SECONDARY CONSIDERATIONS IN NONOBVIOUSNESS ANALYSIS: THE USE OF OBJECTIVE INDICIA FOLLOWING KSR V. TELEFLEX

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One of the basic requirements for patenting an invention is that the invention be nonobvious. Following the Supreme Court's decision in Graham v. John Deere, secondary considerations—also known as objective indicia of nonobviousness—have been considered when determining whether an invention is nonobvious. Secondary considerations provide tangible evidence of the economic and motivational issues relevant to the nonobviousness of an invention. Types of secondary-considerations evidence include commercial success, long-felt but unmet need, and copying by competitors. For many years, the Federal Circuit's teaching, suggestion, or motivation test often eliminated the need for the court to rely on secondary considerations in the obviousness inquiry. Due to the Federal Circuit's stringent application of this test, the obviousness inquiry was generally resolved by examining the prior art.

In 2007, the Supreme Court decided KSR v. Teleflex, which endorsed a flexible obviousness analysis and rejected the Federal Circuit's strict application of the teaching, suggestion, or motivation test. Following KSR, scholars predicted that secondary-considerations evidence would provide a critical tool for patentees seeking to demonstrate the nonobviousness of an invention. Inspired by that prediction, this Note evaluates how secondary-considerations evidence has been utilized in the first few years post-KSR. It finds that the Federal Circuit has continued to impose stringent relevancy requirements on the use of secondary-considerations evidence, and that it remains difficult for patentees to employ secondary considerations in favor of a nonobviousness conclusion. Specifically, secondaryconsiderations evidence has not been used with much success outside of pharmaceutical patent cases. More often than not, the Federal Circuit has summarily dismissed secondary-considerations evidence as insufficient in cases involving mechanical arts patents. This Note concludes by suggesting that the Federal Circuit's current practice for using secondary considerations should inform proposals by scholars for industry-specific tailoring of the patent system and patent law's use of secondary considerations, and that the Federal Circuit should continue to engage with secondary-considerations evidence in order to provide more guidance to lower courts during the post-KSR transition period.

2070

Eye Therapies Exhibit 2049, 1 of 43 Slayback v. Eye Therapies - IPR2022-00142



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Introduction

To qualify for a patent, an inventor must contribute a novel, useful, and significant technical advance. In other words, the advance must not be obvious or trivial. This requirement seems only fair. The national patent system established under the Constitution contemplates such a quid pro quo: In exchange for disclosing his or her invention to the public, an inventor is rewarded with a temporary, exclusive right. The public does not benefit from the award of a patent right for an obvious discovery, since such an award would remove a clear and evident improvement from the public domain for the patent term.

The nonobviousness requirement was first codified in the 1952 Patent Act.³ Although the nonobviousness requirement was a natural addition to the Patent Act, given the patent system's goal of promoting innovation, courts and the Patent and Trademark Office (PTO)⁴ have struggled to create a coherent procedure for determining when a claimed "invention" is in fact nonobvious. Indeed, it is challenging to articulate how *anyone* might go about determining if a claimed invention is nonobvious.

This obviousness inquiry is significant because millions of dollars may ride on a patent examiner's judgment as to whether a patent should issue and on a judge or jury's determination of whether an issued patent is invalid for obviousness.⁵ The inquiry is further compli-

Eye Therapies Exhibit 2049, 2 of 43 Slayback v. Eye Therapies - IPR2022-00142



¹ 35 U.S.C. § 154 (2006) (outlining a patent term of twenty years).

² See Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152 (1950) ("The function of a patent is to add to the sum of useful knowledge. Patents cannot be sustained when, on the contrary, their effect is to subtract from former resources freely available to skilled artisans.").

³ Patent Act of 1952, Pub. L. No. 593, § 103, 66 Stat. 792, 798.

⁴ The Patent and Trademark Office (PTO) is the agency within the Department of Commerce responsible for examining patent applications and granting patents (as well as registering trademarks). The USPTO: Who We Are, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/about/index.jsp (last visited Oct. 23, 2011). During the patent examination process, the PTO staff rejects patent applications that fail to meet the statutory requirements for patentability. A patent examiner with skill in the relevant technology area conducts the first official assessment of the obvious or nonobvious nature of a claimed invention. See Patent & Trademark Office, Manual of Patent Examining PROCEDURE § 2141, at 2100-115 to -118 (6th ed. 2007), available at http://www.uspto.gov/ web/offices/pac/mpep/mpep_e8r6_2100.pdf (setting forth guidelines for an examiner's analysis of the nonobviousness requirement). If the examiner finds the invention obvious, she will reject the application. Id. at 2100-116 to -117. Appeals from PTO denials of patent applications are heard by panels of at least three members of the PTO's Board of Patent Appeals and Interferences. 35 U.S.C. § 6(b). The panels are staffed by administrative patent judges, the Board's directors, and the Commissioner for Patents. Id. § 6(a). These decisions can subsequently be appealed to the United States Court of Appeals for the Federal Circuit. Id. § 141.

⁵ See John R. Allison et al., Valuable Patents, 92 GEO. L.J. 435, 440–41 (2004) (noting median direct litigation costs of \$2 million per party in 2003 in patent suits with \$1 million

cated by the fact that it occurs ex post and is often made by a factfinder⁶ lacking skill in the art.⁷ Technically inexperienced factfinders may allow hindsight to affect the obviousness inquiry.⁸ What seems obvious now may not have been obvious at the time of invention.

In order to guide the obviousness inquiry, the Federal Circuit—the court with appellate jurisdiction over patent cases⁹—adopted a teaching, suggestion, or motivation (TSM) test. A proposed invention was obvious if a teaching, suggestion, or motivation in the prior art pointed to the invention. The TSM test was intended to structure the obviousness inquiry, but instead led to instances of patents of questionable validity being upheld.¹⁰ In the 2007 case KSR International v. Teleflex Inc., the Supreme Court rejected the Federal Circuit's rigid application of the TSM test and emphasized that the touchstones of the obviousness inquiry are flexibility and common sense.¹¹ In the wake of KSR, many predict that it will be easier to prove patents obvious.¹² Decision makers must strike a delicate balance between

to \$25 million at stake); see also James Bessen & Michael J. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk 105 tbl.5.2, 108 tbl.5.3 (2008) (estimating a \$275,000 average value for patents worldwide and a \$332,800 average value for chemical composition patents, based on market regression calculations in 1992 dollars).

- ⁶ Multiple parties may assess the obviousness or nonobviousness of an invention, including PTO examiners, judges, and juries, depending on the stage of the proceeding. For the purposes of this Note, a reference to "factfinder" or "decision maker" implicates the relevant party.
- ⁷ Patent examiners are grouped by specialization. Thus, an examiner often has a technical background that renders her generally competent to examine the patent application assigned to her specialization group. *See supra* note 4 (explaining the PTO procedure). In contrast, judges are often assumed to be laypersons without specialized technical knowledge. *See* Safety Car Heating & Lighting Co. v. Gen. Electric Co., 155 F.2d 937, 939 (2d Cir. 1946) ("Courts, made up of laymen as they must be, are likely either to underrate, or to overrate, the difficulties in making new and profitable discoveries in fields with which they cannot be familiar").
 - ⁸ See infra note 29 (discussing the challenges of hindsight bias).
 - ⁹ 28 U.S.C. § 1295 (2006) (delimiting the Federal Circuit's jurisdiction).
- ¹⁰ See, e.g., Amanda Wieker, Secondary Considerations Should Be Given Increased Weight in Obviousness Inquiries Under 35 U.S.C. § 103 in the Post-KSR v. Teleflex World, 17 Fed. Cir. B.J. 665, 665 (2008) (describing the teaching, suggestion, or motivation (TSM) test's impact on patent quality).
 - ¹¹ KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419–22 (2007).
- ¹² See, e.g., Ali Mojibi, An Empirical Study of the Effect of KSR v. Teleflex on the Federal Circuit's Patent Validity Jurisprudence, 20 Alb. L.J. Sci. & Tech. 559, 581–84 (2010) (conducting an empirical study to test the hypothesis that KSR heightened the standard for finding inventions nonobvious); Janice M. Mueller, Chemicals, Combinations, and "Common Sense": How the Supreme Court's KSR Decision Is Changing Federal Circuit Obviousness Determinations in Pharmaceutical and Biotechnology Cases, 35 N. Ky. L. Rev. 281, 285–86 (2008) (observing that KSR appears to make obviousness easier to establish); Jennifer Nock & Sreekar Gadde, Raising the Bar for Nonobviousness: An Empirical

Eye Therapies Exhibit 2049, 3 of 43 Slayback v. Eye Therapies - IPR2022-00142



ensuring that obvious inventions are not given patent protection and ensuring that an invention that was nonobvious at the time of invention is found nonobvious when later assessed by a court or the patent office.

Patent case law provides for the use of secondary-considerations evidence—also referred to as objective indicia of nonobviousness—to aid the obviousness inquiry.¹³ This evidence is considered more judicially cognizable than the highly technical facts frequently involved with patent litigation, as it is generally rooted in nontechnical facts about the invention, such as industry response or commercial success.¹⁴ Following *KSR*, some scholars have predicted that secondary considerations will be critical to patentees' future efforts in demonstrating that their inventions are nonobvious.¹⁵

This Note examines the state of secondary-considerations evidence in the first few years after KSR. Part I provides an overview of the nonobviousness requirement of patentability, secondary considerations, and the KSR decision. Part II empirically examines the Federal Circuit's treatment of secondary-considerations evidence in the years after KSR and concludes that such evidence has not been used with much success outside of pharmaceutical patent cases. More often than not, courts have summarily dismissed secondary-considerations evidence as insufficient. Part III considers how current use of such evidence should inform proposals for altering the use of secondary considerations. In addition, this Part contends that the use

Study of Federal Circuit Case Law Following KSR, 20 FED. CIR. B.J. 369, 378–81 (2011) (noting that KSR's holding suggests that it will be easier to find an invention obvious and that early predictions and analyses regarding the impact of the decision suggest the same); Diane Christine Renbarger, Note, Putting the Brakes on Drugs: The Impact of KSR v. Teleflex on Pharmaceutical Patenting Strategies, 42 GA. L. REV. 905, 908–09 (2008) (noting that KSR may have heightened the standard for finding pharmaceutical inventions nonobvious).

- ¹³ See, e.g., Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966) (endorsing the use of secondary-considerations evidence to shed light on the obviousness inquiry).
- 14 Id. at 36 ("[Secondary-considerations evidence] focus[es] attention on economic and motivational rather than technical issues and [is], therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation."); see Michael Abramowicz & John F. Duffy, The Inducement Standard of Patentability, 120 YALE L.J. 1590, 1655–57 (2011) (arguing that the inducement standard requiring courts to consider secondary-considerations evidence is "more administrable than the current system"); Richard L. Robbins, Note, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. PA. L. REV. 1169, 1172 (1964) (noting that inquiries into "economic and motivational . . . issues . . . are more amenable to judicial treatment than are the technical facts with which the courts generally struggle").
- ¹⁵ See Daralyn J. Durie & Mark A. Lemley, A Realistic Approach to the Obviousness of Inventions, 50 Wm. & Mary L. Rev. 989, 1004–07 (2008) ("As the legal rules that fight hindsight bias, such as the TSM test, are trimmed back . . . patentees will want to rely more on so-called secondary considerations of nonobviousness").

Eye Therapies Exhibit 2049, 4 of 43 Slayback v. Eye Therapies - IPR2022-00142



of secondary-considerations evidence should be increased to guide the obviousness inquiry with a judicially accessible source of information about the inventive process.

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The Nonobviousness Requirement, Secondary Considerations, and KSR v. Teleflex

A. The Nonobviousness Requirement

Although not initially included in the patent statute passed by the First Congress in 1790,¹⁶ the nonobviousness requirement is now considered the ultimate threshold for patentability.¹⁷ This requirement is codified in § 103 of the Patent Act:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.¹⁸

The nonobviousness requirement reserves patent protection for innovative contributions. However, if the threshold for patentability is too high, then researchers will be less likely to pursue socially beneficial research paths. Promoting the optimal level of innovation requires striking the right balance in defining obviousness. Congress attempted to define obviousness in the context of the patent system as that which would have been obvious at the time of the invention to a person having ordinary skill in the art (PHOSITA), replacing the prior focus on "invention."²⁰

Unfortunately, the statutory codification of the nonobviousness requirement for patentability does not provide a framework for deter-

Eye Therapies Exhibit 2049, 5 of 43 Slayback v. Eye Therapies - IPR2022-00142



¹⁶ Patent Act of 1790, ch. 7, 1 Stat. 109 (repealed 1793).

¹⁷ 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.06, at 5-735 (2010) ("The nonobviousness requirement of Section 103 is the most important and most litigated of the conditions of patentability.").

¹⁸ 35 U.S.C. § 103(a) (2006).

¹⁹ See, e.g., Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 Lewis & Clark L. Rev. 547, 563 (2008) ("If the nonobviousness threshold is . . . set too high, . . . non-optimal and inefficiently difficult projects will have to be undertaken to obtain a patent.").

²⁰ ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 629–30 (4th ed. 2007). *See generally* John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 Tex. L. Rev. 1, 33–43 (2007) (describing the evolution of the standard of invention).

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