, respectively. The PTO is the first government actor to detect a rising trend of innovation and patent applications in a particular technology field, and is thus positioned to identify an emerging field of technology at the outset. The PTO necessarily faces the question of patentability for these patent applications as it receives them. An obviousness rule is most feasible when there are a sufficiently large number of inventions with the same identifiable core of operative facts.[136]

We have seen examples of such an identifiable core of operative facts in the past. For example, when electronics technology was relatively new, many manufacturers applied the then-nascent electronics technology in existing products, such as vehicle acceleration pedals or children's learning toys, in ways that were predictable.[137] Similarly, when gene-sequencing technology was relatively new, researchers applied DNA sequencing technology to known proteins with known amino acid sequences.[138] Though the courts eventually found the inventions in these examples likely to be obvious, this position was not adopted until over a decade later. In doing so, the courts invalidated many patent grants and disrupted expectations. The PTO has the opportunity to consider the obviousness standards at a much earlier stage, voice its opinion, and proactively influence substantive patent law.

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[136] *See infra* Conclusion.

[137] *See e.g.*, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (finding a vehicle acceleration pedal that applies electronics technology obvious); Leapfrog Enter. v. Fisher-Price Inc., 485 F.3d 1157 (2008) (finding children's learning toy that applies electronics technology obvious); Miniauction Inc. v. Thompson Corp., 532 F.3d 1318 (2008) (finding an online auction method obvious).

[138] *See e.g., In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Kubin, 561 F.3d 1351 (Fed. Cir. 2009).

The PTO also has the capacity and expertise to make the right obviousness guideline. First of all, in the above-mentioned historical lessons of electronics technology and gene sequencing technology, the PTO erroneously made the initial decisions to grant the patents, not because it lacked the expertise to understand the technology, but because it was bound by the rigid TSM test. Now that the TSM test is no longer in place,[139] the obviousness doctrine is free from its constraint, and the PTO is can make its obviousness determinations.

The PTO is also an expert agent competent to decide the standard of obviousness.[140] The PTO as an executive agency in general hires over 9,000 examiners with technical expertise and APJs who are experienced patent attorneys with both legal and technical expertise. The Federal Circuit judges have expertise in patent law, and some also have a technical background, but most judges at the district court or the Supreme Court levels are generalist judges and lack technical expertise. In addition, the PTO has the expertise to understand economic implications of patent policy at a broader level. In 2010 the PTO established a Chief Economist Office to develop its expertise in economic analysis,[141] whereas federal judges do not necessarily have an economics expertise. The PTO also has administrative authority to conduct studies and solicit comments from stakeholders regarding the consequences of a proposed guideline, while the court has to focus on the specific case and the parties involved. The PTO examines hundreds of thousands of patents a year, and has access to the full picture of patent grants and rejections, while only thousands of patent litigations are filed with courts each year.[142] The PTO also has more resources and expertise than the courts to make an obviousness guideline.

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[139] *See generally KSR*, 550 U.S. 398.

[140] *See* Burstein, *supra* note 24 (arguing that the case for the PTO to make rules for substantive patent law is at least as strong as other executive agencies).

[141] USPTO *Office of Chief Economist*, http://www.uspto.gov/about-us/organizational-offices/office-policy-and-international-affairs/office-chief-economist/chief (last visited Mar. 22, 2016) ("The OCE initiates and oversees groundbreaking economic analysis in the field on the topics of intellectual property protection and enforcement, with the object of fulfilling the USPTO's statutory obligation to provide the President ... and the administration with advice on intellectual property policy."); Arti Rai, *supra* note 117, at 2054.

[142] *See* Gene Quinn, *Patent Litigation Statistics: 1980-2010*, IPWATCHDOG.COM (Aug. 2, 2011), http://www.ipwatchdog.com/2011/08/02/patent-litigation-statistics-1980-2010/id=17995/ (showing patent litigation statistics from 1980 to 2010); Gene Quinn, *The Rise of Patent Litigation in America*, IPWATCHDOG.COM, (Apr. 9, 2013), http://www.ipwatchdog.com/2013/04/09/the-rise-of-patent-litigation-in-america-1980-2012/id=38910/ (showing patent litigation statistics from 1980 to 2012).

The PTO should decide the timing of the obviousness guideline. Part of the PTO's goal in adopting an obviousness guideline is to convey its purported examination position to the examiners and the public *ex ante*, proactively influencing the substantive obviousness standard. However, the PTO may also want to wait until a better time, for example, when more patents with similar facts are filed, for public opinion and known consequences on obviousness policy to develop more fully, or for the agency to learn more about each stakeholder's position.

The PTO can conduct studies and solicit public opinions to gather needed information.[143] Such information could include information germane to the obviousness determination, such as the level of ordinary skill in the art and the implicit knowledge of practitioners in the field. It would also be helpful to consider information relating to the underlying economic justification of patents, such as the cost of development, market projections, and evidence regarding private parties' incentives to engage in a particular line of research and development. The earlier the PTO wishes to make the obviousness guideline, the more costly it will be to collect the information necessary to make predictions about the consequences of a proposed guideline.

The content of the obviousness guideline can take the form of specific examples. Such an example should comprise the operative facts of an invention, relevant prior art, and the level of ordinary skill, as well as the conclusion that the invention *is obvious* in light of the prior art. The guideline should not provide examples of inventions that are *not obvious* because such examples would be inefficient. The standard of obviousness necessarily rises with the expansion of human knowledge; what was not obvious at an earlier time becomes obvious later.

To illustrate, consider a hypothetical obviousness guideline in response to the emerging area of electronics technology in the 1990s.[144] Such a guideline could include one or more specific examples of inventions that apply the electronics technology on, for example, a children's toy, which uses electronic components to generate sounds.[145] The example would describe Prior Art A, which is a children's toy that uses an electro-mechanical record player to generate sounds. It would

[143] 35 U.S.C. § 2(b)(11) (2006).

[144] I use past technology as examples for the purpose of illustration because the nature of the obviousness inquiry makes it hard to discuss technology that may emerge in the future in much detail. Here we also have to assume that the TSM test does not exist because it would be inconsistent with the current flexible, fact-specific obviousness doctrine and preclude the PTO to make the obviousness guideline.

[145] *See* Leapfrog Enter. v. Fisher-Price Inc., 485 F.3d 1157 (2008).

describe Prior Art B, which includes the knowledge of modern electronic technology. The guideline would then reason that the invention in question is obvious in light of the prior art A and B. This example would provide future examiners with a baseline for examining similar patent applications that adapt an old product using new technology in a commonly understood way.

The obviousness guideline could further articulate a generalized rule on top of specific examples. Articulation of a generalized rule would add to the shared understanding of obviousness and further improve the certainty and consistency in obviousness determinations.

Continuing with the above hypothetical, the guideline with electronics technology could further articulate the rationale for finding the specific example of children's toy obvious. The rationale could be, for example, that the invention merely adapts an old product using new technology in a way that is "commonly available and understood."[146] Alternatively, the rationale could be that the invention merely adapts an old product using technology in a way that is "predictable."[147] The choice of different rationales would be a policy decision, as it may result in different obviousness standards. "Predictable" may indicate a less stringent standard of obviousness than "commonly available and understood," because a new technology may be "commonly available and understood," but may not produce "predictable" results.

The obviousness guideline, however, should still leave enough discretion for the examiner, as required by the contextual and flexible nature of the obviousness doctrine.[148] The examiner is required to take the invention as whole and to consider its specific factual circumstances. Therefore, even for a future patent application that fits closely with the obviousness guideline, it is not necessarily obvious. The examiner is still free to consider other factors, such as evidence of commercial success of the invention and prior art "teaching away" from combining the old product with the new technology.

The specific examples and the generalized rule both add to the shared understanding of obviousness in the particular field, but they impose different costs in rulemaking. Specific examples are relatively easy to find, as the PTO can take examples from patent applications. A generalized definition is harder to come up with because it must be based on analysis of a large number of specific examples

[146] *Leapfrog*, 485 F.3d at 1168.
[147] Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd., 533 F.3d 1353, 1359 (2008) (analyzing *KSR*).
[148] *See supra* Part I.

that share the same core of operative facts. Moreover, it has to be articulated in language that suits different specific examples in the same field. Therefore, an obviousness guideline with a generalized rule is more expensive to make, or has to be made later in time, than an obviousness guideline with only specific examples.[149]

The PTO should also consider the formality of the guideline. The language that the PTO adopts in making a guideline affects how the court will later interpret it. For example, an obviousness guideline should articulate the law in language that closely follows prior case law.[150] The PTO can use recent PTAB decisions as specific examples in the guideline, to show that that it reflects no change in law.[151] Like previous PTO guidelines, the obviousness guideline should also proclaim that it is nonbinding, does not create any legal rights or benefit,[152] and that rejections of patents would be based on substantive law, and it is these rejections that are appealable.[153]

IV
JUDICIAL CHALLENGE TO THE OBVIOUSNESS GUIDELINE

When the PTO promulgates an obviousness guideline to cut back on the patentability of a field of new technology development, a disappointed applicant whose application has been rejected is likely to appeal to the Federal Circuit. There are three ways that the applicant may appeal. First, she may appeal the rejection of the patent itself. Second, she may challenge the guideline, claiming that it exceeded the scope of the PTO's authority; that is, it does not fall within the scope of nonlegislative rulemaking. Third, she may challenge the guideline, arguing that the content of the guideline is not a correct interpretation of the obviousness standard. An obviousness guideline would likely withstand all three challenges.

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[149] A generalized definition also adds more to the shared understanding of the legal term of "obviousness" than a specific example, and thus adds more consistency to the application of the obviousness standard to later patent applications.

[150] *See* Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 927 (Fed. Cir. 1991) (finding that the PTO's Notice on patentable subject matter did not exceed the PTO's authority because it was "merely interpretive of prior decisional rule").

[151] *See id*. at 927-28.

[152] Note that the guideline should claim that it does not create any *private* legal rights or benefits, but it does create significant *public* benefits, as is the main point of this note.

[153] *See e.g.*, 2007 Obviousness Guidelines, *supra* note 91, at 57,526.

A. Challenge of a Patent Rejection

Though a disappointed applicant may challenge the rejection of her patent, this probably will not affect the validity of the obviousness guideline. In the hypothetical articulated in Part III, the proposed guideline would describe specific examples of an obvious invention, and explain the underlying rationale that an invention is likely to be obvious if it "merely adapt an old product using new technology in a way that is commonly available and understood." Because of the flexible nature of the obviousness doctrine, future applications would still be analyzed on a case-by-case basis, rather than by categorical determinations. The examiner would make the decision whether or not the rationale applies to a later invention based on how similar the facts of the invention in question are to the facts of the example in the guideline. Therefore, even if a disappointed applicant challenges the rejection of her patent at the Federal Circuit, and the Federal Circuit reverses, it only means that the guideline would not control in that particular case, not that the guideline itself was invalid.

B. Challenge of the PTO's Rulemaking Authority

A party affected by the guideline could challenge it on the grounds that the guideline exceeds the PTO's delegated authority to promulgate procedural rules under 35 U.S.C. § 2(b)(2)(A).[154] The party could also claim that any legislative rulemaking by an agency requires the notice and comment procedure under 5 U.S.C. § 553(b), (c).[155] These challenges would likely fail because the obviousness guideline would likely qualify as a nonlegislative rule, as either a policy statement or an interpretative rule under 5 U.S.C. § 553(b).[156]

The PTO's nonlegislative rulemaking authority has rarely been challenged in the past.[157] In *Animal Legal Defense Fund v. Quigg*, the Federal Circuit distinguished legislative rules from nonlegislative rules under the test of "whether

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[154] Merck & Co., Inc. v. Kessler, 80 F.3d 1543 at 1550 (Fed. Cir. 1996) (interpreting 35 U.S.C. § 2(b)(2)(A) as conferring the PTO the authority only to promulgate procedural, not substantive rules).

[155] 35 U.S.C. § 553 (2006).

[156] Courts have used the terms "non-legislative" and "non-substantive" to describe agency rule making that is exempt from notice and comment procedures under § 553(b)(A) of the APA. In this paper I will use only "nonlegislative" to avoid confusion with the substantive-procedural distinction in *Merck.*

[157] The Federal Circuit has only heard challenges like this twice before, in *Animal Legal,* and *Mikkimeleni v. Stoll*. 932 F.2d 920; 410 Fed. App'x 311 (Fed. Cir. 2010). Both times the Federal Circuit rejected the challenges and affirmed PTO's guidelines.

or not the rule effects a change in existing law or policy which affects individual rights and obligations."[158] In *Animal Legal Defense Fund*, the PTO promulgated a Notice that "[the PTO] now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter." Before the Notice, the Supreme Court held in *Diamond v. Charkrabarty*,[159] and the Board of Patent Appeal and Interference held in *Ex parte Hibberd*[160] and *Ex parte Allen*,[161] respectively, that live, non-naturally occurring living microorganism, multi-cell plants, and polyploid oysters were eligible for patent protection. The Notice synthesized these three pieces of case law, and expanded the scope of non-natural product to all non-naturally occurring living organisms. Although the Notice expanded the literal reach of the law, the court nonetheless found that it was nonlegislative rulemaking because it represented no change in the law and was merely interpretative.[162]

Under *Animal Legal Defense Fund*, courts will likely look at the substantive effect a nonlegislative rule has over the regulated entities and the extent to which the rule affects individual rights and obligations. Consider the utility guidelines discussed in Part II, which were promulgated at a time when the societal consensus on the issue of ESTs patentability started to emerge.[163] If, hypothetically, the same utility guidelines were promulgated at an earlier time when applicants first started to file patent applications on ESTs, they might fail if challenged under *Animal Legal Defense Fund*. In the hypothetical situation, the PTO might want to argue that the rule did not change the patentability standard, but merely clarified the correct standard and reduced the margin of uncertainty. In other words, it did not affect individual rights and obligations because it merely rejected patents that should not have been granted anyway. However, the court would have likely found the rule constitutes too much of a change to the law because it categorically denies patentability to a whole field of inventions, in a way that unsettles parties' expectations. Thus the guidelines would have significant implications on parties' rights and benefits, and thus could not be made as nonlegislative rules. In reality, the PTO promulgated the utility guidelines after patent examination practice and public consensus had adjusted parties' expectations. Therefore, the rule reflected not a radical change of law, but rather a codification of the new norm.

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[158] *Animal Legal Defense*, 932 F.2d at 927.
[159] Diamond v. Charkrabarty, 447 U.S. 303 (1980).
[160] *Ex parte* Hibberd, 227 U.S.P.Q. 443 (B.P.A.I. Sept. 18, 1985).
[161] *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (B.P.A.I. Apr. 3, 1987).
[162] *Animal Legal Defense Fund*, 932 F.2d at 927.
[163] *See supra* Part II.

The proposed obviousness guideline would likely qualify as nonlegislative rulemaking under the rationale in *Animal Legal Defense Fund*. The aforementioned specific examples of obvious inventions would not change the law, but merely explain how the obviousness doctrine applies to specific cases, and thus would not affect individual rights and obligations. The generalized rule would be articulated in the context of the specific examples, allowing an applicant to draw distinctions between the facts in her patent application and those in the guidelines. She could make nonobviousness arguments based on the full scope of the facts of her invention. The guidelines would not change the fact-specific, flexible nature of an obviousness inquiry, and thus would not have a substantive impact on the rights of each applicant.

Under general principles of administrative law, the obviousness guideline could also fall under the exception of a policy statement because it would tentatively indicate how agency decision makers will exercise a discretionary power, but would not definitively limit the examiners' discretionary power in future examinations.[164] The obviousness doctrine requires the examiner to make the obviousness determination for each individual patent application based on all the facts of the application. If the guideline were to definitively limit examiners' discretion, it should have been rejected on its substance for being a *per se* rule of obviousness.[165] The obviousness guideline should preserve the flexibility of the obviousness inquiry,[166] and examiners should be genuinely open to make obviousness determinations in future examinations.

The obviousness guideline could also be an interpretative rule that construes the statutory language of "obvious" because it does not adversely impact the patent applicant's rights and obligations. The guideline would not change the flexible, fact-specific nature of each obviousness determination. Although some patent applicants would be refused the issuance of a patent, any alleged right to a patent never existed in the first place. The guideline would merely clarify the PTO's interpretation of how the obviousness standard applies to the new technology, and does not reflect a change of substantive obviousness standard. Losing a patent right that the applicant would not have deserved in the first place would not constitute an adverse impact of the patent applicant's right in this situation. The obviousness

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[164] A policy statement is a nonlegislative rule that tentatively indicates how agency decision makers will exercise a discretionary power. *See e.g.*, Simmons v. ICC, 697 F.2d 326 (7th Cir. 1982); Am. Bus Ass'n v. United States, 627 F.2d 525 (D.C. Cir. 1980).

[165] See citations associated with note 46.

[166] *See generally* Asimow, *supra* note 96, at 393.

guideline would also likely deter some patent applications from being filed at all, but the inventors would still be free to file a patent and appeal a patent rejection to the Federal Circuit.

C. Challenge of the Substantive Content of the Guideline

Because the obviousness guideline qualifies as nonlegislative rulemaking, it is likely not reviewable for lack of finality or ripeness. For an agency action to be final, it must be the "consummation of the agency's decision making process," and must be one "by which rights or obligations have been determined, or from which legal consequences will flow."[167] The obviousness guideline would likely not be final because it provides a tentative opinion as to the weight of a particular fact pattern, without determining any legal rights and obligations or creating any direct legal consequences as to the patentability of any application. The obviousness guideline is similarly unlikely to be ripe because it does not directly address regulated entities' conduct. It would not produce direct consequence on patent applicant's action or create any hardship, but would merely clarify the content of the law as applied to a particular fact pattern.[168]

Even if the Federal Circuit decided to review the substance of the obviousness guideline, the PTO's guideline would likely be persuasive under the four factors that the Supreme Court used in Skidmore v. Swift to analyze the persuasiveness of agency's interpretation: (1) the thoroughness of the agency's investigation; (2) the validity of its reasoning; (3) the consistency of its interpretation over time; and (4) other persuasive powers of the agency.[169] Because the guideline would take the narrow scope of listing specific examples of obvious inventions, under the first two *Skidmore* factors, the court would likely look at the facts and reasoning supporting the examples. The court may also look at policy considerations such as the nature of the innovations, the content and scope of patent applications, the potential downstream effect of granting a patent right, and the likely incentivizing effect of a patent right. The PTO would likely be able to provide sufficient support and reasoning regarding the obviousness of specific invention examples.

The third *Skidmore* factor is the consistency of the PTO's interpretation over time. Under this factor, the court would likely consider how the new guidelines

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[167] Mikkilineni v. Stoll, 410 F. App'x 311, 313 (Fed. Cir. 2010) (citing Bennett v. Spear, 520 U.S. 154, 177-78 (1997)); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 375-76 (2011).

[168] Seidenfeld, *supra* note 167, at 381.

[169] Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

substantively differs from pre-existing law, and how the new guidelines had been promulgated and drafted with sufficient reference to previous case law. The obviousness guideline would likely be considered consistent with pre-existing law because they would merely apply the obviousness standard to specific examples, reflecting an incremental, rather than radical, change.

The court would also likely be influenced by public opinion and secondary sources, which also take time to develop and settle. When a field of new technology is in its early development stage, the public lacks sufficient knowledge to analyze the appropriate policy. For the PTO to prematurely promulgate a rule before a public consensus has started to settle, even if the rule eventually turns out to be acceptable, it runs the risk of judicial reversal. However, the obviousness guideline would not be a broadly applicable hardline rule that definitively affects future applications. Rather, the guideline would be based on specific examples, and reasons why these examples are obvious. The controversy on the patentability of the whole area of technology is unlikely to affect the fact-specific obviousness determination regarding the specific examples in the guideline.

The obviousness guideline would be narrow in scope because it would purportedly only address the obviousness of specific examples in the guidelines, and would not substantively affect future patent applications in the field. Therefore, it is within the PTO's ability to draft well supported, and well-reasoned nonlegislative rules that do not reflect an abrupt change in the law of obviousness. Furthermore, it is likely that the court would agree with the content of the guidelines should it chooses to review the guideline on the substance.

V
COST-BENEFIT ANALYSIS OF THE OBVIOUSNESS GUIDELINE

Part V analyzes the potential initial cost of promulgating the guidelines and the ensuing benefits that the guideline will confer on post-guideline adjudications.

A. The Cost

If an agency chooses to promulgate an obviousness guideline, it has control of the timeline. A typical notice-and-comment rulemaking takes about six to twelve months to promulgate. The obviousness guidelines would probably takes a shorter time because nonlegislative rulemaking does not require all the formalities of legislative rulemaking.

The PTO would want to support its position with economic study results and public feedback. These measures are costly, but they help the PTO make the right decision in deciding the content of the guidelines. Moreover, they buttress the guideline's persuasiveness when under judicial review. Public comments have provided helpful inputs and influenced the PTO's nonlegislative rulemaking in the past. For example, the PTO promulgated a Patentable Subject Matter Guidance in March 2014, and after public comment, promulgated another Patentable Subject Matter Guidance in December 2014.[170] In the December Guidance, the PTO incorporated changes from the March Guidance in response to public comments.[171] For example, the December Guidance evaluates whether or not the claimed product is "markedly different" from a naturally occurring counterpart not only in its "structural difference," as articulated in the March Guidance, but also in its "function, or other properties."[172]

B. The Benefit

The obviousness guideline is economically beneficial because it reduces the two types of errors in patent examination, counters the lowered obviousness standard in the examination practice, and reduces the number of unworthy patent applications and therefore the number of unworthy patents.

First, the obviousness guidelines would reduce the indeterminateness of the obviousness doctrine and increase the consistency of obviousness determinations

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[170] USPTO, *March Guidance*, *supra* note 113; 2014 Interim Guidance on Subject Matter Eligibility, 74 Fed. Reg. 74,618 (Dec. 16, 2014) [hereinafter December Guidance].

[171] For all the comments regarding the March Guidance, see USPTO, *Public Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* (Jul. 2, 2014), http://www.uspto.gov/patent/laws-and-regulations/comments-public/public-comments-guidance-determining-subject-matter. The December 2014 Guidelines also eliminated the multi-factor test in the March 2014 Guidelines and adopted a more streamlined process.

[172] 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,619, 74,621, 74, 623 (Dec. 16, 2014). For examples of public comment in response to the guidance, see AARP, *Re: Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products*, at 3, http://www.uspto.gov/sites/default/files/patents/law/comments/mm-a-aarp20140731.pdf (last visited Mar. 27, 2016); American Bar Association, *Re: Comments of the American Bar Association Section of Intellectual Property in Response to the USPTO's Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena & Natural Product*s, at 14-19, http://www.uspto.gov/sites/default/files/patents/law/comments/mm-a-abaipl20140731.pdf (last visited Mar. 27, 2016).

in patent examination. Greater certainty in the obviousness doctrine would reduce instances of both false positives and false negatives.

This phenomenon is demonstrated in Figure 1 below. Suppose before the obviousness guideline, the margin of uncertainty is defined as (–a, a) on the axis of a level of obviousness. An examiner would always reject a patent if the level of nonobviousness is below –a, and always grant a patent if the level of obviousness is above a. Inventions with a level of obviousness between –a and a are uncertain, and it is possible that the examiner may grant it or reject it. The obviousness guideline would add to the shared understanding of obviousness and narrow the margin of uncertainty to (–b, b). An examiner would now reject a patent if the level of nonobviousness is below –b, reducing instances of false positives that may happen in the range of (–a, –b) absent the obviousness guideline. Similarly, an examiner will now grant a patent if the level of nonobviousness is above b, reducing instances of false negatives that may happen in the range of (b, a).

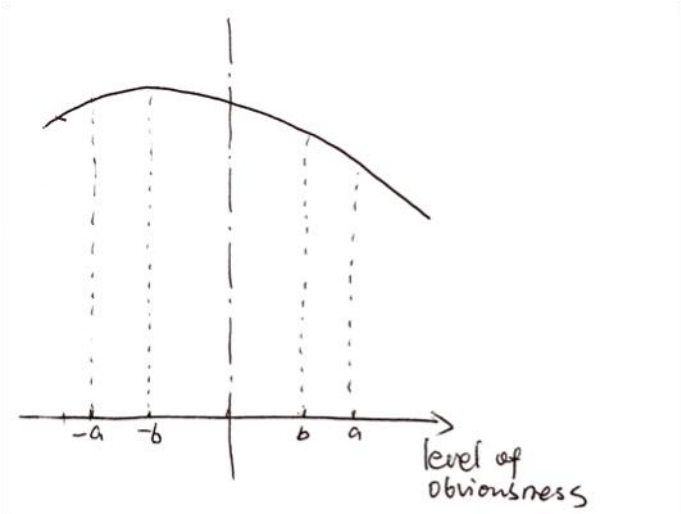

Figure 1: The x-axis indicates level of obviousness; the y-axis indicates distribution of patent applications. The distribution is merely illustrative and is not based on actual data. However, to reflect the fact that there are more minor improvements than major improvements, the curve is skewed towards the left side.

Second, the obviousness guidelines would counter the structural bias in the PTO's examination practice of applying a lowered standard of obviousness, further reducing instances of false positives. Consider Figure 1. It is uncertain whether an inventor should reject or grant a patent with this margin of uncertainty. Suppose

she would grant a patent when on weighing all the evidence, she believes the patent is patentable beyond a level of certainty, say 40%, because she is biased towards granting a patent. We have an effective bar of obviousness at the 40% point between –a and a, that is, on the point of -0.2a. After the obviousness guidelines, assuming the examiner is still biased to the similar extent, the effective bar of obviousness would be at the 40% point between –b and b, on the point of -0.2b. Because the absolute value of a is larger than b, the obviousness guideline effectively raises the bar of obviousness, further reducing the number of obvious patents. The obviousness guideline would thus further reduce the social costs associated with bad patents, including deadweight loss and transaction costs.

Further, obviousness guideline may help the PTO to preserve patent incentives in an emerging field of technology. In the face of a fast emerging technology, the PTO may be concerned about examiners holding too low a standard of obviousness, over-granting patents and lowering patent quality. As a result, the PTO may want to resort to a conservative stance of categorically rejecting inventions in the field with a more rule-based doctrine, such as patentable subject matter.[173] The obviousness guidelines would alleviate this concern, making it is less likely that the PTO would adopt the categorical ban on a new field of technology, and preserving the incentives for research and invention in the new field.

Because the obviousness guideline would effectively raise the obviousness bar at patent prosecution, it would likely deter some patent applications, reducing the number of initial examinations at the first level of the patent funnel. The guideline would also provide a better tool for the examiner to reject an unworthy patent application, correcting the structural bias in the examination process to grant a patent, and further reducing the number of issued patents in the absence of the guidelines.

The guideline also likely saves patent prosecution costs for each application. The patent examination resembles a negotiation between the examiner and the patent applicant, a narrow margin of uncertainty leads to a narrow bargaining range between the parties, and thus will likely lower the negotiation cost for parties to reach an agreement.

C. Comparison with the AIA Proceeding

Besides nonlegislative rulemaking, the formal adjudications under the AIA proceedings provide another means by which the AIA can announce rules on

[173] Wasserman, *supra* note 52, at 420.

obviousness. Although AIA adjudications do not necessarily receive *Chevron* deference, these opinions are closely followed and analyzed by patent practitioners, and thus provide a good way for the PTO to convey information to the public at a time earlier than court litigation.[174] This section compares the costs and benefits of adopting obviousness rules through nonlegislative rulemaking with formal adjudications.[175] The actual obviousness rules will likely have similar contents as detailed in Part III, but these two approaches result in rules promulgated at different times, and with different initial costs.

The earlier an obviousness rule is promulgated, the more post-rule adjudications it will affect, and the more benefit it will confer on later adjudications.[176] For a Post Grant Review (PGR), the earliest of the AIA proceedings, it takes on average more than forty months from the initial filing of the patent to announce a rule on obviousness.[177] For nonlegislative rulemaking, an obviousness guideline could be promulgated in less than a year; a typical notice-and-comment rulemaking takes about six to twelve months, much earlier than the Post Grant Review.

On the other hand, nonlegislative rulemaking is likely to incur more costs than formal adjudication. An AIA proceeding likely will not incur much extra actual cost on the part of the PTO, other than opportunity cost, which exists

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[174] The weight of these formal adjudication decisions is still unknown. Though the Federal Circuit has heard a few appeals from *inter partes* reviews, no opinion has been issued as of now. Arguments have been made that the formal adjudication decisions should receive Chevron deference, but even if they do not, they are likely to receive considerable respect from the court and the public for their persuasive power. The AIA proceedings are structurally similar to court litigations with discovery, oral arguments, and witness testimony. The parties are highly motivated to present their best arguments because of the preclusive effect of the proceedings. The presiding administrative patent judges are highly qualified patent attorneys who have technology backgrounds. They are probably better at understanding the technology-intense facts and the abstruse patent doctrines than normal juries and generalist trial judges.

[175] Though I use the term "rule" here, it only refers to the administrative law term of "rulemaking," and does not refer to the content of the rule. The content of the rule is detailed in Part III of this note, which could take various forms such as specific examples or a generalized rule. See *supra* Part III.

[176] This assumes that the rule does not affect private parties' research and development activities, which is likely true because the proposed obviousness rule only aims to narrow the margin of uncertainty, rather than change the standard of obviousness.

[177] The initial patent examination takes on average 27 months; a PGR petition must be filed within 9 months of issuance, 35 U.S.C. § 321; an institution decision should be made within 3 months of the preliminary response, 35 U.S.C. § 324, and the actual trial should be completed within a year from institution, 35 U.S.C. § 326(a)(11).

because the PTO has much less control over the rule made in an AIA proceeding than in a nonlegislative rulemaking. First, an AIA proceeding is initiated by a member of the public and litigated between private parties. The PTO has limited control over which AIA proceedings are initiated at what time, as well as the specific issues and arguments to be raised in the proceeding. A third party can challenge a wrongly granted patent under PGR within nine months of the grant of the patent,[178] or under an IPR, which does not have a time limit as in a PGR, but is still faster than a court litigation.[179] Second, the PTAB's adjudication function and the PTO's executive function are formally separated, and the executive function of the PTO has little sway in the decision-making of an APJ.

CONCLUSION

The core patentability standard of obviousness is a fact-specific, highly contextual inquiry that is notoriously hard to apply in a consistent way. The flexibility of the doctrine guarantees that each invention be evaluated on the whole scope of the facts in a case, but also creates problems of uncertainty and inconsistency, leading to type I and II errors. This is especially problematic at patent prosecution, when the PTO's structural bias for over granting patents combines with the indeterminateness of the obviousness doctrine, resulting in too many grants of obvious patents.

This note proposes that the PTO should promulgate obviousness guidelines under its authority to make nonlegislative rules. An obviousness guideline would include specific examples of inventions that are obvious, and potentially include generalized rules explaining why the inventions in the examples are obvious. Emerging fields of technology would be a good place to consider making such guidelines, because the obviousness doctrine are the most uncertain in these field.

An obviousness guideline would reduce the indefiniteness of the obviousness doctrine, reduce type I and type II errors, and provide a more stringent standard in counter of the structural bias in patent examination. Thus, it would reduce examination and litigation costs associated with an overflow of dubious patent applications and patents.

Despite the obvious benefits of promulgating such an obviousness guideline, the PTO has not done so in the past. This is likely because of the unique power

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[178] 35 U.S.C. § 322 (2012).

[179] IPRs usually last a year; patent litigation in courts, on average, take 2 to 3 years. *Patent Litigation Cost*, INVENTIONSTATISTICS.COM, http://www.inventionstatistics.com/Patent_Litigation_Costs.html (last visited Mar. 27, 2016).

division between the agency and the courts in the patent area. The Federal Circuit takes a prominent role in making substantive patent policy and refuses to give the PTO *Chevron* deference. Accordingly, the PTO has perceived its own role as merely following the law made by Congress and the courts, rather than actively shaping the law. This is a shaky position because the PTO's examination duty necessarily requires the PTO to constantly make substantive patent law decisions. It is also a waste of the PTO's specialized expertise and knowledge that it can gain through its vital body of patent examination.

The obviousness guidelines provide a good starting point for the PTO to more proactively speak on substantive patent policy. Though the voice would be soft—without *Chevron* deference or binding power—it nonetheless enables the agency to claim a more active role in the U.S. patent regime in the post-AIA patent regime. The flexible nature of the obviousness doctrine ensures that the guidelines do not create substantive rights and obligations, but rather is tentative and flexible. The narrow scope of the guidelines would further make it easy for the PTO to draft the guidelines with adequate support and reasoning to make them persuasive to the courts.