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COMMENT

PATENTLY OBVIOUS:

A DUAL STANDARD SOLUTION TO THE DIVERGING NEEDS OF THE INFORMATION TECHNOLOGY AND PHARMACEUTICAL PATENT INDUSTRIES

INTRODUCTION

Patents are the principal way for companies in the United States to protect their investment in developing new inventions. Congress designed the patent system to promote innovation by providing inventors the opportunity to reap their labor's benefits before turning the invention over to the public. As the United States has grown, innovation has become an increasingly important factor of our economy, and as a result, many U.S. companies heavily rely on the patent system to protect their research and development expenses and continue to operate successfully. Indeed, from 1996 to 2006, the number of patents issued

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1 Patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy. Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (stating the reason Congress has power to legislate in the area of intellectual property is to promote the Progress of Science and useful Arts.); see also EARL W. KINTNER & JACK L. LAHR, AN INTELLECTUAL PROPERTY LAW PRIMER 7-11 (2d ed. 1982).

2 PATENTING BY ORGANIZATIONS 2006, http://www.uspto.gov/go/ocip/taf/topo_06.htm#PartB (a table showing almost all of the top U.S. companies and the number of patents they were granted in 2006).
per year to U.S. companies by the U.S. Patent and Trademark Office jumped from 69,419 to 102,267, an increase of over thirty-two percent. The patent system’s health will therefore impact the U.S. economy’s future.

In order to be granted a patent, an invention must be new, useful, and nonobvious. These requirements measure the level of innovation required to create the new invention and then determine if that level warrants granting the inventor a temporary monopoly over the invention. In particular, the obviousness question tends to be at the forefront because, although most nonobvious inventions are also both new and useful, there are numerous new and useful inventions that are not nonobvious. Nonobviousness is designed to mark the specific level of innovation needed for an invention to be patentable, and although whether an invention is new or useful can indicate some amount of innovation, it does not necessarily indicate that enough has been achieved to meet that level. Consequently, whether an invention is deemed obvious can often be the key factor for determining if a patent should be issued.

Recently, the patent system’s health has degraded to such a point that it has compelled the Supreme Court to address the problem three times in a twelve-month span, culminating with a change to the obviousness standard in the summer of 2007 with its ruling in KSR International Co. v. Teleflex Inc. In KSR, the Supreme Court narrowed the scope of what can be patented by instructing courts to use “common sense” when determining what is obvious, as opposed to the recent trend of analysis where the courts failed to recognize inventors’ creative capabilities. This revision in KSR, however, like past reforms to the patent system, will only be a temporary solution because it comes with more drawbacks than benefits. In order to address the patent system’s needs, at least two discrete standards are required for determining obviousness.

7 Id.
8 See id.
Information Technology (hereinafter “IT”) and pharmaceutical patents allow for the most illustrative analysis of the patent system’s diverse needs and corresponding problems. This is because the IT and pharmaceutical industries contain the most divergent needs with respect to patents, and therefore best represent the two ends of the patent system spectrum in regard to obviousness.\textsuperscript{11} The IT industry is overflowing with patents and as a result a more restrictive obviousness standard is needed to slow the introduction of new patents into the overcrowded industry. Contrarily, due to the huge scope of Markush claims,\textsuperscript{12} which are commonly used in pharmaceutical patents, the pharmaceutical industry is operating with a relatively low number of patents. Accordingly, unlike the IT industry, the pharmaceutical industry needs a less restrictive obviousness standard so it can be confident that each of the few patents it acquires is valid.\textsuperscript{13} Therefore, to be effective, any solution to the obviousness standard issue will have to address both of these fields’ needs, and if flexible enough to accomplish that, the solution will likely also be adequate to address the needs of the fields closer to the middle of the patent spectrum.

Additionally, for the purposes of this discussion, IT patents include computer and Internet software, and Internet related business method

\textsuperscript{11}While every industry has different needs regarding the obviousness standard, the IT and pharmaceutical industries represent the opposite ends of the spectrum in this regard and also represent two of the largest and most important industries in the U.S. economy. Indeed, according to a recent government report the top ten companies in the pharmaceutical industry earned almost $40 billion in net profits in 2006. \url{http://oversight.house.gov/documents/20060919115623-70677.pdf} (last visited on Sept. 28, 2008). Also, in the IT industry, according to \url{www.CNNMoney.com}, the top 5 internet services companies alone earned over $5.6 billion in net profits in 2005. \url{http://money.cnn.com/magazines/fortune/fortune500/industries/Internet_Services_and_Retailing/1.html} (last visited on 9/28/08). Additionally, IT patents “are . . . responsible for a major share of patent lawsuits [and] thus play a central role in the failure of the patent system as a whole. Any serious effort at patent reform must address these problems and failure to deal with the problems of software patents—either with software specific measures or general reforms—will likely doom any reform effort.” JAMES BESSEN AND MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 16 (Princeton University Press 2008), available at \url{http://researchoninnovation.org/ldopatentswork/dopat9.pdf}.

\textsuperscript{12}“A Markush claim is a claim on a patent application that includes elements listing alternative chemicals, materials, or steps in a process. A Markush claim typically has language such as ‘selected from the group consisting of.’ The alternatives must all give the same result, rather than patentably distinct products. The name derives from Ex parte Markush, 1925 Dec. Comm’r Pat. 126.” BLACK’S LAW DICTIONARY (8th ed. 2004); see also Manual of Patent Examining Procedure § 803.02 (2007).

\textsuperscript{13}See FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 5–6 (2003), available at \url{http://www.ftc.gov/os/200310/innovationrpt.pdf} (“The low number of patents contained in a pharmaceutical product means that, as panelists noted, the development of patent thickets is generally not a concern.”).
Pharmaceutical patents include only drug patents that are subject to Food and Drug Administration (hereinafter "FDA") approval. IT does not include hardware, electronics, and other material-based technology, as those industries' needs are closer to those of the pharmaceutical industry.

This Comment proposes the use of a specifically tailored obviousness standard as a new solution to the IT and pharmaceutical patent industries' divergent needs. Part I summarizes the obviousness standard's history in patent law. Part II illustrates how the IT and pharmaceutical industries have divergent needs. Part III describes why using a single standard for the obviousness inquiry is inadequate to meet the needs of both the IT and pharmaceutical industries. Part IV illustrates why the obviousness standard needs to be specifically tailored for the IT and pharmaceutical industries. Finally, Part V concludes that a dual standard for obviousness is needed to effectively address the IT and pharmaceutical industries' needs.

I. THE "OBVIOUSNESS" STANDARD'S HISTORY AND IMPORTANCE

Because of its flexibility, the standard for what is obvious has become the key element in determining what level of innovation merits the grant of a patent. In an effort to perfect the definition of obviousness, the judiciary has struggled with the standard on numerous occasions, changing it from very strict, to fairly lenient, and then most recently back to strict. Despite this effort, none of these strictness levels for the standard has proven to be suitable in the long term. Congress, although trying to help with the problem indirectly by addressing tangential issues,
has chosen to leave the ultimate responsibility of refining the obviousness standard with the judiciary. Therefore, until the judiciary discovers an obviousness standard that can stand the test of time, the patent system will be stuck in what has been a cycle of inadequate refinement.

A. THE OBVIOUSNESS STANDARD IS VITAL TO THE PATENT SYSTEM

Generally, to be patentable an invention must be (1) useful, (2) novel, and (3) nonobvious. Of these elements, the first two—usefulness and novelty—are met by anything (1) having a current use (2) that was not previously in existence. However, what is required for an invention to be nonobvious has resisted precise definition, and as a result, the legislature used broad statutory language when defining obviousness. These definitions' overall effect has been to bring the obviousness standard to the forefront of what warrants a patent because, unlike the first two elements, the flexibility in the obviousness standard has bestowed on the judiciary wide discretion to interpret the standard and thereby control what level of innovation deserves a patent.

An invention is “useful” if (1) it is capable of use, (2) it achieves some human purpose, and (3) that purpose is not contrary to public policy. Generally, this requirement is usually met because most things, especially those for which a patent is sought, can be described as having a use, and those uses can generally be framed in a way that is not contrary to public policy. An invention is novel if the invention has not already been patented and is not already within the knowledge of the relevant public (i.e., within the public domain). This simply means that

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19 See S. REP. NO. 82-1979, at 2399 (1952) (indicating that the language used in § 103 to codify the obviousness requirement had to be sufficiently broad so as to incorporate a legal concept that had been expressed in a large variety of ways); see also 35 U.S.C. § 103 (2004).
21 DONALD S. CHISUM, CHISUM ON PATENTS § 4.01 (2005); see Curtiss-Wright Corp. v. Link Aviation, Inc., 182 F. Supp. 106 (N.D.N.Y. 1959) (“The usefulness required by this section as [an] element of patentability is relative, and implies practicability as distinguished from perfection.”) (internal quotation marks omitted); see also Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 298 F. Supp. 435 (W. D. Mich. 1969) (“Utility, within meaning of this section means that object of patent is capable of performing some beneficial function claimed for it.”) (internal quotation marks omitted).
22 Bonito Boats, Inc. v. Thunder Craft Boats, Inc. 489 U.S. 141, 148 (1989) (“The novelty requirement of patentability is presently expressed in 35 U.S.C. §§ 102(a) and (b), which provide: ‘A
the invention cannot have been already invented or publicly known. Therefore, because most patents can meet the "usefulness" requirement, and the novelty requirement only precludes issuance if the invention was already known, neither requirement is sufficiently rigorous to be used as a measure of an invention's value to society. As a result, obviousness becomes "the ultimate condition of patentability," and serves as the judiciary's most effective means of ensuring that an invention's value to society justifies the grant of a patent.

The judiciary determines if an invention is "obvious" by asking if, given the prior art, a person having ordinary skill in the relevant art (hereinafter "PHOSITA") would find it obvious. More specifically, a PHOSITA is a hypothetical individual created by patent law as a way of defining the ordinary skill level present in any member of the field of innovation. This means that first the court must decide the scope of the person shall be entitled to a patent unless- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of application for patent in the United States . . . . 

Sections 102(a) and (b) operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public.


Although a patent's value to society is impossible to definitively quantify, because the stated purpose of patents is to promote innovation, whether an invention's value merits a patent should be characterized with that goal in mind. Therefore, the social value of an invention could be measured by asking: if a patent was granted for the invention, would the amount of investment in innovation it encourages (by providing security as to the return on that investment) outweigh the amount of innovation it discourages (by forcing other inventors to invent around it or pay for a license to use it in their own inventions). This is an oversimplification, but it represents the balance that the judiciary must keep by determining what deserves a patent.

Prior art in the context of patents is knowledge that is publicly known, used by others, or available on the date of invention to a person of ordinary skill in an art, including what would be obvious from that knowledge. See 35 U.S.C. § 102 (2002). Prior art includes (1) information in applications for previously patented inventions; (2) information that was published more than one year before a patent application is filed; and (3) information in other patent applications and inventor's certificates filed more than a year before the application is filed. Id.


This legal tool is utilized so that the skill of an inventor is measured not against that of a layperson, but against the skill of other ordinary inventors in the same field. Id. Additionally, although it might seem that because a PHOSITA in the pharmaceutical industry would likely be an individual with a doctorate in chemistry, whereas a PHOSITA in the IT industry would often have only a bachelor's degree in computer science, it would create an intrinsically higher obviousness standard for pharmaceuticals. This difference in education level should, in theory, be counterbalanced by an intrinsically more difficult field. In other words, if more education is needed to work in the pharmaceutical field, then it is likely because it is more difficult to innovate in that field. Therefore, what is obvious to a PHOSITA remains relatively the same for both the IT and pharmaceutical industries.
prior art in the relevant field, and then the skill level possessed by an “ordinary person” in that field. Using this information, the court can then decide whether that “ordinary person” with access to that scope of prior art would have found the invention obvious. Each of these determinations—the scope of the prior art, the ordinary skill level, and what the PHOSITA would find obvious—are sufficiently broad that they provide the court with substantial leeway to adjust what is required to meet those elements. This flexibility is critical to satisfy the patent system’s changing needs and distinguishes obviousness from usefulness and novelty as the court’s best tool to accurately control the value society places on inventions.

B. THE HISTORY OF THE OBVIOUSNESS STANDARD

The test for determining whether an invention is obvious has been subject to continual refinement. The Supreme Court first formulated the test in 1851 as a patentability condition, but Congress did not codify the test until the Patent Act of 1952 in an attempt to consolidate the varying obviousness definitions found throughout the courts at the time. In 1966, the Supreme Court created a four-factor test (hereinafter “the Graham factors”) to determine an invention’s level of obviousness, which added limited stability to this new requirement’s interpretation. In the same opinion the Court also listed what are known as “secondary factors” that help illuminate if an invention passes the four-factor test and is therefore nonobvious. The flexibility of the Graham factors

29 Id.
30 “What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” Graham v. John Deere Co., 383 U.S. 1, 18 (1966) (discussing the broadness of what are now known as the “Graham factors” and the resulting expansive leeway allowed for in their interpretation).
34 S. REP. NO. 82-1979 (1952) (stating that obviousness has been expressed in a large variety of ways in decisions of the courts and in writings. Section 103 states this requirement in the title).
36 “Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” Id.
allowed the courts to avoid being tied down to a certain high or low standard, but in practice, without further guidance, the *Graham* factors proved to be too vague for the courts to apply with consistency.37

Despite this effort, a uniform understanding as to what is an “obvious” invention remained elusive, and a patent case’s outcome depended more on where the trial occurred and the particular circuit’s general attitude toward patents than the particular case’s actual facts.38 As a result, in an unprecedented move, Congress in 1982 created the Federal Circuit, an independent patent circuit with a distinct goal of solving the obviousness conundrum.39

The Federal Circuit’s solution to this obviousness problem was to elaborate further on the *Graham* four-factor test, describing a more specific obviousness definition that was substantially easier to apply with consistency.40 This elaboration’s result however, was a loss of flexibility: it forced the Federal Circuit to decide whether the standard would be either minimally restrictive or greatly restrictive on one’s ability to obtain a patent. Ultimately, the Federal Circuit chose a minimally restrictive standard as a way of countering the greatly restrictive standard and anti-patent trend that had revealed itself previously in the federal courts.41 To accomplish this, first the Federal

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40 See KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1730 (2007) (“[S]eeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a ‘teaching, suggestion, or motivation’ (TSM) test, under which a patent claim is only proved obvious if the prior art, the problem’s nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings.”).

41 The Federal Circuit also contributed to this pro-patent bias by increasing the quantity of injunctions for infringement, as well as the money totals awarded for infringement. Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 Minn. J. L. Sci. & Tech. 1, 41 (2007) (“Since its formation, the Federal Circuit has tended to exacerbate these penalties through its increased willingness to order preliminary and final injunctions, award enhanced damages for willful infringement, and its greater flexibility in calculating patent damages in general.”); Michael Davis, *Patent Politics*, 56 S.C.L. Rev. 337, 371 (2004) (stating that since the creation of the Federal Circuit during the pro-business 1980s, however, the country has entered a “pro-patent” cycle that its boosters have coined “The Era of the Patent.”).
Circuit eliminated the "synergy" requirement for combination patents.42 The synergy test stated that if an invention combined two or more pieces of prior art, the result of the combination had to be unexpected to be considered nonobvious.43 This synergy requirement removal thus allowed for more combination patents44 to be granted, which, because they were only a combination of previously known technology, tended to stretch the limits of what could be considered nonobvious.45 Then, in an attempt to create more uniformity and consistency, the Federal Circuit popularized the teaching, suggestion and motivation test (hereinafter "TSM test") to help determine what is obvious.46 Specifically, the TSM test stated that for pieces of prior art to render an invention obvious, the prior art must contain some teaching, suggestion, or motivation that would have led a PHOSIT to modify the prior art to arrive at the claimed invention.47 This added rigidity to the obviousness analysis and further narrowed the realm of what was obvious by stating that unless the prior art contained an express or written teaching, motivation, or suggestion to be combined, then the invention was nonobvious.48

As a result, in its short history the obviousness standard has swung like a pendulum between extremes of leniency and strictness.49 These

44 A combination patent is a patent granted for an invention that unites existing components in a novel way. BLACK'S LAW DICTIONARY (8th ed. 2004).
46 KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007) (“Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the ‘teaching, suggestion, or motivation’ test (TSM test) . . . .”).
47 In other words, an invention is obvious under the TSM test if the pieces of prior art, in addition to cumulatively describing every aspect of the invention, also contain some explicit teaching, suggestion or motivation to combine them. A suggestion or motivation to combine generally arises in the references themselves, but may also be inferred from the nature of the problem or occasionally from the knowledge of those of ordinary skill in the art. See In re Roufett, 149 F.3d 1350, 1355 (Fed. Cir. 1998).
changes have been caused by (1) the importance of refining the obviousness standard due to its direct relationship with the health of the patent system,\(^{50}\) and (2) the elusive task of finding a standard sufficiently flexible so that it effectively meets all of the patent system's needs while simultaneously being sufficiently concrete to permit consistent application.\(^ {51}\) Prior to the Federal Circuit's inception in 1982, there was a swing in the courts toward a more restrictive obviousness standard requiring there be a "flash of creative genius" to merit a patent,\(^ {52}\) which, by expanding what was considered obvious, lowered the number of patents being granted.\(^ {53}\) Then in 1982 the "pro-patent" Federal Circuit was created and the standard for obviousness swung back, becoming more and more lenient and increasing the number of patents issued.\(^ {54}\) Recently, the Supreme Court announced another swing toward a high standard with its holding in *KSR v. Teleflex*, by explaining that common sense should be used in determining if an invention is obvious given the prior art.\(^ {55}\) Essentially, by allowing patent examiners to justify an obviousness rejection of a patent application by citing a broad concept such as common sense, the Court raised the bar for what is nonobvious

and therefore patentable.56

The changes made by the Federal Circuit, coupled with the birth of the Internet and subsequent IT boom, have generally led to an unhealthy influx of IT patents and the need for expensive cross-licensing.57 Basically, the low nonobviousness standard allowed IT patents to be granted in increasing numbers and made it increasingly difficult to create an invention that did not incorporate numerous existing patents.58 As a result, inventors have been compelled to negotiate licenses with all the owners of the previously existing patents, creating a complicated cross-licensing web.59 In total, the volume of patents was stifling innovation in the IT sector.60 The transaction costs61 associated with the cross-licensing, added to the actual licenses' royalty costs, were increasing the cost of business operations. The end result was the gradual elimination of the viability of small market inventors'62 viability.63

56 See id.
57 "To mitigate [a patented product] hold up in the context of a patent thicket, some firms in certain industries have accumulated large patent portfolios . . . This leads the firms to reach licensing agreements with each other, often portfolio cross-licensing agreements." FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2, at 30 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf.
58 See David B. Conrad, Mining the Patent Thicket: The Supreme Court's Rejection of the Automatic Injunction Rule in eBay v. MercExchange, 26 REV. LITIG. 119, 139 (2007) (discussing the increase in patent lawsuits due to the unhealthy influx of IT patents).
59 Alternatively, if the inventor believes that some of the existing patents are invalid, he or she has the option of filing for a third-party reexamination of the existing patent, but this requires both additional time and money and risks the patent being found valid and requiring the inventor to negotiate a license anyway. Also, an inventor sometimes will just document invalidity arguments to the existing patent and move forward with the invention, but this risks the costs of a future infringement lawsuit from the existing patent owner and again the possibility that the existing patent will be found valid.
61 A transaction cost is a “[c]ost connected with a process transaction, such as a broker’s commission, the time and effort expended to arrive at a deal, or the cost involved in litigating a dispute.” BLACK’S LAW DICTIONARY, cost (8th ed. 2004).
62 In this context, "small market inventors" are inventors who either personally manufacture and market their patented products, or who are invested in making good faith efforts to license the right to manufacture and market their patented product in order to recoup their research and development costs and make a profit. This definition is distinguished from "patent trolls," who are not primarily interested in marketing or manufacturing their patents, but instead are interested in finding a manufacturer and marketer who are infringing on their patents and then threaten litigation to obtain exorbitant licensing fees. This distinction is critical because a small market inventor's research and development costs compel it to incur transaction costs in order to profit on the invention, whereas a patent troll has little if any research and development costs and cannot therefore avoid most transaction costs.
63 See FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF
C. CONGRESS’S ATTEMPTS TO ADDRESS THE PROBLEM HAVE BEEN INEFFECTUAL

Patent law reform has been an issue before Congress for the past few years but has yet to produce any results.64 This failure is the result of the anticipated disparate effects that proposed reforms would have on the conflicting interests of the big companies in the IT and pharmaceutical industries.65 The pharmaceutical industry is adamant that reform of the current patent law, which has allowed them to flourish, is largely unnecessary. The IT industry is equally adamant that the current patent law, which has begun to stifle the IT industry, is flawed and needs substantial reform.66 Thus, each time a new patent reform bill is created, the opposing lobbyists from the IT and pharmaceutical industries produce a stalemate in Congress by dividing the vote.67 The most recent proposed legislation illustrates these difficulties. Two of the main proposed reforms in the Patent Reform Act of 2007 are an adjustment to the infringement damages award process and a new post-grant opposition procedure.68

The adjustments to the infringement damages award process, principally, would lower the amount of damages granted for an infringement lawsuit by narrowing the scope of what can be considered in calculating a reasonable royalty. They would also preclude the award of punitive damages for willful infringement as long as the infringer had a good-faith belief that it was not infringing on a valid patent.69 Because both of these effects would be favorable to defendants in infringement lawsuits, they would primarily benefit the big companies in the IT industry, which are constantly defending infringement lawsuits due to “patent trolls” and the overlapping patents created by the IT patent glut.70

64 At the time of this paper, Sept. 1, 2008, the newest version of the Patent Reform Act had been passed by the House of Representatives, but had yet to be passed by the Senate. Patent Reform Act, H.R. 1908, 110th Cong. (2007).

65 “Generally speaking, software and other Big Tech industries want broader revisions of the patent statute, whereas the ‘Big Pharma’ sector does not. According to Alan Fisch, a patent litigator with Kaye Scholer in Washington, D.C., patent reform ‘has pitted two of the leading technology sectors against one another, specifically the computer industry versus pharmaceutical industry.’” Clarisa Long, Our Uniform Patent System, 55 FEB. FED. LAW 44 (2008).

66 Id.

67 See id.


70 “Microsoft’s Brad Smith has said that his company spends ‘close to $100 million annually to defend against an average of 35-40 patent lawsuits simultaneously.’ Often the patent being
On the other hand, big pharmaceutical companies are primarily plaintiffs in infringement lawsuits, due to the importance of preventing infringement of each of their relatively low number of patents, and therefore would be harmed by the proposed amendments.  

Similarly, the proposed post-grant opposition provision has the effect of pitting big IT against big pharmaceuticals. The effect of the post-grant opposition provision would be to allow the validity of patents to be challenged without filing a lawsuit; more significantly, these out-of-court challenges would lack the presumption of validity that issued patents enjoy in court. Again, because the big IT companies are often the defendants in infringement actions, they support the provision as a cheaper way to dispel frivolous but expensive litigation. Predictably, because the big pharmaceutical companies need to protect the validity of their relatively few patents, they oppose this provision because it would provide another opportunity for them to lose their patents. The ultimate result of these disparities on the big IT and pharmaceutical companies is that both the support and opposition to the reform are well-funded and lead to a stalemate in the legislative process. Furthermore, given this difficulty, it is not surprising that Congress has not attempted to amend the actual language of the requirement that an invention be nonobvious, as such a major change would likely only provoke an even greater conflict between the IT and pharmaceutical industries. Accordingly, even if the current bill were passed, it still would not solve the problems with the obviousness standard itself and, as a result, it will be left to the judiciary to fix the current problems in the patent law system until there is significantly increased agreement in the legislature.

71 Id. at 45.
72 See id. at 47.
73 Id. at 46.
74 Id.
75 "Opponents of the proposed reforms say that reforms go too far, weakening the value of patents and making them easier to challenge. "It's almost everything an infringer could ever want," says Phil Johnson, the chief patent attorney for Johnson & Johnson." Id. at 47.
76 See id. at 46-47.
77 Unless, of course, the amendment created a dual standard as outlined in this Comment that satisfied the needs of both the IT and pharmaceutical industries.
78 There is also a possibility that the federal executive branch might attempt to address the problem by defining a new administrative process for interpreting the obviousness standard in the U.S. Patent and Trademark Office regulations; thus far, however, the executive branch has failed to show any inclination to effectuate such a rule change.
D. THE SUPREME COURT’S EFFORTS TO RAISE THE STANDARD FOR OBVIOUSNESS BOTH INDIRECTLY AND DIRECTLY WILL ONLY RESULT IN A TEMPORARY SOLUTION

The Supreme Court recently attempted to address this unhealthy state of patent law in the IT sector with its rulings in three cases in 2006 and 2007. Unfortunately, although they will have some short-term benefits, these rulings either only indirectly address the issue by treating the current symptoms (“patent trolls”) and not the source (the obviousness standard itself), or directly address the issue but create only a temporary solution because they neglect the needs of the pharmaceutical industry. Consequently, with time, these changes will only result in an unhealthy pharmaceutical industry crying out for changes, as the IT industry is now, and the cost of altering the obviousness standard will be incurred yet again.

The first two of these Supreme Court decisions, eBay Inc. v. MercExchange L.L.C. and MedImmune, Inc. v. Genentech, Inc., do not directly address the obviousness issue, but instead focus on its effects, i.e., the viability of “patent trolls.” Specifically, the eBay case restricted the availability of permanent injunctions for patent infringement and the MedImmune case broadened the scope of who has standing to challenge a patent’s validity. In eBay, the Supreme Court found that permanent injunctions to prevent patent infringement should not be granted either “categorically” or as a “general rule” when there is a finding of infringement, rather, an evaluation needs to be made on a


case-by-case basis using the traditional four-factor test. With this holding, the Supreme Court undercut the ability of "patent trolls" to use the threat of injunctions as leverage to obtain excessive licensing fees for their patents.

In *MedImmune*, the Court continued to chip away at the power of "patent trolls" by finding that even the licensee of a patent is not prevented from challenging the patent's validity. Prior to this case, licensees of a patent were prevented from challenging the patent because it was thought that by already paying for the license they were implicitly conceding the patent's validity. In particular, this ruling addressed the dilemma that a licensee faces when confronted with the threat of infringement. Now, instead of having to challenge the patent immediately and put its own products on hold, the licensee will be able to continue fabrication of its allegedly infringing products by acquiring a license for the patent while still researching the validity of the licensor's patent. Although this ruling and that in the *eBay* case provide indirect help by addressing the current symptoms of the problem, they do not provide a long-term solution for the obviousness question itself, and therefore are only short-term "band-aids." In possible recognition of this, the Supreme Court subsequently accepted the *KSR* case and attempted to address the obviousness issue head-on.

In *KSR*, the Supreme Court made a dramatic change to the obviousness standard and shifted the tide of the patent system by increasing the difficulty of obtaining a patent. Although the Supreme Court did not change the wording of the TSM test, it redefined its meaning so as to remove the rigidity of its recent application and allow

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84 "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 390-92 (2006).


90 *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) ("The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents... When a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.").
for a larger consideration of "common sense" in determining if an invention is obvious.\textsuperscript{91} Principally, the Court changed the TSM test, described above, such that instead of only requiring the reference of the motivations of the inventor in the case at hand, the test now requires reference to the motivations of all "ordinary" inventors in the relevant industry; in other words, all the motivations of a PHOSITA.\textsuperscript{92}

These rulings are so recent that the repercussions of these changes have yet to be seen, but it is likely that they will significantly reduce the number of patents granted. In particular, combination patents,\textsuperscript{93} which were already on the boundary of what was obvious because they involve the combination of known technologies, will become increasingly difficult to obtain. As a result, the strain on the IT industry from the glut of patents will likely lessen, but the pharmaceutical industry may suffer due to its need for patents that appear to be simple combinations of previously known compounds.\textsuperscript{94}

II. THE NEEDS OF THE INFORMATION TECHNOLOGY AND PHARMACEUTICAL INDUSTRIES ARE DIVERGENT

Each of the main patent industries has different needs in relation to the strictness of the obviousness standard in order to best promote innovation, but none are as conflicting as those of the IT and

\textsuperscript{91} KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007) ("Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.").

\textsuperscript{92} KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007) ("The first error ... was to ... [hold] that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a [PHOSITA]. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.") (emphasis added, internal citations omitted).

\textsuperscript{93} A combination patent is a patent granted for an invention that unites existing components in a novel way. BLACK'S LAW DICTIONARY, patent (8th ed. 2004).

\textsuperscript{94} Markush claims, which are a common type of claim in pharmaceutical patents, at first glance seem to be complex – and therefore less obvious – due to the large quantity of equivalent molecular subparts described in the dependent claims. However, for the purposes of being "nonobvious" under 35 U.S.C. § 103, only the underlying independent claims need to be analyzed because any independent claim that is found to be nonobvious will also have the effect of making the claims dependent on it nonobvious. Therefore, a Markush claim's apparent complexity is not an accurate indication of its complexity under the obviousness analysis. See Robert Spar, 37 CFR Part 1 Examination of Patent Applications that Include Claims Containing Alternative Language, Federal Register, Department of Commerce, August 10th, 2007, 923 PLI/Pat 53 (2008) (discussing the challenges arising from the use of Markush claims in patent applications).
pharmaceutical industries. A more restrictive obviousness standard that benefits the IT industry hinders the pharmaceutical industry and vice versa. The IT industry is overwhelmed with patents and is in need of a higher standard for obviousness to counteract the problem. In each year since 1995, IT companies have comprised the majority of the top ten organizations in terms of patents granted and for thirteen straight years, IBM, an IT company, has ranked first among non-federal patenting organizations. In contrast, the pharmaceutical field has relatively few patents and, due to the importance of each one, needs a lower obviousness standard to ensure their validity. Combination patents, which stretch the limits of what can be nonobvious, have particular value to the pharmaceutical field. The health of patent law is contingent on addressing all of these needs.

A. THE INFORMATION TECHNOLOGY INDUSTRY NEEDS A MORE RESTRICTIVE OBVIOUSNESS STANDARD TO COMBAT THE CURRENT PATENT GLUT AND "PATENT TROLLS"

The current overpopulation of patents in the IT field is stifling

98 See Brief of Amicus Curiae Pharmaceutical Research and Manufacturing of America (PhRMA) in Support of Respondent at 2, eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (No. 05-130), 2006 WL 622122 (“Given the time and financial expenditures necessary to develop new drugs, intellectual property principles, especially those involving the protection of patent rights, are of critical importance to PhRMA members and their research and development efforts. PhRMA has a strong interest in seeing the law continue to protect those patent rights essential to ensuring future innovation and the timely development of new medicines. As practitioners in an industry where research and development are expensive and competition is fierce, PhRMA’s members need strong patent protection to be able to recoup the costs of their investments.”).
99 FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, at 1 (2003), available at http://www.ftc.gov/os/2003/03/innovationrpt.pdf (“Pharmaceutical and biotechnology representatives testified that strong patent protection is essential to innovation in their industries. Business representatives characterized innovation in these industries as costly and unpredictable, requiring significant amounts of pioneering research to discover and test new drug products. By preventing rival firms from free riding on discoveries, patents allow pharmaceutical firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products.”).
innovation. As a result of years of the Federal Circuit expanding the limits of what can be patented, the IT field has reached a point where the cost of innovation does not primarily come from research and development, but instead from licensing fees for the use of the numerous existing patents. It is estimated that if one is “selling online . . . there are 4,319 patents [that the seller] could be violating.” To begin to fix this situation, the IT field needs a more restrictive obviousness standard to reduce the amount of patents.

The first cause of this situation is the relatively small investment needed to develop IT patents relative to other patents, especially pharmaceutical patents. Although the development of new IT inventions like new software programs involves both trial and error and time, it faces little to no quality regulation. Furthermore, there is no need to synthesize new chemicals or perform clinical trials to demonstrate an IT invention’s efficacy. Consequently, the cost of the average IT invention is relatively small in comparison to the costs in fields like pharmaceuticals, which must spend about $800 million per new drug.

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100 FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, executive summary at 6 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (“In some industries, such as computer hardware and software, firms can require access to dozens, hundreds, or even thousands of patents to produce just one commercial product.”).

101 FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, executive summary, at 6 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (“Many of these patents overlap, with each patent blocking several others. This tends to create a ‘patent thicket’ – that is, a ‘dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.’”).

102 JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK, ch. 9 at 15-16 (Princeton University Press 2008), available at http://researchoninnovation.org/dopatentswork/dopat9.pdf (“The effect of this flood is apparent in e-commerce patents. David M. Martin estimates that ‘if you’re selling online, at the most recent count there are 4,319 patents you could be violating. If you also planned to advertise, receive payments for or plan shipments of your goods, you would need to be concerned with approximately 11,000 . . . It is no accident that most software users do not clear rights. Checking thousands of patents is clearly infeasible for almost any software product. Consequently, firms do not clear their technologies, they inadvertently infringe and costly litigation is the result.’”).

103 Clarisa Long. Our Uniform Patent System. 55 FEB. FED. LAW 44, 45 (2008) (discussing how the cost of much innovation in software industry today is relatively low when compared with the cost required by other industries).

104 This is distinguished from patents involving technologies like semiconductor fabrication, which although associated with computer programming, shares research and development issues with pharmaceuticals, albeit on a lesser scale.

This relatively low investment in the IT field creates an ideal environment for "patent trolls," and when other manufacturers wish to incorporate technology that infringes patents owned by the trolls, they are often forced to negotiate with the trolls. 106 The dynamic is in stark contrast to normal patent license negotiations because usually both parties either have an interest in arriving at a licensing arrangement or have an interest in maintaining a good business relationship in case they wish to enter into future licensing arrangements. This is not to say that all patent owners who do not personally manufacture their patents are patent trolls, but it illustrates the opportunity for exploitation that is created by the circumstances, suggesting that in a capitalist economy such opportunities are frequently exploited.

Indeed, even minimal increase in the number of patent trolls due to this environment is highly undesirable because it stymies growth by creating an imbalance of power in negotiations between the manufacturers and the patent trolls, who do not manufacture and therefore do not have licensing needs of their own. If a manufacturer chooses to purchase a license from a patent troll, it increases its cost of development as well as encouraging claims of infringement by other parties. On the other hand, if the manufacturer chooses to challenge the validity of the troll's patent through litigation, it risks losing the ability to sell its product, essentially resulting in an all-or-nothing situation. This risk is in addition to the base costs of litigation, which can be millions of dollars in legal fees, as well as the cost of significant delays to the release of its invention. 107 This creates a substantial incentive for manufacturers

106 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2, at 31 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("[S]ince NPEs [non-practicing entities/patent trolls] are not vulnerable to an infringement counter attack, MAD [mutually assured destruction] strategies threatening infringement actions do little to constrain their willingness to seek high royalty rates from locked-in downstream actors. Thus, NPEs can threaten other firms with patent infringement actions, which, if successful, could inflict substantial losses, without fear of retaliation.").

107 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2, at 29 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("If an innovator or producer learns that it has infringed a patent only after it has committed ... costs to its innovation and production – and thus locked in to the effort – the patentee may be in a position to demand supra-competitive royalty rates. If, before lock in, the downstream actor had known about the patent and could have designed its product or innovation around it, then the firm might have used the opportunity to adopt alternative designs as leverage for seeking a competitive royalty rate. But after lock in, the downstream actor no longer has that option. Redesigning a product after significant costs have been sunk may not be economically viable. And the cost of being preliminarily enjoined is high: as one industry participant noted, losing a motion for a preliminary injunction in an infringement lawsuit 'would be detrimental to a firm if it means shutting down a high-volume manufacturing facility [since the] loss..."
to pay for questionable licenses rather than risk total loss, and thereby increases the cost of product development. Because of this imbalance in the distribution of financial risk, economics does not encourage manufacturers to challenge weak patents in court, and therefore a more restrictive obviousness standard is needed to balance the equation.

The second cause of this patent glut is the incremental nature of IT development. Numerous small "innovations" are required to develop a new IT product, and because a less-restrictive obviousness standard allows each of these "increments" to be patented, the result is a myriad of patents – often held by numerous different companies – with only slight variations. Most IT products are built upon obvious combinations of the prior art and consequently create the need for complicated cross-licensing of existing patents between software developers. Similar to the patent trolls noted above, this complication stifles innovation by increasing costs. Each of the patents involved in the product must be licensed from the owner, compounding the cost of developing a new product. This particularly hurts smaller upstart companies that lack their own portfolios of patents or the finances to purchase all the licenses.

III

Under what is called "mutually assured destruction," of one week's production alone can cost millions of dollars.


109 "Much of this thicket of overlapping patent rights results from the nature of the technology; computer hardware and software contain an incredibly large number of incremental innovations. Moreover, as more and more patents issue on incremental inventions, firms seek more and more patents to have enough bargaining chips to obtain access to others' overlapping patents." FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, executive summary at 6 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

110 See Clarisa Long, Our Uniform Patent System, 55 FEB. FED. LAW 44, 45 (2008) ("The Coalition for Patent Fairness—whose members include Apple, Cisco, Microsoft, Sun Microsystems, Applied Materials, Chevron, Time Warner, and Visa—says, 'These complex cases cost millions in legal bills and can coerc[e] large settlements that cost upwards of $100 million or much more for claimed 'inventive contributions' that represent a miniscule part of targeted products.'") (illustrating the possible risks of not incurring the licensing costs while developing a new product and then being sued for patent infringement).

111 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 51 nn. 335-336 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (observing that the preparation, filing and prosecution of a routine patent in the software area costs between $30,000 and $40,000, and that "although a few thousand dollars may not be a major expense for a large company, it is far too expensive for many small businesses and independent software developers who cannot even afford an office").

112 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2 at 30 (2003), available at
mitigation strategy, larger companies use their own extensive patent portfolios as bargaining chips in negotiations to lower the cost of licensing the patents owned by other companies.\textsuperscript{113} Essentially, because each company will likely need to license from the other's patent portfolio in the future, they both have incentive to operate in good faith and come to a reasonable amount of royalties for the licenses.\textsuperscript{114} This mitigation method however, leaves small and newly formed companies at a disadvantage because they do not have large patent portfolios of their own to offer as a way of balancing the negotiation power and similarly mitigating the licensing costs.\textsuperscript{115} In sum, small companies in the same mold as Vonage\textsuperscript{116} and Akamai Technologies\textsuperscript{117} could be forced out of the business at an early stage, not because of competition, but because of the financial burden of cross-licensing several IT patents. Reducing the number of IT patents is the most efficient way to remedy all these issues, and this can best be accomplished by raising the standard for obviousness.

B. THE PHARMACEUTICAL FIELD NEEDS A LESS RESTRICTIVE OBVIOUSNESS STANDARD TO BALANCE OUT ITS COSTS, MAINTAIN THE DIVERSITY OF DRUGS, AND PROVIDE SECURITY FOR ITS INVESTMENTS

Pharmaceutical patents are on the other end of the patent spectrum. Due to high costs and the unique value of subtle alterations to existing drugs, pharmaceutical patents rely heavily on the validity of their patents.\textsuperscript{118} Although an issued patent is presumed to be valid in court, it

http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("The prospect of mutually assured destruction (or "MAD") ensures detente, and design freedom, for such firms. Each firm takes into account that, if it tried to extract excessive royalties or impede the other's innovation efforts through threats of patent infringement litigation, the other firm could retaliate by suing it for patent infringement and enjoining its production. This leads the firms to reach licensing agreements with each other, often portfolio cross-licensing agreements. Such agreements can give each firm the freedom to design and operate without fear of being sued by the other.").

\textsuperscript{113} See id.
\textsuperscript{114} Id.
\textsuperscript{115} Id.
\textsuperscript{116} Vonage is a pioneer in the broadband phone industry, setting the standard for pricing, features, call quality and reliability for the entire VoIP category. http://www.vonage.com (last visited on Mar. 15, 2008).
\textsuperscript{117} Akamai Technologies, Inc., http://money.cnn.com/magazines/business2/b2fastestgrowing/2007/snapshots/1.html (featured as one of the 100 fastest-growing tech companies, it provides services for accelerating and improving the delivery of content and applications over the Internet).
\textsuperscript{118} FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2 at 11 (2003), available at
can still be found invalid if it is not sufficiently novel, useful, or nonobvious. Therefore, due to the high investment costs involved, pharmaceutical companies have considerable interest in being able to rely on their issued patent's validity in court. Unlike in the IT field, the risk of too high a volume of pharmaceutical patents is not a concern. Many drugs only require four to fifteen patents to be fully protected. Accordingly, ensuring that patents are available, even for what appear to be simple combinations or modifications, is vital even to a brand-name pharmaceutical company's survival. New drug development can easily cost over one hundred million dollars in research and development, and, therefore, to balance out this investment, drug companies need to be sure that their research will produce nonobvious and therefore patentable drugs. Also unlike in the IT industry, the

http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("[The] pharmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection."); see also id. at 1 ("Pharmaceutical companies, for example, rely on patents to prevent free riding, recoup their R&D investments, and learn about new technological breakthroughs, according to many panelists.").


120 Although patents issued by the U.S. Patent and Trademark Office are presumed to be valid in court, this presumption is rebuttable and the court can still find a patent invalid upon submission of sufficient evidence. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1737 (2007); 35 U.S.C. § 282 (2002).

121 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 5-6 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("The low number of patents contained in a pharmaceutical product means that, as panelists noted, the development of patent thickets is generally not a concern.").

122 See FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 8 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("The other main type of innovation in the pharmaceutical industry consists of enhancing known chemical entities by formulating new dosage forms or additional methods of use for existing chemical entities. This type of innovation is generally described as incremental, which, in general terms, means that today's advances build on and interact with many other features of existing technology. In the pharmaceutical industry, incremental innovation generally falls into one of three categories. The modified product may use a new formulation, such as a transdermal patch instead of a pill, may combine two previously approved active ingredients, or may use a new salt or ester, which is a more purified form of the original chemical entity. Several panelists suggested that brand-name companies have responded to effective patent term reduction and the increasing cost of discovering and developing [new chemical entities (hereinafter "NCE")] by implementing product life-cycle management, including the use of [incrementally modified drugs (hereinafter "IMD"). Some have noted that IMDS provide a high return on investment.") (internal citations omitted). An IMD is an "incrementally modified drug," or in other words a small improvement on an existing drug line. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 6 n. 12 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

pharmaceutical industry has little to fear from “patent trolls” because the high costs of research and development and low quantity of patents in the field make trolling behavior significantly less profitable. Moreover, unlike small product changes in other fields, in the pharmaceutical field a wide range of slightly different drugs with the same effect can be particularly beneficial to consumers. If a high standard for obviousness is utilized, the patentability of these slightly different drugs will become both unpredictable and increasingly costly, and will ultimately cause pharmaceutical companies to struggle to maintain their financial stability. Accordingly, the health of pharmaceutical companies is contingent on a lenient obviousness standard.

significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high. Brand-name companies spend a substantial amount in development costs over the course of 10 to 15 years to bring a product involving an NCE to market from the initial research stage. The brand-name companies’ trade association reports that most newly marketed drugs do not cover their average development costs.

124 Jeremiah S. Helm, Why Pharmaceutical Firms Support Patent Trolls: The Disparate Impact of Ebay v. MercExchange on Innovation, 13 MICH. TELECOMM. & TECH. L. REV. 331, 339 (Fall 2006) (“The main reason for the pharmaceutical industry’s interest in preserving the automatic injunction rule set out by the Federal Circuit stems from the difference between typical products in the pharmaceutical and information technology industries. Whereas a firm like eBay utilizes a number of different patents in its product, thus giving rise to the opportunity for a troll to extract more than the actual value of a patent, a pharmaceutical firm can ensure market exclusivity for a drug with a single patent on the active molecule.”).

125 FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 8-9 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (“IMDs benefit consumers by providing more convenient dosing or ‘superior therapeutic properties than the original formulation,’ or by serving certain patient populations better than the original product. The brand-name companies’ trade association stated that if physicians and consumers choose IMDs in preference to generic alternatives of the original brand-name product, the modified drug is warranted.”).

126 FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 11 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (“By removing obstacles to generic competition, the Hatch-Waxman Amendments (also known as the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417, 98 Stat. 1585 (1984)), codified at 21 U.S.C. § 355 and 35 U.S.C. 156 & 271) stimulated the development of a generic pharmaceutical industry in the United States. Since the law’s passage, the generic industry’s share of the prescription drug market has jumped from less than 20 percent to almost 50 percent today. The Hatch-Waxman Amendments have fostered significant price competition in those markets with generic entry. The generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams. Brand name companies often have introduced IMDs for which they can seek patent protection to lessen the impact of this generic competition.”) (internal quotation marks omitted).

127 Robert P. Merges, One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000, 88 CAL. L. REV. 2187, 2226 (2000) (“Economic models suggest that lowering the standard of patentability for high-cost research projects makes economic sense. The Federal Circuit seems to have reached much the same intuition so far with respect to biotechnology inventions.”); Id. at 2225-26 (“In certain cases, the skilled inventor might have predicted technical success, but the cost of
Drug development is expensive because of (1) the unpredictability of the science, (2) the increasingly stringent tests administered by the FDA that new drugs must pass before they can be marketed to the public, and (3) the general economic factors that reward investment in confronting complex viruses with "blockbuster drugs." Unlike IT areas, such as programming, the chemistry behind pharmaceutical patents remains an inexact science. Often what appear to be simple combinations produce unexpected results, and slight alterations can have dramatic effects on a drug's performance. As a result, drug companies must take broad approaches to solving problems, expending money to explore every avenue because the solution can often come from an unexpected route. Costs are thereby increased due to the breadth of research undertaken and the need to take journeys down errant paths that, in a more predictable art, would be identified earlier as dead ends.

Additionally, the substantial risk of harming humans that drugs pose has resulted in ever-increasing regulations by the FDA before a drug can be marketed to the public. These FDA standards slow the conducting the key experiment was very high. Courts have at times seen this as a deciding factor, holding in effect that high-cost research justifies a less stringent standard of purely technical nonobviousness.

128 "Blockbuster" drugs, such as Lipitor or Viagra, are drugs that due to the large market demand are worth billions in profits. See, e.g., NAT'L INST. FOR HEALTH CARE MGMT. RES. & EDUC. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 16 (May 28, 2002), available at http://www.nihcm.org/~nihcmor/pdf/innovations.pdf.


130 Id.

131 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 5 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("[D]iscoveries typically require significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high. Brand-name companies spend a substantial amount in development costs over the course of 10 to 15 years to bring a product involving an NCE [new chemical entity] to market from the initial research stage. The brand-name companies' trade association reports that most newly marketed drugs do not cover their average development costs. Brand name companies typically rely on a small number of 'blockbuster' drugs to recoup their overall investment in innovation, including R&D costs for failed products.").

132 Id. at 4-6.

development of new drugs by requiring that they endure long trial periods as well as increasing the overall new drug failure rates because the standards require the drugs to meet a very high safety level. Consequently, it takes an average of over thirteen years to develop a drug, and only one out of every 10,000 tested molecular combinations ("drugs") goes on to be marketed. Compounding the problem, this added testing and FDA approval process also shortens the time pharmaceutical companies have to sell the drugs under patent protection. Owners of other types of patents can immediately begin reaping the profits of their investment in the patent for the full twenty-year grant, whereas pharmaceutical companies can often lose three or more years of their grant waiting for the drug to be approved by the FDA. Congress attempted to address this inequity with the Drug Price Competition and Patent Term Restoration Act, but even with its patent term extension provisions, the effective marketable term of a drug patent is only about eleven years. Therefore, the FDA regulations both increase costs and lower profits for drug patents.

Moreover, economic demands also contribute to the cost of drug research and development. The economic reality for pharmaceutical companies is that they must choose between primarily developing new molecular elements (hereinafter "NME"), which are not related to any

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134 Id.; FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, at 6 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("In general, the brand-name companies’ trade association reported [that] only 20 in 5,000 compounds that are screened enter preclinical testing, which involves laboratory and animal testing.") (internal quotation marks omitted).


136 Despite the Hatch-Waxman Amendment [21 U.S.C. § 355], which restores up to five years of patent lifetime lost due to the clinical testing process, the “[p]harmaceutical companies report, however, that by the time clinical trials are complete and a drug product is ready to market, the effective patent life for a drug patent – even with patent term restoration – is typically about 11 years, substantially shorter than the 20-year statutory patent term.” FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3 at 7 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

137 Id.


existing drugs and are often needed to combat more complex viruses (e.g., AIDS, cancer), or developing drugs that are similar to existing drugs and are therefore less of a risk, but not necessarily as beneficial to society. If the pharmaceutical companies choose to combat complex viruses by developing NMEs, they face an uphill battle with a high reward, but an equally high chance of failure. On the other hand, if they choose to develop variations on existing drugs, which due to their marketability have a low risk of failure, they simultaneously risk being beaten by numerous other companies racing toward the same goal. Both avenues share high costs and contribute to the overall cost of research and development. Indeed, due to the uncertainty, high standards, and economic demands, drug development costs will continue to stay high, and a less restrictive obviousness standard is needed to stabilize this investment.

Pharmaceutical patents also need a less restrictive obviousness standard because of the unique value of slightly variant drugs to pharmaceutical companies and the public. Having a diverse selection of drugs to match the diversity of people provides both physicians and individuals with a range of options. For example, many different drugs designed to lower cholesterol and to combat depression can have similar molecular compositions and active ingredients, but they can also have different measures of success and/or side effects on different individuals. Therefore, if a drug that successfully treats one patient

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140 Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3 at 4 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf (“R&D in the pharmaceutical industry generally produces two main types of innovation: (1) discrete innovation, which means, in general terms, that the invention might be improved, but does not point the way to wide-ranging, subsequent discoveries of new chemical entities (NCEs); and (2) incremental innovation, which describes the development of improvements to existing drug products, often referred to as product line-extensions [also known as “me too” drugs].”).

141 Id.

142 Id.

143 Some commentators argue that slightly variant drugs are harmful to innovation because they block the introduction of cheaper generic drugs; however, “assuming these ‘me too’ drugs are obvious over the first drug, then there is a strong chance they infringe the first drug patent, preserving its market power. Further, if the ‘me too’ drugs are not major advances, market power in the first drug is not prolonged by obtaining patents on the ‘me too’ drugs, because people will just use the first drug when its patent expires instead of using the pricier ‘me too’ drugs that don’t do much more.” Posting of Joe Smith to PatentlyO, http://www.patentlyo.com/patent/2007/03/routine_experim.html (Mar. 27, 2007, 12:34 PST).

has ill effects on another, the patient can turn to a slight variant on that
drug. Similarly, if an individual becomes resistant to the principal form
of a drug, slightly variant drugs provide an alternative.\(^\text{145}\) Furthermore,
the creation of these similar drugs has the added effect of creating more
competition in the marketplace, which results in lower prices for
consumers.\(^\text{146}\) This diversity would be crippled if a more restrictive
obviousness standard were applied, damaging both the pharmaceutical
industry and the general public.

A less restrictive standard for obviousness is the most efficient way
to ensure that pharmaceutical companies are compensated for the large
investment required to develop a new drug. Pharmaceutical companies
have less incentive for continued research if there is a high obviousness
standard because they know it will be difficult to obtain the type of
patents that result from the research. Also, the certainty that a less
restrictive obviousness standard would provide permits pharmaceutical
companies to invest in drugs that are borderline obvious but still valuable
to the public. Without a less restrictive obviousness standard, research in
derivative drugs would decrease and the public would suffer due to
decreased drug variations. A less restrictive obviousness standard allows
the pharmaceutical industry to better serve the public while enabling
continued profitability.

III. A SINGLE STANDARD FOR OBVIOUSNESS CANNOT
EFFECTIVELY ADDRESS BOTH INDUSTRIES' NEEDS
SIMULTANEOUSLY

Given the inverse nature of the needs of the IT and pharmaceutical
industries, a single standard cannot effectively address both. If a single
less restrictive obviousness standard is used, although the pharmaceutical
industry is benefited, the result is an overcrowded IT sector.\(^\text{147}\) This

\(^\text{145}\) See id.

\(^\text{146}\) U.S. Gov't Accountability Office, Report to Congressional Requesters: New
Drug Development, GAO-07-49 at 29 (Nov. 2006), available at
http://www.gao.gov/new.items/d0749.pdf ("In addition, analysts report that 'me too' drugs increase
competition, which can lower the price of drugs in the market.").

\(^\text{147}\) The pre-KSR state of the patent system is an example of the consequences of a low
obviousness standard. As the IT sector was clamoring for a higher obviousness standard, the
pharmaceutical industry did not want what was the current obviousness standard to change. See
Brief of Altitude Capital Partners, Expanse Networks, Inc., Inflexion Point Strategy, LLC,
patent overpopulation suffocates innovation in a field where little incentive is needed to drive progress. Contrarily, if there is a single more restrictive obviousness standard, while benefiting the IT sector, pharmaceutical companies are forced to adjust their investments to reflect the probability their inventions will be found obvious. This will


148 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 2 at 11 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("[P]harmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially

http://digitalcommons.law.ggu.edu/ggulrev/vol39/iss1/3
discourage the development of new drugs that are not certain to pass the more restrictive obviousness standard and limit the selection of drugs available to the public. Clearly, both these situations are less than ideal.

There are only two ways to stretch a single standard to fit the needs of both the IT and pharmaceutical industries, and both are inadequate. The first way is to apply the standard differently depending on the type of patent. However, with such polar needs, this “stretching” of the standard results in one so amorphous that it is difficult to apply uniformly, thereby causing confusion and unpredictability in the industry.149 Anytime the law governing an industry is confusing or unpredictable it causes companies to shy away from investment in that industry and impedes its growth.150 Conversely, the second way to stretch a single standard is to maintain a definite standard, keeping it easy to apply, but producing undesired results in differing industries whose needs do not mesh with the single definite standard’s effects.

Previously, this second option of maintaining a single definite standard was largely the strategy taken by the Federal Circuit with its implementation of the TSM test, because the first option is unmanageable and therefore impractical.151 Predictably, however, it has resulted in the current undesired IT patent glut because the IT industry’s needs do not mesh with the TSM test’s effects.152 By choosing to maintain a single definite standard, the Federal Circuit avoided the first option’s difficulty with application and predictability, but was forced to choose between a less or more restrictive obviousness standard. Accordingly, the Court settled for a less restrictive standard that conflicted with the IT industry’s needs.153

introduced absent patent protection.”).


150 “It was clear that patents could never serve as reliable investment incentives when their fate in the courts was so unpredictable, and the judicial attitude in general so hostile.” Pauline Newman, Origins of the Federal Circuit: The Role of Industry, 11 FED. CIR. B.J. 541, 542 (2001).

151 Id.


153 “This test, designed largely to combat hindsight bias and to create predictability in patent decisions, led to questions about patent overissuance.” The Supreme Court 2006 Term Leading Cases, 121 HARV. L. REV. 375, 376 (2007).
In *KSR*, the Supreme Court held that the Federal Circuit needs to adjust the TSM test such that the test considers common sense in its obviousness determination.\(^\text{154}\) However, this new holding only creates another definite standard under the second option described above, but with a more restrictive standard than that previously settled on by the Federal Circuit. Although this will address the needs of the IT industry, it will conflict with the needs of the pharmaceutical industry, the ultimate result being a future unhealthy pharmaceutical industry similar to the currently unhealthy IT industry. Indeed, as long as a single standard under the second option is utilized, the standard will still need to continually swing from strict to lenient as each disadvantaged field reaches a point of enough loss to compel the Supreme Court to revise the standard.

This solution is inefficient. Each time the standard changes, a transition period begins, with inefficiencies in both fields as the industries adjust. If the switch is from a less strict standard to a very strict standard, as was the effect of the *KSR* ruling, the result is a copious number of questionable patents. This is because patents in both fields that were valid under the less strict standard now would have questionable validity under the new strict standard. Litigation is the main way to remove these questionable patents, and it comes with a high cost, ranging on average from $650,000 to $4,500,000.\(^\text{155}\)

If the switch is from a high to low standard, similar inefficiency occurs. In this situation, both the IT and pharmaceutical fields race to patent what would have been obvious previously. Instead of concentrating on creating new technologies, companies would need to focus on getting “defensive patents”\(^\text{156}\) to prevent patent trolls and protect

\(^{154}\) “The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents . . . . when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs . . . . Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741-42 (2007).

\(^{155}\) Marc J. Pensabene & Thomas S. Gabriel, *To Sue Or Not To Sue: Risks of Unlocking Value Through Patent Litigation*, 19 No. 9 IPTLJ 18, 21 (2007) (citing AIPLA Report of the Economic Survey 2005 at 22 (AIPLA, Arlington, Va.) (analyzing average patent litigation expenses; range of $350,000 in fees for a simple patent case to over $3,000,000 for a more complex case, with a total cost ranging from $650,000 to $4,500,000)).

\(^{156}\) “Defensive patents” are patents that are similar to a principal patent intended for use in a product, that are not themselves obtained to be incorporated into the owner’s products, but are utilized as a way of blocking other companies and or patent trolls from obtaining those patents and then suing the owner for its use of the principal patent. See FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, executive summary at 6 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.
their products.\textsuperscript{157} In either situation there are costs that hinder innovation, and the costs must be incurred again and again as the cycle continues. Each switch is not a solution, but instead simply resets the clock until the patent field reaches another unhealthy state. A long-term solution is needed.

IV. A SEPARATE OBVIOUSNESS STANDARD TAILORED TO THE NEEDS OF BOTH INDUSTRIES IS THE MOST EFFICIENT LONGTERM SOLUTION

By giving separate consideration to the needs of the pharmaceutical and IT industries and creating individual obviousness standards, the Supreme Court and Federal Circuit can fashion a solution that allows both industries to operate in ideal conditions and capitalize on their full potential. Unlike previous solutions, individual standards will be capable of addressing both the IT and pharmaceutical industries’ needs concurrently while still maintaining a clear definition. As a result, the courts will be able to easily determine which standard applies in each case, as well as consistently and uniformly administer the appropriate standard. All this can be achieved with a minimal cost that principally arises out of a one-time adjustment period, as opposed to the recurring costs that arise from solutions that are inadequate in the long term. By acknowledging that the IT and pharmaceutical industries have incompatible needs that must be individually addressed, a beneficial, administrable, and efficient long-term solution is possible.

A. A DUAL STANDARD OBVIOUSNESS SOLUTION CAN ADDRESS THE INDUSTRIES’ CONFLICTING NEEDS – AND BE COMPATIBLE WITH PROPOSED LEGISLATION – WITHOUT SACRIFICING APPLICABILITY

As long as the industries have incompatible needs, a dual standard solution for what is obvious will always have a key advantage over a single standard. Because of the nature of the circumstances surrounding our patent system, a single standard cannot address the diverging needs of both industries while being unambiguous and easy to apply. The more vague the standard is, the more it can stretch to address both industries’ needs, but the harder it becomes to apply consistently. The less vague the standard is, the easier it is to apply, but the more it ignores the needs

\textsuperscript{157} \textit{id.} at 6-7 ("One panelist asserted that the time and money his software company spends on creating and filing these so-called defensive patents, which ‘have no... innovative value in and of themselves,’ could have been better spent on developing new technologies.").
of one of the industries.

A dual standard, on the other hand, can address the needs of both while maintaining its applicability. The dual standards would address both the needs of the IT industry and the needs of the pharmaceutical industry because the two standards would be created with the relevant needs in mind. Furthermore, dual standards can accomplish this without sacrificing applicability. Each standard could be thoroughly defined so as to address one industry’s set of problems, while providing ample detail regarding how it should be applied. Accordingly, using a dual standard allows the wording of each to be simple and easy for the courts to apply consistently.

A dual standard also has the advantage of both encouraging and being compatible with the current proposed patent legislation. None of the proposed provisions in the current version of the Patent Reform Act—including the first-to-file system, new infringement damages calculations, and third-party prior art submissions discussed above—would be incompatible with two separate standards for obviousness, because they are not contingent on the type or number of obviousness standards applied. Indeed, by creating a solution that addresses the needs of both industries, a dual standard may actually help Congress come to an agreeable compromise regarding other areas of patent law needing reform. It is likely that having the comfort of knowing there is a predictable obviousness standard in place to protect their needs, the IT and pharmaceutical industry lobbyists will be more willing to negotiate on other matters such as those being currently debated in the 2007 Patent Reform Act. As it stands, the lobbyists for the industries that the current single standard solution neglects are more likely to be inflexible in their positions because, without an obviousness standard that addresses their needs, they can ill afford to compromise their positions further in other areas.

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159 Although the 2007 version of the Patent Reform Act was passed by the House of Representative on September 7, 2007 (H.R. 1908, 110th Cong. (2007), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h1908eh.txt.pdf), it still faces stiff opposition in the Senate as illustrated by a letter to Senate Majority Leader Reid and Senate Minority Leader McConnell, on behalf of more than 430 organizations raising continuing concerns regarding the terms of the act, S. 1145 ("Patent Reform Act"), available at http://www.thelen.com/resources/documents/G430_Senate_Letter.pdf.
B. THE COST OF IMPLEMENTING A DUAL STANDARD SOLUTION IS COMPARABLE TO THE COST OF THE CURRENT SOLUTION WHILE OFFERING THE ADVANTAGE OF LONG-TERM EFFECTIVENESS

As with all doctrinal changes, there will be some initial inefficiency and costs involved in switching to a dual standard solution. However, these costs will be far outweighed by the healthy returns for the patent system. The principal costs of using two standards include (1) adjusting the industries to the new standard and (2) determining which of the standards applies to any given case. Each of these costs, however, either is balanced by an equal or greater cost of implementing alternative solutions or is relatively minimal when considering the potential benefit.

1. The Adjustment Cost Associated with a Change to the Obviousness Standard Will Be Less With a Dual Standard Solution Than With a Single Standard Solution

One of two costs will always be incurred when there are changes to the obviousness standard. If the change if from a low standard to a high standard, the cost of determining what patents are valid under the new higher standard is incurred. If the change is from a high standard to a low standard, the cost of defending one’s patents against formerly obvious slight alterations to the patent that might curtail the original patent’s use is incurred. In the case of a switch from a less strict to a very strict standard, patents that do not meet that standard are “bad patents” because, by not meeting the ideal level, they hinder innovation. As a result, there is little justification for grandfathering them under the previous standard. Thus, a switch from a less strict standard to a very strict standard will likely lead to increased litigation; the limits of the new standard will have to be tested to determine which previously existing patents meet the new standard.

In the case of a switch from a very strict to a less strict standard, although none of the current patents is called into question, it creates space for the patenting of slight variations of patented inventions, which

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160 Jason Rantanen, *Slaying the Troll: Litigation as an Effective Strategy Against Patent Threats*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 159, 166 (2006) (“Bad patents are a commonly recognized problem, and there is significant evidence that such patents deter innovation.”).

if acquired by a competitor or a patent troll, could be used against the original patent owner to demand royalties.\textsuperscript{162} This leads to companies expending time and effort filing "defensive patents"\textsuperscript{163} to prevent others from impeding their current patents.\textsuperscript{164} A dual standard is no exception to these costs, but it minimizes the effect compared to single standard solutions.

The cost incurred by the patent industries and the court system by switching to a dual standard will be proportional to the amount the obviousness standard needs to be adjusted. Greater adjustment means greater costs, because there will be either a larger number of questionable patents or a larger number of formerly obvious patents that will be subject to "defensive patenting." Therefore, when the standard is changed from less strict to very strict, as the Supreme Court did recently with its ruling in \textit{KSR}, a substantial cost is incurred as the industry adjusts.\textsuperscript{165} Though likely exaggerated, these possible ramifications were discussed in the \textit{KSR} amicus briefs presented by the pharmaceutical industry.\textsuperscript{166}

Unlike a single standard, however, a dual standard minimizes this cost by only changing the standard for one of the industries. For example, compared to the \textit{KSR} low-to-high standard switch, a dual

\begin{quote}
\textsuperscript{162} \textit{FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY} ch. 2, at 31 (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("Since NPEs [non-practicing entities/patent trolls] are not vulnerable to an infringement counter attack, MAD [mutually assured destruction] strategies threatening infringement actions do little to constrain their willingness to seek high royalty rates from locked-in downstream actors. Thus, NPEs can threaten other firms with patent infringement actions, which, if successful, could inflict substantial losses, without fear of retaliation.").

\textsuperscript{163} "Defensive patents" are patents filed by companies not because they intend to manufacture what is described in the patent, but because the patent is similar to another patent that they do manufacture and they want to create a legal buffer around the invention by patenting all devices that are closely similar to it. Additionally, a defensive patent can be used "(1) to maintain detente with rivals; (2) to obtain portfolio cross-licenses from rivals; and (3) to raise a patent infringement counter-claim should a rival sue a firm for patent infringement." \textit{id. at} ch. 3, at 52.

\textsuperscript{164} Because of the importance of protecting their current patents, many "companies may have to divert resources from R&D to fund their defensive patent programs . . . reallocate[ing] roughly 20 to 35 percent of their developer's resources and sign on two separate law firms to increase their patent portfolio for purely defensive reasons." \textit{id. at} ch. 3, at 52-53.

\textsuperscript{165} These likely consequences of a change from a low to a high obviousness standard were summarized by PhRMA (a group consisting of numerous leading companies in the pharmaceutical industry) stating that "[s]uch an undesirable change in the law will significantly undermine the confidence of innovators . . . in their ability to enforce patents against free-riding infringers who use the fruits of research and clinical-testing efforts of [companies] without incurring the costly expenses associated with developing, testing, and obtaining approval of new drug products." Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America in Support of Respondents at 3, \textit{KSR Int'l} Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007) (No. 04-1350), available at 2006 WL 2967758.

\textsuperscript{166} \textit{id.}
\end{quote}
standard would change the definition of obviousness only for the IT industry, leaving the less strict standard for the pharmaceutical industry unchanged. The result is an obviousness standard change for fewer patents – only the IT industry – and therefore less cost. Similarly, a high-to-low standard switch would also require a standard change only for the pharmaceutical industry and would therefore involve less cost. Consequently, although a dual standard still involves some costs of adjustment, when compared to a single standard, the cost of adjustment will always be less. A concrete single standard solution neglects one of the industries and must be periodically adjusted once that industry reaches a point where innovation is being substantially stifled. A vague single standard is so difficult to apply that it must be periodically redefined to combat inconsistent application. A dual standard, however, only requires an adjustment cost once because it does not neglect a patent system nor is it hard to apply.

2. The Cost of Determining Which of the Dual Standards Applies Will Be Minimal Due to the General Distinctiveness of Pharmaceutical Patents and Distinctions Already Being Made

The second main cost of a dual standard solution is the effort required to determine which standard applies to each situation. Unlike a single standard solution that applies to every situation, with a dual standard the courts must determine what qualifies as a pharmaceutical patent and what qualifies as an IT patent. The cost necessitated by this need to differentiate depends on the distinctiveness of the categories. Generally, when categories are more distinct it takes less effort to categorize them and apply the correct standard. Luckily, the inherent distinctiveness of pharmaceutical patents combined with differentiating rules already simplifies this determination, which minimizes cost.

Pharmaceutical patents are inherently distinctive because of a drug’s molecular nature. Unlike many other types of patents, pharmaceutical patents describe innovations made on a molecular level. Instead of using materials to create moving parts like a mechanical patent, or as a platform to perform complex Boolean logic like a computer program

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168 Id.
169 Boolean is defined as “of, related to, or being a logical combinatorial system that represents symbolically relationships (as those implied by the logical operators AND, OR, and NOT) between entities (as sets, propositions, or on-off computer circuit elements).” WEBSTERS’ NEW INTERNATIONAL DICTIONARY (3d ed. 2002). Boolean logic is a type of logic that can be used in the
patent, pharmaceutical patents involve the design of a material itself and thereby are easily distinguishable from other types of patents. Accordingly, it is easy to distinguish pharmaceutical elements from IT elements even in patents that incorporate both. For example, if a patent is sought for a computer program that describes the makeup of a drug, a high standard would be used to test the computer program for obviousness, regardless of what it described, and a low standard would be used to test the drug itself for obviousness, regardless of the medium – in this hypothetical a computer program – used to describe it. Thus, the cost of determining the applicable standard can first be minimized by easily disqualifying any patent that does not deal with molecular makeup.

Another way to distinguish pharmaceutical patents is to utilize rules already in place that are designed to distinguish pharmaceutical patents from other patents for the purpose of regulation and patent term extension. First, as discussed above, the FDA reviews all pharmaceutical drug patents to ensure their quality and safety. This requires that they distinguish pharmaceutical patents from all other patents. Therefore, one way to distinguish pharmaceutical patents would be to either use the definition already being applied by the FDA or to reference the drugs listed in the “Orange Book.” And because this categorization of all

creation of computer software and hardware.


172 Id.

173 The definition of a new drug subject to FDA approval is as follows: “the term ‘drug’ means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.” Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321; available at http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm.

174 The “Orange Book,” officially entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” is a “list of patents on drugs or drug products for which generic-drug applications may be submitted to the Food and Drug Administration. The expiration dates of the patents are also listed. An applicant may submit a generic-drug application at any time, but the applicant must either accept deferral of FDA approval until the patent expires or contest the patent’s validity.” WEBSTERS’ NEW INTERNATIONAL DICTIONARY (3d ed. 2002).
patents is already being performed, there will be little if any additional cost associated with a standard based on this same differentiation.

Additionally, federal patent law itself distinguishes pharmaceutical patents from other patents under the patent term extension provision of the Drug Price Competition and Patent Term Restoration Act. Accordingly, the definitions provided therein could also be used to distinguish pharmaceutical patents from other patents. Indeed, these distinctions could be even more effective than using pharmaceutical patents’ inherent distinctiveness, because they distinguish other types of patents that deal with molecular makeup from pharmaceutical patents.

Moreover, the distinctions made by these rules are directly associated with the exorbitant costs that play an important role in why pharmaceutical patents need a low standard for obviousness in the first place. The regulation by the FDA is one of the major causes of the increased pharmaceutical patent costs, and the patent term extension provision was carefully worded so as to apply only to those patents affected by the increased costs due to matters such as FDA regulation. Consequently, the already distinctive character of pharmaceutical patents, combined with rules already in place designed to distinguish them from other patents, result in the cost created in applying a dual standard being minimal.

V. CONCLUSION

In an era of what seems like continual innovation, the health of the U.S. patent system is connected to the overall economic health of the nation. Accordingly, because the standard for obviousness is the key to the health of the patent system as a whole, its definition is critical to the U.S. economy. As a result, it is no surprise that the Supreme Court’s reform of the obviousness standard in KSR has garnered the attention of both the U.S. government and the leading companies in nearly every industry. This attention not only is an indication of the importance of

176 Id.
the obviousness standard to the nation, but it is also a reflection of the diverse needs that the standard must address.

When faced with a dynamic problem, the solution will often need to be equally dynamic, and the solution to the problems with the obviousness standard is no exception. Despite the best efforts of the Supreme Court, a single standard solution for obviousness will never be able to effectively address the needs of the patent system. Because of the circumstances of our current patent system, if a single standard is utilized, the more dynamic that standard is, the more difficult it will be to apply. A dual standard solution is needed to address the diverse needs of the patent system. Only a dual standard is capable of being sufficiently dynamic to address the patent system’s diverse set of needs, while not sacrificing the ease with which it can be applied. Although the creation of a dual standard creates with it new costs, these costs are minimal when
compared to the cost of trying to apply a single standard to such a
dynamic problem. The Supreme Court has been struggling with the use
of a single standard for obviousness since its inception. It is time to
finally acknowledge that, in order to address the dynamic nature of the
problem, there is a need for an equally dynamic dual standard solution.

Andrew Moody*