NONOBVIOUSNESS: A COMMENT ON THREE LEARNED PAPERS

by

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This Article, a comment on the contributions of John Duffy, Rebecca Eisenberg, and Gregory Mandel, addresses three areas where improvements could be made in the law on nonobviousness. First, the quantum of inventiveness required for patentability should reflect the capabilities of the ordinary artisan. Second, the asymmetry in the error rate of nonobviousness determinations should be taken into account in setting the standard of nonobviousness. Third, the concept of nonobviousness—or, better, inventive step—should be operationalized by considering the opportunities, risks, and nonpatent incentives the inventor faced at the time of the innovation.

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The Supreme Court’s decision in KSR v. Teleflex provides an opportunity to reconsider the nonobviousness requirement. Professors Gregory Mandel, Rebecca Eisenberg, and John Duffy have each done an admirable job taking up the Court’s invitation. As they make clear, the nonobviousness “question” actually encompasses three related issues. The first is the standard of nonobviousness—the quantum of inventiveness, which appears as the “nonobviousness threshold” in Professor Mandel’s figures. The second is the indeterminacy of the nonobviousness decision—a problem that has plagued the patent system from the moment the requirement was introduced by Thomas Jefferson. The third is the procedure for determining nonobviousness and for reviewing decisions applying it.

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1 127 S. Ct. 1727 (2007).


Within much of the literature and policy initiatives, these three problems are highly intertwined and often conflated. For example, section 103, the statutory requirement for nonobviousness, is actually a procedure for determining it.\(^4\) Suggesting that the methodology was introduced into the statute to reduce indeterminacy, Mandel notes that the failure to define the quantum of inventiveness is the provision’s most spectacular flaw.\(^5\) The Federal Circuit, which was also largely created to reduce the indeterminacy of nonobviousness decisions,\(^6\) has chosen to police the requirement through the stringent application of procedural rules. As Eisenberg illustrates with the example of DNA sequencing,\(^7\) the Federal Circuit rarely discusses the only part of section 103 that sets a standard, which is the level of skill in the art. Further, the court’s favored procedure—the “‘teaching, suggestion, or motivation’ test,” which was adopted as a check on indeterminacy, has been applied so rigidly it effectively lowers the standard.\(^8\) And, as Duffy points out, none of these initiatives moves the law to the theoretically optimal standard of patentability, which would grant “patents only for inventions that need the patent incentive.”\(^9\) This Comment attempts to unpack these three issues by discussing each in turn.

I. THE STANDARD OF INVENTIVENESS

As noted above, the level of ordinary skill in the art is the only part of the nonobviousness analysis that determines how large an advance is needed to merit patent protection. All three authors comment on it. However, they make somewhat contradictory points. Eisenberg worries that the Court fails to consider the “changing expectations [of success] of those working in a field” and “ignore[s] their problem-solving approach[es].”\(^10\) In other writing, she has criticized the Federal Circuit’s failure to acknowledge that the people who self-select as scientists and technologists do so because they have some creative capacity.\(^11\) Mandel highlights the paucity of case law on the question of the level of ordinary skill in the art; he also notes that little attention is paid to whether

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\(^4\) 35 U.S.C. § 103(a) (2000); Id. at 17–18.
\(^5\) Mandel, supra note 2, at 335.
\(^7\) Rebecca S. Eisenberg, Pharma’s Nonobvious Problem, 12 LEWIS & CLARK L. REV. 375, 379 (2008).
\(^10\) Eisenberg, supra note 7, at 402–03, 407.
ordinary artisans have the resources available to make the invention. In other writing, he has stressed the hindsight bias that he says can lead decision-makers to assume that ordinary artisans have the same level of skill as the inventor.\textsuperscript{12}

These observations point in opposing directions because Eisenberg’s argument is, essentially, that the quantum of inventiveness is too low (real artisans are more creative than assumed, so some advances that ordinary artisans could generate are nonetheless patented), whereas Mandel’s observations about hindsight suggest that the quantum of inventiveness is too high (that in the real world, artisans are less skilled than assumed, and so could not have generated the advance disclosed in the patent application). My own intuition is that, as a general matter, the level of inventiveness is set too low. Indeed, I read the central message of \textit{KSR} as adopting that view as well, and I give Professor Eisenberg’s earlier work credit for two key lines in the opinion: the Court’s discussion of the person of ordinary skill as “a person of ordinary creativity, not an automaton” and its admonition that consideration be given to the “creative steps that a person of ordinary skill in the art would employ.”\textsuperscript{13}

Nor do I believe this view to be controversial. I take it that it is also the main thrust of Duffy’s claim that the current standard of nonobviousness is an imperfect proxy for the “patent-induced” standard.

\section*{II. INDETERMINACY}

In a sense, the above description of Mandel’s position is not entirely fair. While Eisenberg and Duffy are concerned with the standard of inventiveness, Mandel’s main focus is on the question of indeterminacy. Thus, his view is that the threshold of nonobviousness is set correctly, but that errors in making the determination are throwing a monkey wrench into the system. These include type I errors—false negatives—inventions that are nonobvious which are nonetheless considered obvious, as well as type II errors—false positives—advances that are obvious which are nonetheless considered nonobvious. He supports his argument with his earlier experimental work, where he demonstrated the cognitive impossibility of putting oneself into the position of thinking about whether an invention one knows \textit{has} been made was nonobvious \textit{when} it was made.\textsuperscript{14}

\begin{itemize}
\item \textsuperscript{13}\textit{KSR}, 127 S. Ct. at 1741–42.
\item \textsuperscript{14}See Mandel, \textit{Patently Non-Obvious II}, supra note 12, at 3; Mandel, \textit{Patently Non-Obvious}, supra note 12, at 1400.
\end{itemize}
I, however, also disagree with the more subtle version of the argument. Mandel is clearly right that the incidence of error cannot be judged by the raw numbers. As he perceptively explains, because there are so many more marginal advances than major ones made, the same level of uncertainty on both sides of the threshold will produce more wrongly granted patents than wrongly denied patents. As a result of all the wrong issuances, it will look to observers as though the standard of inventiveness is set too low even when it is set in the right place.

Still, it is hard to believe that there is real symmetry here, for there are structural features in the patent system that systematically create type II, and only type II, errors. Examiners operate under resource constraints. They have imperfect information because patentees can be less than candid, because prior art searches can be difficult to conduct,\(^\text{15}\) and because there is art that is secret which nonetheless counts for nonobviousness purposes.\(^\text{16}\) In addition, examiners have notoriously little time to think through the relationship between the known prior art and the advance claimed and, as Robert Merges has suggested, the incentive structure in the Patent and Trademark Office (PTO) favors allowances.\(^\text{17}\) As Mandel notes, a vicious cycle can take hold: the more indeterminate the decision, the more patent applications are filed; the more applications, the more work for the PTO; the more work, the more grants—and the more indeterminate the standard will appear, leading to even more applications.\(^\text{18}\)

In litigation, there are analogous sources of type II errors. The “clear and convincing evidence” standard is difficult to overcome and applies regardless of whether the PTO reviewed the prior art presented at trial.\(^\text{19}\) Aside from the hindsight bias issue, jury trials are particularly likely to skew in favor of patentability. Kimberly Moore’s work shows that juries


\(^{16}\) See, e.g., Oddzon Products, Inc. v. Just Toys, Inc., 122 F.3d 1396, 1401–02 (Fed. Cir. 1997) (discussing art available under 35 U.S.C. § 102(e), (f), and (g)). The problem of secret prior art is also at the heart of the “mistake” Duffy claims the Supreme Court made in considering Livingstone prior art. Duffy, supra note 9, at 363. The reference was considered prior art because under § 102(e), information in a patent application is technically available as of the date the patent application is filed, even if the inventor could not have seen it.


\(^{18}\) Mandel, supra note 2, at 342. See also ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 11–13 (2004).

tend to favor American inventors over infringers. In high-technology cases, the “wow” factor—the tendency of juries to be awed by technological complexity—can be very strong. Additionally, practitioners often complain that jurors uninterested in technology (or in jury duty) tend to stop listening as soon as they hear about the presumption of validity. To put this another way, cognitive problems arise only where there is real cognition—hindsight bias is an issue only for decision-makers who have a reasonable opportunity to make decisions.

To the extent that the indeterminacy problem is insolvable (and its persistence throughout the history of the patent system suggests it is insolvable), one way to reduce the number of type II errors is to shift Professor Mandel’s nonobviousness threshold to the right—to require advances to display much more ingenuity than that possessed by the ordinary artisan. Of course, the move would not be costless, for the number of type I errors would rise. In my view, however, the distortions produced by erroneous grants vastly outweigh the cost of erroneous denials. Type II errors take material out of the public domain, increase patent thickets and transaction costs, act as barriers to entry and to cumulative research, and encourage trolling. But while type I errors may be bad for the inventor, they can be very advantageous to society. Without a patent, users get important inventions for free. The Kohler and Milstein principle for making monoclonal antibodies, described by Duffy, is an example. A foundational development, its free availability meant that the biotechnology could quickly advance and influence “virtually all aspects of basic research in immunology, cell biology, biochemistry, and medicine.”

Admittedly, as the risk of not acquiring a patent increases, incentives to invent could decrease. However, the problem is likely to be significant only if the shift in patentability is very dramatic. After all, there are reasons to innovate that are not dependent on patents. Kohler and Milstein were awarded the Nobel Prize for Medicine in 1984. Less dramatically, competition and predictable obsolescence produce their

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22 Mandel, supra note 2, at 329.


24 Duffy, supra note 9, at 360.


own dynamics of innovation. As important, there are methods outside the patent system for appropriating returns on inventive investment. Thus, it is worth noting that when the Supreme Court interpreted the nonobviousness requirement in 1966 in *Graham v. John Deere Co.*, it was writing against a backdrop of a very aggressive preemption rule: *Sears/Compco*, which held state unfair competition law preempted by federal patent policy, had been decided two years earlier. The Court did not retreat from its skeptical view of state protectionism until 1974, when it decided *Kewanee Oil Co. v. Bicron Corp.* and upheld state trade secrecy law. Since that time, courts have also enforced contractual restrictions that promote the capture of returns from innovation. Furthermore, in many modern technologies, lock in and network effects can vastly prolong first-mover advantages. Patent rights are, in short, no longer the only game in town.

Greater reliance on non-patent incentives could interfere with the disclosure function of patents. But even here, the shift in patentability would have to be fairly drastic before it had real bite. In many fields (including research science), there are strong norms of sharing. Besides, the litigation literature and experience with Rule 11 indicate that lawyers tend to believe in their cases. Thus, just as many unmeritorious cases are pursued to trial, so, too, most of the same patent applications will be prosecuted. And again, the law has changed since *Graham* was penned; where patent applications were once kept confidential unless the patent issued, current rules require disclosure of most pending applications eighteen months after they are filed. Finally,

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31 See, e.g., ProCD, Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996); Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed Cir. 1992).
35 35 U.S.C. § 122 (2000). Those who file only in the United States can seek an exemption, but most important inventions are also patented abroad and cannot make use of the exemption.
even if material is kept secret, the technologies of reverse engineering have improved, making early disclosure more likely.\textsuperscript{36}

I read the Supreme Court as largely in agreement on the question of the relative cost of type I and type II errors. In \textit{KSR International Co. v. Teleflex, Inc.}, the Court emphasized that "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility."\textsuperscript{37} And in his dissent from the dismissal of the petition of certiorari in \textit{Laboratory Corps v. Metabolite Laboratories}, Justice Breyer warned that "too much patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’"\textsuperscript{38} None of the recent cases discusses type I errors.

III. PROCEDURE

All three of these authors largely agree—correctly in my view—that as currently portrayed by commentators, section 103 cannot be the right way to measure inventiveness. Eisenberg demonstrates quite convincingly that the provision is not applied as consistently as is often contended and that the Federal Circuit is actually fairly sensitive to context. It varies its approach, depending on whether it is deciding the invention is obvious or nonobvious. Chemical cases have their own standard (which involves a different use of hindsight), and for pharmaceuticals, the court is more likely to uphold a patent on a new therapeutic agent than to allow the patentee to engage in "evergreening."\textsuperscript{39}

Mandel even provides an explanation for the court’s behavior: if the level of skill in the art were accurately identified and utilized, the consequences would be perverse, for the more sophisticated a field, the higher the risk that advances in it would not be regarded as patentable. Taken to the extreme, there would be insufficient investment in the fields where society has the greatest interest (as measured by the resources devoted to it and the level of training within it).\textsuperscript{40} Presumably, the opposite would also hold, and the ease of acquiring patents in “stupid” arts could draw investment to areas in which society has very little interest. It is no surprise then that the court would (as Eisenberg demonstrates) be resistant to updating the level of skill in biotechnology at the time when the field was in its period of early growth.\textsuperscript{41}


\textsuperscript{37} \textit{KSR Int’l Co. v. Teleflex Inc.}, 127 S. Ct. 1727, 1732 (2007).

\textsuperscript{38} 126 S. Ct. 2921, 2922 (2006) (Breyer, J., dissenting).

\textsuperscript{39} Eisenberg, \textit{supra} note 7, at 429–30.

\textsuperscript{40} Mandel, \textit{supra} note 2 at 325.

\textsuperscript{41} \textit{See, e.g.}, \textit{In re Deuel}, 51 F.3d 1552, 1559 (Fed. Cir. 1995).
artisans were taken as understanding the genomic vocabulary, patent incentives would have been significantly compromised at a time when they may, in fact, have been necessary to spur the production of knowledge.

That said, I am skeptical about the substitute analysis Mandel proposes. While I think Duffy’s approach has much to recommend it, I have some concerns about it as well.

Mandel would focus the decision-maker’s attention on the point in the inventive process that required ingenuity and would ask the probability that a person of ordinary skill would have made the same advance. As to the probability issue, the question is when. In the fullness of time, it is highly likely that every invention will be made; to a large extent, the real goal of patent law is not to induce invention, but instead to induce it sooner rather than later. Or as Duffy suggested in earlier work, patent law’s aim is to move the invention from the drawing board through the patent system and out into the public domain. If the ordinary artisan is given forever (or even a long time) to come up with the invention, this goal would be defeated.

Mandel’s discussion of the simultaneity of invention as a defense to infringement suggests that “when” actually means at the exact same time as the inventor. If so, then his proposal has a great deal of resonance with Duffy’s notion of examining how the patent race is affected by external factors, including demand-side and supply-side changes, because these changes would also tend to produce the simultaneous development of obvious advances. The problem with this approach is that it, too, may lead to perverse consequences. If inventors monitor other researchers and react strategically to their progress—as many commentators posit then a simultaneity bar may lead researchers to abandon their efforts once they learn that others are working on the same problem. In his paper, Duffy slips rather quickly past his own observation that inventors are often racing for a patent. If the patent opportunity is eliminated, there is a question whether they will race at all.

In fact, KSR suffers from the same problem. According to the Court, if the market would induce the invention, there is no need for a patent. But strong market demand will also induce rapid imitation. Without significant lead time and the opportunity to develop networks (or lock in), there is a real danger that in some fields, appropriability will be compromised and the incentives to innovate reduced. Duffy’s reliance on

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44 Duffy, supra note 9, at 345.
“supply side” factors is not quite as vulnerable to this criticism, for in the absence of strong demand, there is little reason to think that potential imitators will be quick to realize that there is an innovation worthy of free riding. However, if supply-side changes also improve the technologies of reverse engineering, these could also erode the first-mover advantage. Duffy’s “supply-side” argument also depends on the genuine public availability of the new art. Under current law, however, there is art that is technically available under section 103, which is not knowable by the inventor because it is secret.46

Mandel’s approach also suffers from other problems. It is difficult to imagine that it will be less indeterminate than the current analysis. If the answer to “when” is a reasonable time, then decision-makers are likely to evaluate the prospects differently.

More important, Mandel’s suggestion that decision-makers localize the point of inventiveness within the inventive process—be it at conception, implementation, or reduction to practice—assumes a model of invention that may not be universally applicable. It echoes the linear progression from fundamental to applied science suggested by Vannevar Bush, President Roosevelt’s scientific adviser.47 That view has, however, been largely discredited. Invention is now generally perceived as a much messier business. Consider the example of Post-Its. Mandel uses it to show that conception can be the nonobvious step. In fact, there are cases that do revolve around the problem of conception.48 However, the Post-It story is quite different. It was apparently invented accidentally by a researcher looking for a strong, enduring bonding agent. Once invented, it took time to find its “killer” application.49 And this is not a trivial case. Viagra was developed to grow hair, and only later used to treat erectile dysfunction.50 Tamoxifen was discovered to prevent breast cancer only after it failed as a morning-after pill.51 The statutory experimental use

46 See supra note 16.
48 See, e.g., Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45, 68 (1923) (holding an invention nonobvious based on the difficulty of identifying the problem, even though the solution was clear once the problem was identified).
51 V. Craig Jordan, Tamoxifen (ICI46,474) as a Targeted Therapy to Treat and Prevent Breast Cancer, 147 BRIT. J. OF PHARMACOLOGY S269, S269 (2006) available at http://www.nature.com/bjp/journal/v147/n1s/full/0706399a.html (the research method used to achieve the current successes [in breast cancer prevention] seen in
case that was the focus of the Supreme Court’s attention in 2005 similarly involved identifying new (and better) uses for a previously invented compound.\textsuperscript{52}

Indeed, Eisenberg’s paper is largely about the chaotic business of inventing. Sometimes an invention is known, but not its best use (as with Post-Its); sometimes a minor characteristic of one molecule leads to the identification of a major use for a structurally similar entity (as in \textit{In re Dillon} \textsuperscript{53}); sometimes there is a question of finding a salt that will make a compound useful (as in \textit{Pfizer, Inc. v. Apotex, Inc.}\textsuperscript{54}); and sometimes a new technique for synthesis opens up a host of other opportunities (as in \textit{In re Durden} \textsuperscript{55}). If the doctrine were to require parties to force the business of invention into one of the three Procrustean beds Mandel posits, much satellite litigation is likely to ensue. Of course, if Mandel is simply suggesting that courts focus on the locus of invention when there clearly is one, there may well be cases where this part of his analysis will illuminate decisions on nonobviousness.

\textbf{IV. CONCLUSION}

Although the failure to articulate a quantum of inventiveness may be section 103’s most spectacular flaw, these papers make it clear that the problem is likely unavoidable. Thus, it is not insignificant that, like policymakers and courts, all three authors focus on procedure, not on the actual standard of ingenuity. Given the way that that systematic errors fall, and the higher cost attached to type II errors, a procedure that promotes a very high level of inventiveness is likely superior to one that sets it too low. That, perhaps, is the essence of \textit{KSR}.

For the future, the law needs to better operationalize the notion that patent rights are instrumental, that they are not meant as rewards for invention, but as ways to promote the progress of the useful arts. Now that \textit{KSR} has recognized the diversity of inventive pursuits and modern technologies, and has emphasized the issue of the predictability of the disclosed advance,\textsuperscript{56} perhaps it is time to take the focus off \textit{ordinary artisans} and look instead at \textit{inventors}. But rather than look at the circumstances of invention (an analysis that has largely been rejected\textsuperscript{57}),

\textit{the clinic was not linear but was based on the changing fashions in research and the application of appropriate testing models\textsuperscript{56}).}

\textsuperscript{52} Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
\textsuperscript{53} 919 F.2d 688 (Fed. Cir. 1990).
\textsuperscript{54} 480 F.3d 1348 (Fed. Cir. 2007).
\textsuperscript{55} 763 F.2d 1406 (Fed. Cir. 1985).
\textsuperscript{57} See 35 U.S.C. § 103(a) (2000) (“Patentability shall not be negatived by the manner in which the invention was made”); Roberts v. Sears, Roebuck & Co., 697 F.2d 796 (7th Cir. 1983) (Posner, J.), vacated, Roberts v. Sears, Roebuck & Co., 723 F.2d 1324 (7th Cir. 1983).
courts should consider how potential inventors and their investors react to the problems they face.

John Duffy is right to start by looking at what has changed, whether it be new demand or new inventive supply. However, it is important not to stop there. Also to be considered are the risks the inventor faced and all of the incentives to innovate in the inventor’s sector (patents, trade secrets, lead time, competition, norms and benefits of sharing, obsolescence). In addition, consideration should be given to the challenges posed by the technology at issue, including the extent to which invention in the field is cumulative or free standing, the ratio between patents and products, and the costs of moving from lab bench to marketplace. Eisenberg demonstrates that such an approach is not as far-fetched as it might seem. As her discussion of enantiomers shows, there are contexts in which the Federal Circuit is already behaving in a remarkably flexible way.

I would also suggest dropping the word “nonobviousness” and joining other nations in focusing on the “inventive step.” “Nonobviousness” specifies a particular quantum of ingenuity; post-KSR, the issue is what the quantum of invention ought to be. And since the term invites the question “obvious to whom?,” it also suggests the procedure for determining the level of ingenuity required—a procedure that we now know is rife with uncertainty and indeterminacy. KSR requires reexamination and these three papers—along with the rest of this Conference—are a wonderful way to begin that enterprise.

59 Eisenberg, supra note 7 at 425.