

BILCARE, *KSR*, PRESUMPTIONS OF VALIDITY,
PRELIMINARY RELIEF, AND OBVIOUSNESS IN PATENT
LAW

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Jurisprudencia Argentina)

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Patent validity is a curious thing. Patents are issued, and by virtue of their very existence are assumed to be valid by the granting authority. If a patent is invalid, it either should not have been issued or, if issued, should have been invalidated so as to avoid wrongly conveying exclusive rights that may impose innovative, competitive, and consumer harms. After all, patent offices have the authority to unilaterally cause patents to be reviewed and (after appropriate legal process) to revoke granted patents.¹

Patent statutes often declare the truism that issued patents are assumed to be valid,² provisionally inferring the “ought” of their validity from the “is” of their existence.³ In the United States, for example, “[a] patent shall be presumed valid The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”⁴ But it takes some form of legal process and evidence to prevent or to invalidate a wrongly granted patent. The legal process for granting patents may not reach the correct result, while the legal process for invalidating wrongly issued patents either may never occur or may not reach the truth of the matter. Thus, a guarantee of validity from the mere grant of a patent is not appropriate. Accordingly, the Indian Patent Act declares that “[t]he examination and investigations required . . . shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.”⁵ Not all existing patents are valid, and not all patents always ought to be treated as if they were valid.

The law calls the assumption that fills the gap between the existence of the patent and the conclusion that it is valid a “presumption.” A presumption is “[a] legal inference or assumption that a fact exists, based on the known or proven

¹ See, e.g., 35 U.S.C. § 303(a) (2007) (“On his own initiative, and at any time, the Director may determine whether a substantial new question of patentability is raised”).

² See, e.g., Stefan A. Riesenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 U. PA. L. REV. 291, 309 (1954) (arguing that the 1952 United States Patent Act “elevates the presumption of validity to the dignity of a statutory mandate.”).

³ Cf. 2 DAVID HUME, A TREATISE OF HUMAN NATURE 246 (T. H. Green & T. H. Grose eds., Longmans, Green & Co. 1898) (“For as this *ought*, or *ought not*, expresses some new relation or affirmation, ‘tis necessary that it shou’d be observ’d and explain’d; and at the same time that a reason should be given; for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it.”).

⁴ 35 U.S.C. § 282 (2007).

⁵ The Patents Act, No. 79 of 1970, § 13(4); India Code (2005). See P. NARAYANAN, PATENT LAW ¶ 1-19 (3d ed. 1998).

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existence of some other fact or group of facts.”⁶ The existence of a patent historically provided a presumption of validity of the granted rights, effectuated in judicial proceedings by entering the patent into evidence. The presumption arose from the logical inference that the process resulting in the grant was proper and that it reached a correct result.⁷ As explained in 1890 by Professor William C. Robinson in his seminal patent treatise:

[t]he bestowal of the patent privilege depends entirely upon the provisions of the statutes, and the conditions named therein must be fulfilled or the letters-patent will be null and void. With these prerequisites the Patent Office has no power to dispense, though of their existence and sufficiency the Commissioner is in many cases the final judge; and that they did exist and were sufficient the issue of the letters-patent is always *prima facie* evidence.⁸

Unlike evidence (which may include the granted patent), a presumption of validity of a patent is only a logical inference to be drawn that the granted patent is valid. As an inference from proved facts, the presumption of validity does not conclusively demonstrate the truth of the presumed facts or of any legal conclusions of validity based on the presumed facts. The presumption of validity— like any other presumption — can be overcome (rebutted) by additional relevant evidence sufficient to disprove the inference that the presumption embodies.⁹ Because the presumption of validity— like any other presumption — may reflect both the strength of logical inferences and social policies, however, it also may shift the burden of persuasion of the presumed fact.¹⁰ The United States Patent Act thus contains both the statement of the presumption and the placement of the burden of persuasion on the party challenging validity.

As with presumptions in other areas of the law,¹¹ the nature of

⁶ BLACK’S LAW DICTIONARY (8th ed. 2004). In addition, a “natural presumption” is “[a] deduction of one fact from another, based on common experience” and a “presumption of law” is “[a] legal assumption that a court is required to make if certain facts are established and no contradictory evidence is produced.” *Id.*

⁷ *See, e.g.,* Morgan v. Daniels, 153 U.S. 120, 123-24 (1894) (noting different review standards applied to proof of prior invention and priority of invention, and stating that “there is always a presumption in favor of that which has been once decided”). *Cf.* 2 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 424, at 10 n.2 (1890) (stating that the Commissioner “acts judicially in granting or refusing a patent”).

⁸ *Cf.* 2 ROBINSON, *supra* note 7, § 423, at 9 (citing Dorsey Harvester Rake Co. v. Marsh, 6 Fisher 387 (1873)). *See id.* § 424, at 11 n.5 (noting the presumption of regularity of proceedings in the Patent Office, and citing Eagleton Mfg. Co. v. West, Bradley, & Cary Mfg. Co., 2 Fed. Rep. 774 (1880)).

⁹ *See, e.g.,* Paul R. Rice, *The Evidence Project: Proposed Revisions to the Federal Rules of Evidence with Supporting Commentary*, 171 F.R.D. 330, 428 (1997).

¹⁰ *Id.* at 432.

¹¹ *Id.* at 429 (noting the historic dissatisfaction and consequent disregard by courts of the limited presumption of validity imposed by Fed. R. Evid. 301, which does not shift the

the patent law presumption of validity is the subject of frequent and heated academic and practical dispute.¹² The nature of the presumption and the strength of the logical inference it provides are vigorously contested, as are the burden of persuasion of invalidity that it may impose and the type of evidence that can be used to rebut the logical inferences from the presumption (and from any additional evidence of validity). The nature and strength of the presumption of validity and its concomitant burdens of production and persuasion may determine the outcome of countless challenges to patent validity.¹³

In this article, I discuss the nature and strength of the patent law presumption of validity in varying procedural and substantive contexts. To do so, I first discuss (in Part I) the nature of evidentiary presumptions in general and (in Part II) the history of the presumption of patent validity in the United States. (Readers familiar with the theory and history may wish to scan or to pass over these Parts.) Following discussion of these first principles, I focus (in Part III) on the recent decision of the Indian High Court of Delhi in *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*,¹⁴ which addressed the presumption of patent validity in regard to preliminary relief. The *Bilcare* decision upheld the vacatur of ex parte injunctions, based on traditional preliminary injunction considerations of a prima facie case,¹⁵ balance of convenience, and irreparable loss.¹⁶ I then discuss (in Part IV) the recent United States Supreme Court decision in *KSR International Co. v. Teleflex, Inc.*¹⁷ The *KSR* decision addressed the legal standard for

burden of persuasion).

¹² See, e.g., Clarence J. Fleming, *Should the Clear and Convincing Evidence Standard for Rebutting the Presumption of Validity Apply When the Challenger Raises a Substantial New Question of Patentability?*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 146 (1998); Mark D. Janis, *Reforming Patent Validity Litigation: The "Dubious Preponderance"*, 19 BERKELEY TECH. L.J. 923 (2004).

¹³ See, e.g., FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8, 10 (2003) [hereinafter FTC INNOVATION REPORT 2003], available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (noting that "presumptions and procedures [in the Patent Office] tip the scales in favor of the ultimate issuance of a patent" and that "the 'clear and convincing evidence' burden can undermine the ability of the court system to weed out questionable patents"). *But cf.* Janis, *supra* note 12, at 935 ("[T]he evidentiary standard might make little difference in case outcomes.").

¹⁴ *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, No. FAO 70/2007, (New Delhi H.C. 2007), available at <http://www.delhicourts.nic.in/Mar07/BILCARE%20VS.%20THE%20SUPREME%20INDUSTRIES.pdf>.

¹⁵ *Cf.* PAUL R. RICE, EVIDENCE PRINCIPLES & PRACTICES: 150 THINGS YOU WERE NEVER TAUGHT, FORGOT, OR NEVER UNDERSTOOD 12 (Matthew Bender 2006) ("The *prima facie* standard is not a characterization of the level of the [evidentiary] burden. It is only a characterization of how the decision is made – on the face of the evidence without considerations of credibility.").

¹⁶ See *Bilcare*, No. FAO 70/2007 at ¶ 25.

¹⁷ *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007).

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determining obviousness — or inventive step — under United States law, and rejected the excessively narrow test for proving obviousness that had been applied for many years by the United States Court of Appeals for the Federal Circuit (Federal Circuit) — which possesses nearly exclusive appellate jurisdiction over patent matters — and consequently the United States Patent and Trademark Office (Patent Office).¹⁸ I conclude (in Part V) by discussing recent studies of patent granting conditions and validity rates¹⁹ that provide reasons to believe that the logical inference of validity from the grant of a patent is weak, as well as policy considerations that provide additional arguments for placing only a minimal burden of persuasion on parties challenging validity. In doing so, I join the United States Federal Trade Commission and a number of legal commentators in calling for a “preponderance of the evidence” burden of persuasion, at least in regard to initial grants of patents.²⁰

In reviewing and discussing the *Bilcare* case, I seek to highlight the importance of providing an opportunity for evidentiary rebuttal of the presumption of validity in all procedural contexts, even at preliminary stages of patent litigation. If a presumption of validity supplies only a rebuttable inference based on evidence, challengers should be allowed to

¹⁸ *Id.* at 1739-43.

¹⁹ *See, e.g.*, FTC INNOVATION REPORT 2003, *supra* note 13, at 8-10 (discussing the lack of Patent Office facilities for evaluating inventions and the lack of resources for examination, as compared to the increasing volume of applications); *American Innovation at Risk: The Case for Patent Reform. Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 38-40 (2007) (statement of Daniel B. Ravicher, Exec. Dir, Public Patent Found.) (noting a 35% invalidity rate in litigation in 2005 and a 90% rate of finding a “substantial new question of patentability” in regard to reexamination requests) (citing Patstats, <http://www.patstats.org>) [hereinafter Patstats], available at <http://judiciary.house.gov/media/pdfs/ravicher070215.pdf> (last visited Dec. 24, 2007); J. Michael Buchanan, *Deference Overcome: Courts' Invalidation of Patent Claims as Anticipated by Art Considered by the PTO*, 2006 STAN. TECH. L. REV. 2, 39-40 (discussing data from Patstats, indicating invalidation rates from 29% to 58% during the years 2000 to 2003). *See generally* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998) (finding that 54% of challenged patents in a sample of 300 litigated were held valid).

²⁰ *See, e.g.*, FTC INNOVATION REPORT 2003, *supra* note 13, at 8-10; Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 63 (2007) (recommending the preponderance of the evidence standard for initially granted patents but a higher standard for patents surviving post-grant opposition proceedings); Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007) (noting that Patent Office expertise cannot efficiently and effectively be employed during routine examination and recommending a preponderance presumption for routinely issued patents, as well as a higher standard for an optional “gold-plat[ing]” process and for various adversarial determinations, including International Trade Commission decisions and potential opposition proceedings). *Cf.* Stuart M. Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 319 (2007) (recommending increased deference to Patent Office denials of patents than to grants, as the former are “much more likely to take advantage of PTO expertise than is factfinding in grants”).

present evidence that would disprove the inference. Even for preliminary relief, there should be some opportunity to demonstrate invalidity before being subject to significant consequences, except where extremely strong policies outweigh the goal of finding the truth about validity.²¹ For example, preliminary injunctions may dramatically affect the ability of the public to obtain low-cost generic pharmaceuticals. Some opportunity thus should be provided to demonstrate that the asserted patent is invalid before an injunction issues that would bar the production and sale of the generic medication, even if providing the opportunity for proving invalidity might diminish somewhat the incentives provided by the grant of the patent.²²

In reviewing and discussing the *KSR* case, I seek to demonstrate that the Supreme Court has adopted various substantive rules of law (triggered by presentation of evidence regarding the nature of the patented invention) that may be used to disprove the inference of non-obviousness that arises from the presumption of validity. These substantive rules shift to the patent holder the burdens of production and persuasion in regard to the validity of the challenged patents, and may limit the evidence that can be used to prove non-obviousness. These substantive rules also should apply to determining validity in the Patent Office.²³ Establishing the proper rules for determining validity is extremely important. Erroneous decisions regarding patent validity may have enormous costs to society, as well as to the parties involved, as decisions to enforce invalid patents may dramatically affect

²¹ See *infra* notes 108-40 and accompanying text.

²² See, e.g., *Abbott Labs., Inc. v. Andrx Pharms.*, 452 F.3d 1331, 1334-45 (Fed. Cir. 2006) (discussing the standards for obtaining preliminary injunctive relief in a case addressing generic pharmaceuticals); Michael W. Carroll, *Patent Injunctions and the Problem of Uniformity Cost*, 13 MICH. TELECOMM. TECH. L. REV. 421, 433-34 (2007) (noting that if competitors enter the market, "the injury cuts to the quick, for it undermines the very purpose for rewarding inventors with patents in the first instance"); Lichtman & Lemley, *supra* note 20, at 108-15 (rejecting arguments to preserve a heightened presumption of validity based on avoiding redundant and inferior evaluations and on increased risks to investments in development and commercialization, with specific reference to pharmaceutical inventions).

²³ See *infra* notes 148-49, 224-27 and accompanying text. Other commentators have recently suggested that the Court in *KSR* adopted a rebuttable presumption framework, although they have not focused on the limitation of evidence created by the Court's adoption of a substantive rule. See, e.g., Joseph S. Miller, *Remixing Obviousness*, 16 TEXAS INTELL. PROP. L.J. (forthcoming 2007), available at <http://www.lclark.edu/faculty/jsmiller/> (last visited Dec. 24, 2007) (arguing for a presumption of invalidity specific to combination claims similar to the presumption of obviousness for a claimed range overlapping within a prior art range) (citing and rejecting presumptive approaches described in Brief of Amicus Curiae International Business Machines Corp. in Support of Neither Party at 18, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1530), and in Timothy R. Holbrook, *Obviousness in Patent Law and the Motivation to Combine: A Presumption-Based Approach*, SLIP OPINIONS, Mar. 21, 2007, http://washulrev.blogspot.com/2007_03_01_archive.html).

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sequential innovation and investment.²⁴

Finally, I hope to shed light on and thereby exorcise a persistent specter of confusion that haunts validity analysis when the presumption of validity comes into play. Presumptions of validity, like all presumptions, operate in regard to findings of fact and factual inferences to be drawn. In contrast, validity determinations are legal conclusions, based on the facts that have been found and the factual inferences that they supply.²⁵ There is an unfortunate and erroneous tendency to confuse both procedurally and substantively questions of fact with legal conclusions regarding validity of the patent (particularly with regard to non-obviousness).²⁶ As a result, presumption of validity is treated as if it affected the weight to be accorded to the relevant legal factors or to the competing conclusions drawn from the factual inferences. But the presumption of validity is not a direction to bias the legal scale's measurements. Rather, it is at most (where it supplies heightened burdens of proof) an evidentiary thumb on one side of the scale.²⁷

²⁴ See, e.g., Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991) (discussing effects of patent rights on sequential innovation); Lawrence B. Ebert, *NTP/RIM Settlement to lead to patent reform?*, IPBIZ, Mar. 6, 2006, <http://ipbiz.blogspot.com/2006/03/ntprim-settlement-to-lead-to-patent.html> (discussing a settlement of patent infringement litigation for \$612 million between NTP, Inc. – the patent holder – and Research in Motion – maker of the Blackberry® – notwithstanding that the patents had been subjected to reexamination proceedings and were initially rejected therein by the Patent Office). Cf. Cecil D. Quillen, Jr., *Innovation and the Patent System*, 1 VA. L. & BUS. REV. 207, 217-25 (2006) (discussing adverse effects on businesses – including increased costs of capital – and on innovation of excessive patent damages awards).

²⁵ See, e.g., *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1745 (2007) (“The ultimate judgment of obviousness is a legal determination.”); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375-76 (Fed. Cir. 1986) (“[P]rior invention is a question of law, requiring like other validity issues proof of the facts by clear and convincing evidence in light of the presumption of validity in 35 U.S.C. § 282.”); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007) (“Whether a claim satisfies the enablement requirement . . . is a question of law Anticipation is a question of fact, but validity is a question of law.” (citations omitted)); *Glaxo Group, Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1345 (Fed. Cir. 2004) (“A determination of whether a patent satisfies the written description and definiteness requirements . . . is also a question of law that we review de novo.” (citations omitted)).

²⁶ See *infra* notes 185-86 and accompanying text; *Compare, e.g., Teleflex, Inc. v. Ficos North Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002) (noting that “[w]hat a prior art reference discloses in an anticipation analysis is a factual determination that we review for substantial evidence when decided by a jury” (emphasis added)) with *TI Group Automotive Sys., Inc. v. VDO North Am., L.L.C.*, 375 F.3d 1126, 1133 (Fed. Cir. 2004) (“An *invalidity determination* based on anticipation is a question of fact, reviewed for substantial evidence when tried to a jury.” (emphasis added) (citing *Teleflex*, 299 F.3d at 1323)). See generally Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1042-44, 1049-51 (2003) (discussing the law-fact distinction – and application of law to fact – in theory and the role of facts in patent validity, nonobviousness, and disclosure determinations).

²⁷ See, e.g., *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1323 (Fed. Cir. 2004) (“On the legal issue of obviousness (as opposed to the underlying factual issues) the grant of a patent does not create a presumption of validity beyond the requirement that

Whether validity questions ultimately should turn solely on factual findings (as to which the presumption of validity has bearing) or also involve legal judgments based on the factual findings (as to which it does not) is at the heart of disputes over the proper legal standard for obviousness. Prior to *KSR*, the Federal Circuit had stated that its “precedent requires that the party urging obviousness demonstrate a teaching, suggestion, or motivation [TSM] to combine references,”²⁸ and prescribed the TSM test to avoid uncertainties of legal judgment that may be supplied by hindsight analysis.²⁹ As the Federal Circuit has acknowledged, however, “[t]he presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact . . . as is the presence or absence of a ‘reasonable expectation of success’ from making such a combination.”³⁰ The Supreme Court has previously held that it did not need to set aside any findings of fact nor resolve any factual disputes in order to substitute a more exacting legal “standard of invention” than that applied by the lower courts.³¹ Obviousness decisions therefore may require not only finding facts, but also the exercise of administrative and judicial policymaking discretion.³² It would be better if the actual grounds

the party seeking to invalidate a patent must prove invalidity by clear and convincing evidence.” (citing *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 375 (Fed. Cir. 1983)); *Legille v. Dann*, 544 F.2d 1, 6 n.24 (D.C. Cir. 1976) (“We distinguish the presumption ‘of law’ – the procedural rule dictating a factual conclusion in the absence of contrary evidence – from the presumption ‘of fact,’ which in reality is not a presumption at all . . . and from the ‘conclusive’ presumption, which is actually a substantive rule of law.” (citations omitted)). Cf. *Lichtman & Lemley*, *supra* note 20, at 117 (describing the presumption as a judicial “thumb . . . on the scale,” reflecting deference to the Patent Office’s decision-making without regard to evidentiary basis).

²⁸ *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007).

²⁹ See, e.g., *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006)

By requiring the Board to explain the motivation, suggestion, or teaching as part of its *prima facie* case, the law guards against hindsight in all cases — whether or not the applicant offers evidence on secondary considerations — which advances Congress’s goal of creating a more practical, uniform, and definite test for patentability.

See also *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) (“The Court of Appeals for the Federal Circuit’s and its predecessor’s ‘motivation to combine’ requirement likewise prevents statutorily proscribed hindsight reasoning when determining the obviousness of an invention.” (citing *In re Kahn*, 441 F.3d at 986, and *In re Fridolph*, 134 F.2d 414 (C.C.P.A. 1943))). See generally Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391 (2006) (discussing the pervasive effect of hindsight bias on obviousness determinations and noting that both secondary consideration evidence and the TSM test were developed to prevent such bias).

³⁰ *Alza Corp.*, 464 F.3d at 1289 (citations omitted).

³¹ *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 153-54 (1950). See also *id.* at 156 (Douglas, J., concurring) (“[I]t is the ‘standard of invention’ that controls No ‘finding of fact’ can be a substitute for it in any case.”).

³² See *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1739 (2007) (noting that *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966), reaffirmed the “functional approach” of *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 265 (1851), which required “more

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for such legal conclusions were explicitly articulated,³³ although it may be asking too much to expect either complete legislative or judicial specification of the relevant policies and coherent results from their application.³⁴

I. PRESUMPTIONS IN GENERAL IN THE UNITED STATES

Presumptions come in different shapes and sizes. They need not specify the burden of persuasion, but may simply create a burden of producing evidence (of varying degrees of probative strength) to negate the factual inference that the presumption otherwise would require to be drawn from the evidence that triggers it.³⁵ The nature of the presumption and the strength of the evidence required to overcome it therefore require careful specification, so as to best arrive at the truth. Presumptions also may serve goals other than arriving at the truth, and thus may need calibration to achieve these goals.

What kind of presumption and what weight should attach to the presumption of validity that exists by virtue of patent grant and statutory declaration? The answer to the question should have a two-fold character. First, the strength of the presumption should reflect the likelihood that the presumed fact of validity of the granted patent is true given the truth of the proven fact that the patent was issued. After all, if invalid patents are commonly granted, reliance on the presumption may routinely result in errors of holding invalid patents to be valid. Second, the weight of the presumption should reflect public policies regarding the importance of various outcomes (or errors) in different substantive and procedural contexts. For example, a weak presumption may result either in errors of holding valid patents to be invalid or delays in providing appropriate relief. Although it should be clear that one shape and size of presumption is unlikely to fit all procedural and substantive contexts,³⁶ non-uniformity also

ingenuity or skill required to construct the knob in this way than that possessed by an ordinary mechanic acquainted with the business"). See *infra* note 186 and accompanying text.

³³ Cf. *KSR Int'l, Co.*, 127 S. Ct. at 1741 ("To facilitate review [of whether there was an apparent reason to combine], this analysis should be made explicit." (citing *In re Kahn*, 441 F.3d at 988)).

³⁴ Cf. Janis, *supra* note 12, at 935 (noting concerns that reducing the strength of the presumption of validity might "open the door to a plurality of different approaches to implementing the presumption in individual cases").

³⁵ See, e.g., 2 MCCORMICK ON EVIDENCE, § 337, at 414 (5th ed. 1999); PAUL R. RICE & ROY A. KATRIEL, EVIDENCE: COMMON LAW AND FEDERAL RULES OF EVIDENCE 1309-13 (5th ed. 2005).

³⁶ See, e.g., Sag & Rohde, *supra* note 20, at 7 (proposing, *inter alia*, "a variable presumption of validity depending on the level of review that a patent has been subject

has its costs³⁷ and finders of fact may be unable to make the fine distinctions that would be required to apply such presumptions.³⁸

Presumptions of patent validity also express normative beliefs regarding the applicable legal rules.³⁹ The normative message of the presumption (and the behaviors that it seeks to condition) may be affected (or not) by the choice of the evidentiary standard adopted.⁴⁰ Properly specifying the nature and strength of the presumption of validity thus is an even more complex undertaking than simply calibrating proof to experience and seeking to make dispute resolution more accurate, efficient, and fair.

Traditionally, presumptions arise as the result of legislated or judicial decisions to allocate burdens of production and proof, and to simplify efforts at proof.⁴¹ Legislation, however, is not always carefully drafted regarding how burdens should be apportioned, at different stages of trials, and thus who should bear the burdens of pleading, production, and persuasion (particularly of exceptions to general provisions).⁴² Factors to consider in regard to allocating burdens (initially or ultimately) include “special policy considerations such as those disfavoring certain defenses,” “convenience,” “fairness,” and “estimate of the probabilities.”⁴³

A presumption is a standardized practice of accepting one fact, Fact B (presumed fact), as proven by proof of another fact, Fact A (basic fact) Presumptions are created for much the same reasons that frequently influence initial allocations of the burdens of production and persuasion. The most common reason for the recognition of a presumption is a strong probability that the presumed fact is true if the basic fact is true ((proof of Fact A almost always tends to indicate the presence of Fact B). Other factors would include fairness (access to

to”).

³⁷ See, e.g., Glynn S. Lunney, Jr., *Patent Law, The Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 S. CT. ECON. REV. 1, 3-7, 67-78 (2003) (discussing benefits of lower levels of more tailored protection and expressing concerns over the costs of increased uniformity of protection from raising obviousness standards and from limiting claim scope and equivalents protection). See generally Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 71-79 (1983) (discussing conditions for optimal precision of legal standards); Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002); Peter S. Menell, *A Method for Reforming the Patent System* (Berkeley Ctr. for Law and Tech., Working Paper No. 34, 2007) available at <http://repositories.cdlib.org/bclt/lts/34> (last visited Dec. 24 2007).

³⁸ See, e.g., Janis, *supra* note 12, at 927-28 (citing *Addington v. Texas*, 441 U.S. 418, 424-25 (1979)).

³⁹ See *id.* at 925-27.

⁴⁰ See *id.* at 927-28.

⁴¹ See RICE & KATRIEL, *supra* note 35, at 1309.

⁴² See 2 MCCORMICK ON EVIDENCE, *supra* note 35, § 337, at 414.

⁴³ *Id.* § 337, at 415. See also *id.* § 340, at 424-27 (discussing reasons for adopting a “clear and convincing” standard of proof rather than the traditional “preponderance of the evidence” standard).

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proof), and the social policy of favoring or disfavoring particular claims.⁴⁴

Rebuttable presumptions traditionally may be understood in two different ways. The first, most-popular view of presumptions — commonly referred to as the “bursting-bubble” approach and attributed to Thayer and Wigmore — is that presumptions shift only a burden of producing evidence to respond to the presumption, but do not shift the burden of persuasion of the presumed fact.⁴⁵ If evidence is introduced that, by itself, would be sufficient to disprove the presumed fact, then the bubble bursts and the presumption disappears (although the inference from the proven fact to the presumed fact remains, requiring the trier of fact to simply weigh all the evidence under the relevant burden of persuasion).⁴⁶ The second view — attributed to Morgan and McCormick — not only shifts the burden of production but also shifts the burden of persuasion of the presumed fact.⁴⁷

Presumptions also may be in conflict,⁴⁸ in which case courts must decide whether they may be used to rebut each other (or whether other evidence may be required to rebut them) and which should supersede in the event of a conflict. “One approach to resolving conflicting or inconsistent presumptions is a more-or-less mechanical rule: conflicting or inconsistent presumptions cancel each other, and the judge and jury should proceed without regard to either.”⁴⁹ For example, in *Legille v. Dann*,⁵⁰ the District of Columbia Court of Appeals reversed the District Court and held that the (bursting-bubble) presumption of timely filing of a patent application based on normal mail delivery schedules and triggered

⁴⁴ RICE & KATRIEL, *supra* note 35, at 1309.

⁴⁵ *Id.* at 1311-14 (citing JAMES B. THAYER, PRELIMINARY TREATISE ON EVIDENCE AT THE COMMON LAW 353-89 (1898)); J. WIGMORE, EVIDENCE § 2491 (Chadbourn rev. 1961)).

⁴⁶ RICE & KATRIEL, *supra* note 35, at 1313-14, 1317-19. *Cf. id.* at 1317 (noting the tendency for courts to “confuse[] the presumption with the strength of the logical inference that often forms the basis for it”).

⁴⁷ *See id.* at 1312, 1319 (citing Edmund M. Morgan, *Instructing the Jury Upon Presumptions and Burdens of Proof*, 47 HARV. L. REV. 59 (1933)); E. MORGAN, BASIC PROBLEMS OF EVIDENCE 34-44 (1962); MCCORMICK ON EVIDENCE § 338 (3d ed. 1984)).

⁴⁸ *But cf. Legille v. Dann*, 544 F.2d 1, 10 n.58 (D.C. Cir. 1976)

Presumptions do not conflict. The evidentiary facts, free from any rule of law as to the duty of producing evidence, may tend to opposite inferences, which may be said to conflict. But the rule of law which prescribes this duty of production either is or is not at a given time upon a given party. If it is, and he removes it by producing contrary evidence, then that presumption, as a rule of law, is satisfied and disappears; he may then by his evidence succeed in creating another presumption which now puts the same duty upon the other party, who may in turn be able to dispose of it satisfactorily. But the same duty cannot at the same time exist for both parties, and thus in strictness the presumptions raising the duty cannot conflict.

(quoting 9 J. WIGMORE, EVIDENCE § 2493, at 292 (3d ed. 1940)).

⁴⁹ 29 AM. JUR. 2D EVIDENCE § 201 (2007).

⁵⁰ *Legille*, 544 F.2d 1 (D.C. Cir. 1976).

by affidavits (required in the case to establish validity of the claims, given the need to claim foreign priority) was rebutted by the presumption of untimely filing in the Patent Office based on date stamping practices and triggered by other affidavits.⁵¹ Thus, having dispensed with both presumptions, a disputed issue of fact remained (precluding summary judgment) regarding the balance of inferences from the competing evidence.⁵² However, “[a] second approach requires the judge to determine which presumption should prevail, based on factors such as public policy . . . [and] if the considerations of policy are of equal weight, neither presumption applies.”⁵³

The Federal Rules of Evidence codified in Section 301 a bursting-bubble approach to presumptions for federal judicial proceedings, which does not by itself authorize a heightened burden of production or persuasion.⁵⁴

In all civil actions . . . not otherwise provided for by Act of Congress . . . , a presumption imposes . . . the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion, which remains throughout the trial upon the party on whom it was originally cast.⁵⁵

The Federal Rules of Evidence failed to address the level of evidence sufficient to rebut (and thus destroy) the presumption in regard to the burden of production,⁵⁶ and nevertheless permitted judges to instruct juries about rebutted presumptions.⁵⁷

Nothing in the codified language of the Patent Act’s presumption of validity in Section 282 suggests a heightened evidentiary standard for production or persuasion, or an exemption from the generally applicable requirements of Section 301 of the Federal Rules of Evidence. Unlike the Administrative Procedure Act, Section 301 does not suggest an exemption to its

⁵¹ See *id.* at 5-10.

⁵² See *id.* at 10 (“Viewed as the mere procedural devices we hold that they are, presumptions are incapable of waging war among themselves.”).

⁵³ 29 AM. JUR. 2D EVIDENCE, *supra* note 49, § 201.

⁵⁴ See FED. R. EVID. 301 (advisory committee’s note) (adopting the Senate amendment to the House bill, and noting that if evidence to contradict the presumed fact was offered, “the court cannot instruct the jury that it may *presume* the existence of the presumed fact from proof of the basic facts. The court, however, may instruct the jury that it may infer the existence of the presumed fact from proof of the basic facts.” (emphasis added))

⁵⁵ FED. R. EVID. 301.

⁵⁶ See 2 MCCORMICK ON EVIDENCE, *supra* note 35, § 338, at 416-21 (discussing the need for more than a “scintilla,” and particular difficulties when rebuttal evidence is circumstantial, and the need for judicial judgment regarding the inferences).

⁵⁷ See RICE & KATRIEL, *supra* note 35, at 1346-47; Buchanan, *supra* note 19, at 15 (quoting published model patent law jury instructions of the Northern District of California, which recited inability of drafting committee to agree on whether to instruct the jury about the existence of the presumption, and thus including such a presumption in brackets with an explanatory footnote) (citations omitted).

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application for heightened standards recognized by the judiciary but not expressly provided for by Congress.⁵⁸ Nevertheless, Congress when enacting Section 282 expressed a desire to codify and stabilize the presumption of validity that had previously been applied in varying ways.⁵⁹ Although unlikely to be a correct interpretation (particularly given its nature as boilerplate language to codify what the judiciary had already determined), if Section 282 were construed to codify heightened burdens of production or persuasion, or a different approach to the nature of the presumption than adopted by Section 301, Section 282 would then stand on its own merits.

II. THE PATENT LAW PRESUMPTION OF VALIDITY IN THE UNITED STATES

In the United States, the statutory presumption of validity (which was adopted in 1952 and replaced the earlier “morass of case law” on the subject⁶⁰) does not by itself resolve the nature or strength of the evidentiary standard to be applied, although it places the ultimate burden of persuasion on the party challenging validity.⁶¹ Historically and currently, the judiciary has had to shoulder the task of articulating how the presumption of validity should apply in various contexts. In doing so, the judiciary has rejected both the bursting-bubble approach and the preponderance of the evidence burden.

During the 1970s and 1980s, the majority of federal appellate jurisdictions (and some earlier Supreme Court cases) adopted a relatively strong standard of proof for the presumption of patent validity in infringement litigation.⁶² Although various

⁵⁸ See *Dickinson v. Zurko*, 527 U.S. 150, 153-61 (1999) (rejecting the argument that a heightened “clearly erroneous” court-to-court evidentiary standard was historically recognized for judicial review of Patent Office fact-finding prior to the enactment of the APA); 5 U.S.C. § 559 (2007) (stating that the APA does “not limit or repeal additional requirements . . . recognized by law”).

⁵⁹ See Riesenfeld, *supra* note 2, at 309 (citing H.R. REP. NO. 82-1923, at 7 (1952)). Cf. Pasquale P. J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. (1954 ed.), reprinted in 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 215 (1993) (“The statement of the presumption in the statute should give it greater dignity and effectiveness.”).

⁶⁰ *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

⁶¹ See 35 U.S.C. § 282 (2007).

⁶² See *Janis*, *supra* note 13, at 928-29 (citing, *inter alia*, *Hobbs v. U.S. Atomic Energy Comm’n*, 451 F.2d 849, 856 (5th Cir. 1971) and 2 DONALD S. CHISUM, PATENTS § 5.06 n.84 (2003)); *Morgan v. Daniels*, 153 U.S. 120, 124-25 (1894) (holding that Patent Office decisions regarding priority of invention “are to be taken as presumptively correct . . . unless some obvious error has intervened in the application of the law, or some serious or important mistake has been made in the consideration of the evidence”); see also *id.* at 124 (adopting a higher standard than a preponderance of evidence, because the action was in the nature of “set[ting] aside the conclusions reached by the administrative department,” which would be conclusive but for the statutory right to challenge the decision); *Radio*

formulations were employed, they were characterized by the need for the party challenging validity to produce evidence that would sustain “an abiding conviction that the truth of [the] factual contentions [we]re ‘highly probable.’”⁶³ In contrast, under the preponderance of evidence standard, disputed facts only must be proved more likely than not to be true.⁶⁴

The Federal Circuit has treated the presumption of validity as imposing unvarying burdens of production and persuasion in all contexts by “clear and convincing evidence.”⁶⁵ This elevated standard applies even to prior art that had not been considered by the Patent Office during the examination process, although the Federal Circuit has recognized that it may be easier to carry this burden when the evidence of invalidity produced at trial is more pertinent than that examined by the Patent Office.⁶⁶ The

Corp. of Am. v. Radio Eng'g Labs., 293 U.S. 1, 5-10 (1934) (noting the presumption that issues of fact decided in the Patent Office should be decided the same way in subsequent litigation “unless the contrary is established by testimony which in character and amount carries through conviction” and the presumption that concurrent findings of lower courts will be accepted “unless clear error is shown,” and requiring to overcome the presumption of validity that the “countervailing evidence is clear and satisfactory”) (citations omitted).

⁶³ *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984); citing *American Hoist & Derrick Co.*, 725 F.2d at 1360)). See *Radio Corp.*, 293 U.S. at 7.

⁶⁴ See, e.g., *Metro. Stevedore Co. v. Rambo*, 521 U.S. 121, 137 n.9 (1997) (discussing the preponderance of evidence standard for proponents of administrative rules or orders under the Administrative Procedure Act, 5 U.S.C. § 556(d) (2007); citing *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Fund Trust*, 508 U.S. 602, 622 (1993) for the premise that the preponderance standard requires proof that the fact at issue is more likely than not to be true).

⁶⁵ *American Hoist & Derrick Co.*, 725 F.2d at 1360. Cf., e.g., FED. CIRCUIT BAR ASS'N., MODEL PATENT JURY INSTRUCTIONS 36-44 (2007), available at <https://www.fedcirbar.org/documents/selectedarticles/OTHER%20SELECTED%20MATERIALS/MODEL%20JURY%20INSTRUCTIONS%20%28UPDATED%202007%29.PDF> (reciting “clear and convincing” evidence standard of proof of invalidity generally and for specific jury instructions on anticipation, obviousness, written description, enablement, best mode, and indefiniteness under 35 U.S.C. §§ 102, 103, 112(1)–(2) (2007), and for unenforceability for inequitable conduct); Buchanan, *supra* note 19, at 15 (quoting published model jury instructions of Northern District of California, using both “highly probable” and “clear and convincing” formulations) (citations omitted).

⁶⁶ See, e.g., *Alco Standard Corp. v. Tenn. Valley Auth.*, 808 F.2d 1490, 1497-98 (Fed. Cir. 1986) (citing, *inter alia*, *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984)); Fleming, *supra* note 12, at 147. In contrast, neither the presumption of validity nor proof by clear and convincing evidence applies to administrative reexamination and reissue proceedings in the Patent Office when a substantial new question of patentability is raised, even though the patent has already been issued. See *id.* at 149 (citing *In re Etter*, 756 F.2d 852 (Fed. Cir. 1985), and *In re Sneed*, 710 F.2d 1544 (Fed. Cir. 1983)); 37 C.F.R. § 1.555 (2007).

A *prima facie* case of unpatentability of a claim pending in a reexamination proceeding is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Although the Patent Office bears a bursting-the-bubble burden of production of a

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placement of the ultimate burden of persuasion of invalidity on the party asserting it is clearly warranted by the statutory language.⁶⁷ It would also make little sense to require a higher burden of production to rebut the presumption than the burden ultimately established to persuade the factfinder.⁶⁸ But whether the clear and convincing burdens of production and proof are warranted is highly debatable. As one lawyer put it almost a decade ago, “[s]urely, there can be no presumption of administrative correctness with respect to prior art, such as a prior use or sale, for example, which was completely unknown to the [Patent Office] during the examination process.”⁶⁹

Given that patent grants are administrative actions and that Congress did not articulate an intent to except patent grants or denials from the Administrative Procedure Act (APA), deferential statutory administrative law review standards (and therefore a

prima facie case and the burden of persuasion on unpatentability in examiner rejections, in appeals to the Board of Patent Appeals and Interferences, the appellant bears the burden of establishing examiner error and the Board “will not start with a presumption that the Examiner is wrong.” *Ex parte* McBrearty, Appeal No. 2007-1340, 2007 WL 2161571, at 10 (B.P.A.I. July 27, 2007) (non-precedential) (citing *In re* Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984)).

⁶⁷ See *American Hoist & Derrick Co.*, 725 F.2d at 1358.

⁶⁸ Cf. FTC INNOVATION REPORT 2003, *supra* note 13, at 10 (arguing that “it does not seem sensible to treat an issued patent as though it had met some higher standard of patentability” when evaluated earlier only under a preponderance of evidence standard). In contrast, one could readily impose a low burden of production and a higher burden of proof, considering that the presumption operates solely as an inference in the absence of evidence. Where the presumption runs with the heightened burden of proof, additional evidence may be needed to sustain it. Where the presumption runs the other way, the presumption should suffice, as evidence is required to sustain the burden of proof but not to establish it.

⁶⁹ Fleming, *supra* note 12, at 147. See Stefan A. Riesenfeld, *The New American Patent Act in the Light of Comparative Law: Part II*, 102 U. PA. L. REV. 723, 741 (1954) (noting that the Patent Office was not bound by *res judicata* in reconsidering invalidity in light of new references, once courts had found validity in regard to other references) (citing *Hoover v. Coe*, 325 U.S. 79, 89 (1945), and *Jeffrey Mfg. Co. v. Kingsland*, 179 F.2d 35 (D.C. Cir. 1949)); Buchanan, *supra* note 19, at 13 & n.36 (citing cases prior to creation of the Federal Circuit that had held the presumption of validity to be “weakened or destroyed when a challenger relied on PTO-unconsidered art.”). *But cf.* *American Hoist & Derrick Co.*, 725 F.2d at 1359-60

When an attacker, in sustaining the burden imposed by § 282, produces prior art or other evidence *not* considered in the PTO, there is, however, *no reason to defer* to the PTO so far as *its* effect on validity is concerned. Indeed, new prior art not before the PTO may so clearly invalidate a patent that the burden is fully sustained merely by proving its existence and applying the proper law; but that has no effect on the presumption or on who has the burden of proof. (emphasis added); *Corning v. Burden*, 56 U.S. (15 How.) 252, 271 (1854)

It is evident that a patent, thus issued after an inquisition or examination, made by skilful and sworn public officers, appointed for the purpose of protecting the public against false claims or useless inventions, is entitled to much more respect, as evidence of novelty and utility, than those formerly issued without any such investigation.

Buchanan, *supra* note 19, at 4 & n.10, 13 n.37 (citing Federal Circuit and earlier cases treating the presumption as strengthened when the art was considered by the Patent Office).

relatively strong presumption of validity) should apply to *direct* judicial review of agency denials (and of some grants) of patents.⁷⁰ In contrast, judicial actions for infringement or for declaratory relief may not be reviews of administrative action, particularly as the administrative agency normally is not a party to the litigation determining validity of the granted patent (and thus cannot seek to justify the action taken on the administrative record before it), and as new evidence is almost always adduced and new issues regarding validity are sometimes raised.⁷¹ Instead, such actions may be better characterized as *de novo* determinations of the validity of a granted patent, posing novel legal issues that must be pled and joined without estoppel effects. The deferential APA agency review standards thus should not apply in this context. Nevertheless, the factual findings, legal interpretations, and applications of law to fact of the United States Patent and Trademark Office (PTO or “Patent Office”) may be accorded varying degrees of deference in subsequent judicial actions for infringement or declaratory relief.⁷²

⁷⁰ See Benjamin & Rai, *supra* note 20, at 280-84. See also *id.* at 284-93 (arguing that the APA’s “arbitrary and capricious” standard, 5 U.S.C. § 706(2)(A) (2007), should govern review of factual determinations by the Patent Office).

⁷¹ See 35 U.S.C. § 143 (2007) (establishing the administrative record for an appeal under 35 U.S.C. § 141); *Cf. American Hoist & Derrick Co.*, 725 F.2d at 1360 (“When new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to *disagree* with the PTO or with *deferring* to its judgment or with taking its expertise into account.”) (emphasis added). Similarly, because the issues may be determined *de novo* with newly adduced evidence, deferential APA review standards should not apply to trials following patent denials, even though the administrative agency is a party. See also 35 U.S.C. § 145 (2007) (civil actions to obtain patents); 35 U.S.C. § 146 (2007) (civil actions in case of interferences); *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999) (rejecting arguments regarding inconsistency of review standards for such district court challenges, based on new fact-finding and the possibility of new evidence). *Cf.* 5 U.S.C. § 706(2)(F) (2007) (creating a category of APA “*de novo* review” for agency action “unwarranted by the facts to the extent that the facts are subject to trial *de novo* by the reviewing court,” which review standard has not been applied except where expressly provided by another statute). The case for APA review in trials is stronger for those resulting from denials by the Board of Patent Appeals and Interferences than for grants, particularly given that the statute provides for a determination regarding claims “involved in the decision of the Board” 35 U.S.C. § 145 (2007). In contrast, in infringement and declaratory litigation, only the patent need be offered into evidence, and not any of the prosecution history or reasoning of the Patent Office. Thus, APA review standards should likely apply only on direct review of the record of administrative action in appeals from patent denials and in appeals from grants in interferences and in *inter partes* reexaminations. See 35 U.S.C. § 141 (2007) (appeals from the Board of Patent Appeals and Interferences). The Patent Act does not provide jurisdiction for third parties to challenge grants of patents on the record of the Agency’s action, although such actions, if allowed, would likely be subject to deferential APA review standards. *Cf.* Benjamin & Rai, *supra* note 20, at 280-84 (arguing that APA review standards apply to such judicial challenges to granted patents).

⁷² See *American Hoist & Derrick Co.*, 725 F.2d at 1359

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some

III. *BILCARE* AND PRELIMINARY RELIEF IN INDIA AND THE UNITED STATES

In *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, the appellate court decided two appeals from trial court orders vacating earlier *ex parte* injunctions,⁷³ during which appeal one of the respondents had filed administrative opposition proceeding in the Indian Patent Office to invalidate the patent at issue. The patent addressed moisture-resistant, translucent, multi-layer, metal-coated, polyvinylchloride (PVC) films for packaging medicine tablets.⁷⁴ The appellate court noted that the “controversy . . . swirl[ed] around the question, ‘is there any presumption in favour of the validity of the patent for grant of temporary injunction in

expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

Cf. id. at 1360 (noting that new prior art or other new evidence “eliminate[s], or at least reduce[s], the element of deference due” to the Patent Office); Benjamin & Rai, *supra* note 20, at 294-301 (arguing that agency applications of law to fact are likely subject to the same review standards as interpretations of law, that patent grants should be subject to *Skidmore* deference – which applies to non-precedential decisions and depends on the thoroughness of the agency’s reasoning – rather than *Chevron* deference – which applies to agency decisions to which Congress delegated authority to create law and under which reasonable agency interpretations of an unclear provision should be sustained; that patent denials should be accorded greater deference either under *Chevron* or *Skidmore* as they are more likely to go through multiple layers of review; and that policy decisions are subject either to the APA “abuse of discretion” and “arbitrary and capricious” standard of 5 U.S.C. § 706(2)(A) (2007), which is actualized through evaluating whether the agency took a “hard look” at the competing policies) (citing *United States v. Mead Corp.*, 533 U.S. 218, 226-30 (2001), *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-44 (1984), and *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *Al-Fayed v. CIA*, 254 F.3d 300, 308-09 (D.C. Cir. 2001) (noting that the “application of a legal standard to a set of underlying facts . . . may perhaps best be classified as a mixed question of law and fact,” but noting that the proper appellate review standard for such questions “is often difficult to determine”); *NLRB v. Hearst Publ’ns*, 322 U.S. 111 (1944) (articulating the pre-APA standard for applications of law to fact). Even if APA review standards were to apply to facts found by the Patent Office, however, they should not apply to factual questions where new (perhaps even cumulative) evidence is introduced at trial, which must be determined *de novo*). See *supra* note 71; Benjamin & Rai, *supra* note 20, at 319 (noting that APA deference cannot apply to fact-finding where the agency has not passed on the question).

⁷³ *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, No. FAO 70/2007, ¶¶ 1, 2 (Mar. 20, 2007), available at <http://www.delhicourts.nic.in/Mar07/BILCARE%20VS.%20THE%20SUPREME%20INDUSTRIES.pdf>. See Posting of Mrinalini Kochupillai to SPICY IP, *The Bilcare Decisions by the Delhi High Court: Preliminary Injunctions and the Presumption of Validity of a ‘New’ Patent*, <http://spicyipindia.blogspot.com/search/label/Injunction> (May 12, 2007) (noting strategic reasons for filing in different courts). By filing in the District Court, *Bilcare* sought to avoid transfer to the Delhi High Court and the possibility of a caveat that might delay issuance of an *ex parte* injunction, based on the prior filing of an opposition by one defendant.

⁷⁴ See *Bilcare*, No. FAO 70/2007, ¶¶ 1, 2 (citing Indian Patent No. 197823). See also *id.* ¶ 5 (noting the patent holder’s disclaimer of two-layered films, in light of prior art regarding such films dating to 1975, when applying for the corresponding United States patent). In contrast, the Supreme Industries produced two-layer films. See Manisha Singh Nair, *India: Grant of Patents Does Not Guarantee Validity*, MONDAQ, (May 14, 2007), available at www.mondaq.com/article.asp?articleid=48346&email_access=on&print=1.

favour of patentee.”⁷⁵ More precisely, the question is what kind of presumption should apply in the context of preliminary relief?

The appellate court first noted the patent holder’s arguments that it had established (i) “a prima facie case [of infringement], (ii) the balance of convenience [ay] in its favour, and (iii) it would suffer irreparable injury if [an] injunction [was] not granted.”⁷⁶ Although the patent holder had argued that it “may not be appropriate for any court to hold a mini-trial at the stage of grant of temporary injunction,”⁷⁷ the appellate court nevertheless held that the trial court should consider the strength of the prima facie cases of validity and infringement,⁷⁸ and engaged in a detailed evaluation of five considerations: (a) “[w]hether the Act in question is really an invention,” (b) “[w]hether it is not of recent origin,”⁷⁹ (c) “[w]hether it pertains to three-layered product or two-layered product” and thus infringes, (d) “whether the damages will provide adequate remedy should the claim succeed,” and (e) “whether it will be proper for the appellate court to upset the trial court order which has made perspicacious judgment.”⁸⁰

The appellate court also quoted an earlier case holding,

⁷⁵ *Bilcare*, No. FAO 70/2007, ¶ 1.

⁷⁶ *Id.* ¶ 6. *See also id.* ¶¶ 7-12. In other cases, the preliminary injunction test is framed as a four-part inquiry similar to that in the United States, including reasonable likelihood of success and impact on the public interest; Tarun Mathur, *Patent Litigation Trend in India* 30-31 Social Science Research Network, Working Paper No. 995994, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=995994 (citing *Godrej Soaps Ltd. & Ors. v. Hindustan Lever Ltd. & Ors* PTC (Suppl.) (1) 501 (Cal) (DB)).

⁷⁷ *Bilcare*, No. FAO 70/2007, ¶ 8 (quoting *Anand Prasad Agarwalla v. Tarkeshwar Prasad*, 5 Sup. Ct. Cas. 586 (2001)).

⁷⁸ *See id.* ¶ 9 (arguing that consideration is required not only of these issues but also of appropriate security, and rejecting the holding in *American Cyanamid Co. v. Ethicon Ltd.*, ILR 1976 Karnataka 426, that it was not necessary to make out a prima facie case of infringement in order to obtain an interlocutory injunction so long as the claim is not frivolous) (quoting *Giridhari Balam Radhakrishnani v. M/S Mahisa Elecs.*, ILR 1995 Karnataka 2010, ¶ 10-15)). In a related case, Judge Sanjay K. Kaul of the Delhi High Court noted that *Bilcare* had not established a prima facie case for preliminary relief given evidence raising doubts about validity. *See M/S Bilcare Ltd. v. M/S Amartara Private Ltd.*, IA NOS 10848/2006, 13971/2006 and 11160/2006 IN CS(OS) No.1847/2006, ¶¶ 51-59 (Mar. 20, 2007).

⁷⁹ *See Bilcare*, No. FAO 70/2007, ¶ 9 (stating that no temporary injunction would issue “when the patent is a recent one and its validity is questioned.” (quoting *Giridhari Balam Radhakrishnani*, ¶ 15)); *id.* at 21

[I]f a patent is a new one, a mere challenge at the bar would be quite sufficient for a refusal of a temporary injunction but if the patent is sufficiently old and has been worked the court would . . . presume the patent to be valid one. If the patent is more than 6 years old and there has been actual user it would be safe for the court to proceed upon this presumption.

(quoting *M/S Nat’l Research Dev. Corp. of India, New Delhi v. M/S The Delhi Cloth & Gen. Mills Co. Ltd.*, AIR 1980 Delhi 132)). In contrast, *Bilcare* had relied on *M/S Metro Plastics Indus. v. Galaxy Footwear*, AIR 2000 New Delhi PTC (20) 1 (Del.) (FB), which held that an injunction should not be refused merely because the registration was recent. *See Nair, supra* note 74.

⁸⁰ *Bilcare*, No. FAO 70/2007, ¶ 13.

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[T]he grant and sealing of the patent or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent. . . . It is pertinent to note that this position . . . is now expressly provided in Section 13(4) of the Patents Act, 1970. In the light of this principle, [counsel's] argument that there is a presumption in favour of the validity of the patent cannot be accepted.⁸¹

Further, the appellate court noted that “the onus of showing a prima facie case justifying the grant of an injunction is a heavy one and it is comparatively easy for the respondent to establish a defense sufficient to prevent the granting of such an injunction “⁸² Interlocutory relief is “an exceptional remedy . . . for which exceptional cause [is] to be shown.”⁸³ The appellate court thus noted that it would require more than a disagreement with the conclusion of the trial judge to reverse its decision on a preliminary injunction, if the trial judge’s discretion “has been exercised . . . reasonably and in a judicial manner.”⁸⁴ In conclusion, the appellate court considered that the suit was filed before the patent was six years old, and given that there were

tangible grounds for suspicion of the alleged invention⁸⁵ [t]here lies no rub in granting damages which would provide an adequate remedy should the claim succeed All the three essential conditions viz., prima facie case, balance of convenience and irreparable loss lean on the side of the respondents.⁸⁶

In summary, the appellate court in *Bilcare* appears to have: (1) adopted the traditional three-part framework for assessing preliminary relief with a high burden of justification placed on the party seeking it; (2) rejected a presumption of validity based on the existence of the patent or on the time that elapsed since its grant (particularly given the language of the statute rejecting a

⁸¹ *Id.* ¶ 16 (quoting *Bishwanath Prasad Radhey Shyam v. H.M. Indus.*, AIR 1989 SC 1444, ¶ 33). See *id.* ¶¶ 17-20; Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation* 173 (Social Science Research Network, Working Paper No. 923538, 2007), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=923538 (last visited Dec. 25, 2007) (noting the absence of an elevated burden of proof of invalidity, suggesting that revocation would be easier in India than in the United States).

⁸² *Bilcare*, No. FAO 70/2007, ¶ 23 (quoting *Hindustan Lever Ltd. v. Godrej Soaps Ltd. and Others*, [1997 PTC (17) 756], ¶ 24).

⁸³ *Id.* ¶ 23 (quoting *Hindustan Lever Ltd. v. Godrej Soaps Ltd. and Others*, [1997 PTC (17) 756, ¶ 48 (quoting BRIAN C. REED, A PRACTICAL GUIDE TO PATENT LAW 113 (2d ed. 1993)).

⁸⁴ *Id.* ¶ 24 (quoting *Telemechanique & Controls (I) Ltd. v. M/s Schneider Elec. Indus. SA*, [2002 IAD (Del.) 451]).

⁸⁵ See *id.* ¶ 14-5 (discussing a prior art publication that referenced multi-layer films of varying finish, placing “a large question mark over the so called invention,” which would require “evidence of experts, investigation and other evidence”).

⁸⁶ *Id.* ¶ 25.

presumption of validity); (3) imposed an even higher burden on the patent holder to justify an injunction (given that the trial judge had vacated it and particularly given that the patent faced an opposition); and (4) considered the evidence and evaluated whether the patent likely was invalid. I focus below on the first two of these decisions, incidentally discussing the last two.

A. *The Presumption of Validity and the Preliminary Relief Framework*

The three-part framework for granting preliminary relief is a commonplace, as is a high burden of justification, at least among former British Commonwealth countries.⁸⁷ In the United States, for example, preliminary injunctions are treated as “extraordinary relief,” and a four-part framework substitutes for the three-part framework, with likelihood of success on the merits substituting for a prima facie case and with consideration of the “public interest” in granting or refusing a preliminary (or permanent) injunction supplementing the other factors.⁸⁸ Irreparable harm and likelihood of success are normally considered the most important of the factors.⁸⁹

It would be difficult to make a convincing argument that courts (at least in the United States) should be able to presume irreparable harm and inadequacy of damages simply from the existence of the patent and a refusal to grant a preliminary injunction.⁹⁰ This is particularly true given the United States

⁸⁷ See, e.g., Brian Daley, et. al., *Pre-Trial Proceedings in Patent Infringement Actions: A Comparison Among Canada, the United Kingdom, and the United States of America*, 35 AIPLA Q.J. 113, 118 (2007) (describing essentially the same three factors under Canadian law for interlocutory injunctions) (citing *RJR MacDonald Inc. v. Canada*, [1994] 1 S.C.R. 311, 314-15 (Can.)); *id.* at 134 (describing the requirements to persuade the court “that there is a serious issue to be tried, that damages would not be an adequate remedy, and that the balance of convenience favors the granting of an injunction” (citing *Am. Cyanamid Co. v. Ethicon*, (1975) A.C. 396 (H.L.) (U.K.)). *But cf.* David W. Hill & Shinichi Murata, *Patent Litigation in Japan*, 1 AKRON INTELL. PROP. J. 141, 181-82 (2007) (noting that provisional injunctions in Japan are decided in a separate proceeding from the main infringement action, where the issues are scrutinized as closely as in the main suit and which employs a two-part test of proving infringement and the necessity of temporary relief, based on considering relative hardship of denying or granting the provisional injunction without hearing witnesses and without considering the amount of damages).

⁸⁸ Daley et. al., *supra* note 87, at 148-49 (citing *T.J. Smith & Nephew Ltd. v. Consol. Med. Equip., Inc.*, 821 F.2d 646, 647 (Fed. Cir. 1987) and *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1348 (Fed. Cir. 2003)).

⁸⁹ See, e.g., John J. Feldhaus, *Preliminary and Permanent Injunctions in Patent Cases*, 804 PLI/PAT 521, 534 (2004). See generally M.A. Cunningham, *Preliminary Injunctive Relief in Patent Litigation*, 35 IDEA 213 (1995).

⁹⁰ See, e.g., *z4 Techs., Inc. v. Microsoft Corp.*, 434 F.Supp.2d 437, 439-40 (E.D. Tex. 2006) (rejecting arguments for a presumption of irreparable harm for permanent injunctions once validity and infringement have been found - raised by patent holder’s citation to Supreme Court dicta regarding preliminary injunctions and analogy to copyright cases, because the only lost licensing revenues were from the infringer and a reasonable royalty would adequately compensate for them) (citing *Amoco Prod. Co. v.*

Supreme Court's recent decision in *eBay, Inc. v. MercExchange, L.L.C.*,⁹¹ which held that traditional equitable considerations apply to permanent injunctions in patent law and that there is no general rule that courts should issue such injunctions.⁹² If a Court may not issue an injunction once it has determined a patent to be valid and infringed, it should have even less reason to do so in a preliminary relief setting.⁹³ Rather, courts must carefully evaluate the nature of the patent in question, how the patent holder has sought to exploit it, and how the alleged infringement will affect the patent holder's interests before determining whether irreparable harm will result and a damages remedy will be inadequate.⁹⁴ An economic analysis of the incentive effects and need for preliminary or permanent injunctive relief for the wide variety of patentable subject matter, industries, and patent-holder and competitor practices is far beyond the scope of this article.⁹⁵

Assessing the balance of hardships to the parties also may require detailed economic analysis of the specific patent, industry, and patent holder and competitor practices.⁹⁶ Uncertainties

Vill. of Gambell, 480 U.S. 531, 542, (1987)).

⁹¹ *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006).

⁹² *Id.* at 1841 (requiring courts to consider permanent injunctions under "the traditional four-factor framework that governs the award of injunctive relief" and that courts' equitable discretion "must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards"). *See also id.* at 1839, 1841 (rejecting the lower court's articulation of "the general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances") (quoting *MercExchange L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005));

⁹³ *See Carroll*, *supra* note 22, at 431-32 (noting that such a presumption is unwarranted in light of the *eBay* decision even after the plaintiff has shown a likelihood of success on the merits).

⁹⁴ *Id.* at 432-35 (citing, *inter alia*, Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991 (2007)). *Cf. Novozymes A/S v. Genencor Int'l, Inc.*, 474 F.Supp.2d 592, 612-13 (D. Del. 2007) (finding irreparable harm from losses suffered by the patent holder's subsidiary-licensee because "the statutory right to exclude represents a benefit that, under these circumstances, cannot be equated by an award of cash" by preventing the patent holder from having "to assist its rival with the use of proprietary technology").

⁹⁵ For a useful discussion of these issues, focusing on whether injunctive relief is well-tailored to restrict only the property interest at issue and considering comparative competence of courts and agencies that might adopt compulsory licenses, see Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783 (2007). *See also* Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 292-93 (2007) (arguing that in some cases patent holders should not be entitled to recover the full social benefits of their inventions, and thus should receive compensation but not an injunctive property right to control uses). *See generally* Andrei Iancu & W. Joss Nichols, *Balancing the Four Factors in Permanent Injunction Decisions: A Review of Post-eBay Case Law*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 395, 396-404 (2007) (reviewing recent court decisions applying *eBay*); Jeremy Mulder, *The Aftermath of eBay: Predicting When District Courts Will Grant Permanent Injunctions in Patent Cases*, 22 BERKELEY TECH. L.J. 67, 72-79 (2007) (same).

⁹⁶ *See Carroll*, *supra* note 22, at 435-37 (discussing the situation articulated in *eBay* where disproportionate harms may result by granting an injunction because the patent is a small component of the product sold) (citing *eBay*, 126 S. Ct. at 1842)).

regarding the scope or validity of a particular patent or class of patents thus should affect the willingness of courts to grant injunctive relief.⁹⁷ The “public interest” prong also may involve consideration, articulation, and development of relevant policies for balancing the need for injunctive relief to protect patent system incentives with the need to preclude such relief and override those incentives, as both are for the public’s benefit.⁹⁸ After *eBay*, courts should not merely state that public policy favors injunctive relief and that public interest exceptions to such relief are (and should be) “rare and limited.”⁹⁹ As the appellate court in *Bilcare* noted, however, the need for such tailored determinations regarding the nature of the patent holder’s market and effects on that market have the potential to turn preliminary matters into mini (if not large) trials.¹⁰⁰ Although the presumption of validity may be relevant to such decisions, it cannot by itself supply the requisite policies nor limit the evidence to be considered.

In regard to likelihood of success (or the prima facie case), it is important to note that *Bilcare* addressed review of an order vacating ex parte injunctions. In this context, both the issue of validity and the issue of infringement had already been considered, and the patent holder as appellant was faced with (but did not carry) the practical burden of persuasion, given that the status quo would leave the injunctions vacated. However, the appellate court was not clear in detailing what were the legal burdens of production and persuasion for preliminary relief, although these burdens appeared to be unaffected by any presumption of validity (as none was found to apply).¹⁰¹ Traditionally, the patent holder seeking preliminary relief bears the burden of production and persuasion in regard to both

⁹⁷ See *id.* at 435-37 (discussing the business method patent concerns articulated in *eBay* as exemplifying patents for which scope is difficult to determine and validity is questionable, resulting in fairness and reliance interests to avoid costs of injunctions requiring switching of technologies and lost investments) (citing *eBay*, 126 S. Ct. at 1842).

⁹⁸ See *id.* at 439-42 (noting the non-uniformity of public interest considerations, that “the public interest factor [for injunctive relief] is particularly salient in intellectual property cases because the very point of granting the owner a right to exclude is to encourage investments that will serve the public interest,” and that static versus dynamic efficiencies must be considered, which require considerations beyond the particular case before the court).

⁹⁹ Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech., Inc., 492 F. Supp. 2d 600, 607 (E.D. Tex. 2007) (“The public has an interest in a strong patent system. In general, public policy favors the enforcement of patent rights However, there are rare and limited circumstances in which an injunction would be contrary to a significant public interest such as health and safety concerns.”) (citations omitted).

¹⁰⁰ Cf. *supra* note 79 and accompanying text.

¹⁰¹ See *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, No. FAO 70/2007, ¶ 25 (Mar. 20, 2007), available at <http://www.delhicourts.nic.in/Mar07/BILCARE%20VS.%20THE%20SUPREME%20INDUSTRIES.pdf>.

infringement and validity.¹⁰²

In regard to infringement, the appellate court in *Bilcare* recited a case holding that it was not necessary for the patent holder to present a prima facie case, but only to demonstrate “that the claim is not frivolous or vexatious,” following which the court should consider the balance of convenience.¹⁰³ In regard to validity, the decision in *Bilcare* likely imposed either a heightened evidentiary standard (precluding injunctive relief where “the validity of the patent itself has been questioned and a revocation petition has been filed”¹⁰⁴) or weighed the evidence under the ultimate burden of persuasion (which might have been placed on the patent holder, given the absence of a statutory or judicial presumption of validity) and concluded that no prima facie case was established given evidence of lack of novelty produced by the respondents.¹⁰⁵ It is important to reiterate, however, that the burden of legal justification for the injunction may not be the same as the factual burdens of production and persuasion. Nevertheless, if preliminary relief is to be “exceptional,” courts may impose high burdens of production and persuasion so as to minimize the risks of erroneous judgments.

In the United States, a very complex interaction has been established between the presumption of validity and the burdens of production and persuasion for preliminary relief. The current standards are worth quoting from a recent (split) appellate decision:

As to [the patent holder’s] likelihood of success on the merits “if [the defendant] raises a substantial question concerning . . . validity, i.e.,] . . . [an] invalidity defense that the patentee cannot prove ‘lacks substantial merit’” then the patentee has not established a likelihood of success on the merits As to the burden regarding invalidity allegations, “[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial.” . . . As this court has stated . . . “[i]n resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus

¹⁰² See, e.g., Feldhaus, *supra* note 89, at 535.

¹⁰³ *Bilcare*, No. FAO 70/2007, ¶ 9 (quoting Giridhari Balaram Radhakrishnani v. M/S Mahisa Elecs., ILR 1995 Karnataka 2010, ¶ 10).

¹⁰⁴ See *id.* ¶ 20 (quoting M/S Standipack Pvt., Ltd. v. M/S Oswal Trading Co. Ltd., [AIR 2000 Delhi 23], ¶ 16).

¹⁰⁵ See *id.* ¶ 25 (“Secondly, there are tangible grounds for suspicion of the alleged invention.”).

requires less proof than the clear and convincing showing necessary to establish invalidity itself. When moving for the extraordinary relief of a preliminary injunction, a patentee need not establish the validity of a patent beyond question. The patentee must, however, present a clear case supporting the validity of the patent in suit.¹⁰⁶

In sum, in the United States the patent holder seeking preliminary relief bears the burdens of production and persuasion of likelihood of success regarding validity, but the party opposing the injunction bears the burden of producing evidence to raise a substantial question regarding validity. The burdens of production and persuasion then shift back to the patent holder to prove likelihood of validity by demonstrating that the substantial question “lack[s] substantial merit” without resort to the clear and convincing evidence burden of persuasion imposed by the presumption of validity.¹⁰⁷ Evidence of a substantial question regarding validity also negates any potential for irreparable harm and, absent any other relevant concerns, inclines the public interest to favor denying a preliminary injunction.¹⁰⁸ If this were not enough, factual determinations made in this context are reviewed on appeal only for clear error.¹⁰⁹

As noted in the recent appellate decision, this approach both alters the burden of persuasion and eliminates the presumption of validity that supposedly attaches at all stages of litigation.¹¹⁰ The patent holder would merely need to rely on the presumption in regard to validity, or if the challenger had presented sufficient evidence to demonstrate it was likely to rebut the presumption the patent holder would need only to present sufficient evidence to

¹⁰⁶ *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (citing, *inter alia*, *Amazon.com, Inc. v. Barnesandnoble.com*, 239 F.3d 1343, 1350-59 (Fed. Cir. 2001), and *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). The standard for appellate review of the grant or denial of the preliminary injunction is the abuse of discretion. *See id.* at 1334-35 (citing *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996)).

¹⁰⁷ *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374-75 (Fed. Cir. 2006) (citing *Genentech, Inc.* 108 F.3d at 1364). *See* *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1365 (Fed. Cir. 2006) (“[I]n order to defeat the injunction on grounds of potential invalidity . . . the party bearing the burden of proof on the issue at trial, must establish a substantial question of invalidity.”) (citing *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 428-431 (2006))). Given the burden on the patent holder to demonstrate likely success on the merits, it is unclear whether the patent holder must bear a burden of production regarding the lack of substantial merit of an anticipated (but not yet produced) showing of a substantial question of invalidity. *But cf. Sanofi-Synthelabo*, 470 F.3d at 1378 (noting argument that the District Court erred in concluding that challenger had not raised a substantial question of patentability).

¹⁰⁸ *See Sanofi-Synthelabo*, 470 F.3d at 1347-8.

¹⁰⁹ *See, e.g., Sanofi-Synthelabo*, 470 F.3d at 1379-80.

¹¹⁰ *See Abbott Labs.*, 452 F.3d at 1350 (Newman, J., dissenting) (citing, *inter alia*, *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed.Cir.1998) and *PPG Indus., Inc. v. Guardian Indus., Inc.*, 75 F.3d 1558, 1566 (Fed.Cir.1996)).

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preserve the likelihood that it would succeed in preventing the challenger from proving invalidity under the applicable burden of persuasion (by clear and convincing evidence).¹¹¹ In contrast, to have the likelihood of success factor weigh in its favor, the alleged infringer would need to produce sufficient evidence not only to raise a substantial question of patentability but also to rebut the presumption of validity and to likely overcome under the clear and convincing burden of persuasion any additional evidence to be introduced by the patent holder.

The point I wish to make here is not to resolve which evidentiary approach is correct (although the dissent's approach has the virtue of greater simplicity). The choice of burdens of production and persuasion for preliminary relief would be much simpler if the presumption of validity either did not arise in such a context or were treated as a bursting bubble and imposed no heightened burden of persuasion. Rather, I wish to emphasize that policy choices are needed in regard to whether and how presumptions of validity should apply in different procedural contexts. Policies must be developed not only regarding the legal weight to be accorded to various equitable balancing factors, but also regarding the evidentiary burdens to be imposed when demonstrating the facts that trigger the conclusions regarding those factors.¹¹²

Perhaps the most important point about *Bilcare* is that the court permitted consideration of evidence of invalidity at all. A separate administrative opposition was pending, which clearly affected the appellate court's consideration, and the court either could have either refused to consider the issue of validity and looked at the prima facie case of infringement, or could have deferred action until after administrative resolution. In many jurisdictions, validity may be decided separately from infringement, either by different courts or by administrative agencies. Even more complex policy choices therefore are presented regarding where and when to permit challenges to validity, whether and how the presumption of validity will apply in the different settings, and what preclusive effects decisions in each setting may have.¹¹³ Given that the timing of decisions in the

¹¹¹ See *Abbott Labs.*, 452 F.3d at 1350.

¹¹² See, e.g., *Praxair, Inc. v. Atmi, Inc.*, 479 F. Supp. 2d 440, 443 (D. Del. 2007) (noting that to prove an entitlement to permanent relief, a patent holder must demonstrate "*inter alia*, irreparable injury and the inadequacy of legal remedies," but "the quantum of evidence required is relatively unclear").

¹¹³ See, e.g., J. Steven Baughman, *Reexamining Reexaminations: A Fresh Look at the Ex parte and Inter partes Mechanisms for Reviewing Issued Patents*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 349, 354-56 (2007) (noting the absence of the "clear and convincing" evidentiary presumption and burden of persuasion in reexamination proceedings, as well as different

different systems for assessing validity may vary, additional questions are raised regarding whether to defer decisions in one system until decisions are reached in the other.¹¹⁴ As courts may not be as efficient as administrative agencies in invalidating invalid patents,¹¹⁵ and administrative agencies typically are not authorized to determine infringement questions (and may lack enforcement powers),¹¹⁶ the resolution of the policy choices are not self-evident.

These issues, moreover, are not limited to the context of preliminary or permanent injunctions. They also apply to awards of damages. As a recent English decision held that, based on the importance of achieving stability of judicial judgments, awards of damages will not be set aside (after all appeals have been run) even if the patent is later invalidated by the European Patent Office.¹¹⁷ The author of the decision was quite candid regarding the uncertain policy choices involved, particularly given the

claim construction rules and the ability to avoid discovery and cross-examination); Hill & Murata, *supra* note 87, at 177-78 (discussing a relatively recent decision permitting “courts presiding over infringement actions [to] decide whether it is clear that a patent is valid,” in which case no injunction will issue, and a new statutory provision preventing the patent holder from enforcing the patent if it has been held invalid in the Japanese Patent Office (citing *Texas Instruments v. Fujitsu*, 54 MINSH 1368 (Sup. Ct., Apr. 11, 2000) and TOKYO H [Japanese Patent Law], Law No. 120 of 2004, art. 104-3, *translated at* <http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf>)).

¹¹⁴ See *e.g.*, Baughman, *supra* note 113, at 355 & nn. 27-8 (noting the potential for stay of litigation when a reexamination is pending, depending on how much litigation activity has occurred, whether the reexamination is posed for proper purposes or delay, whether reexamination is likely to simplify trial issues, and whether a court believes that it would benefit from having the Patent Office make a first assessment of invalidity evidence, and noting statutory provisions for expedited consideration and for stay unless it “would not serve the interests of justice” in case of *inter partes* reexaminations) (citing 35 U.S.C. §§ 305, 314(c) (2007), and quoting 35 U.S.C. § 318 (2007)); Hill & Murata, *supra* note 87, at 178 (noting that judgments based on changed administrative actions provide cause for retrial, but that administrative determinations may have one-way effect to permit retrial only when a decision of invalidity follows a judicial finding of validity but not when a determination of validity follows a judicial finding of invalidity, and noting provisions for consultation – but not deferral – between the courts and the Japanese Patent Office). See also Kenji Shimada, et al., *Patents as Property: International Injunctive Relief*, 14 CASRIP Newsletter (2007) (noting the German rule that an injunction may be denied if there is any doubt as to the patent’s validity and also the strategic filing in Italy, where patents are rarely granted but filing will preclude another signatory country from taking jurisdiction under the Brussels Convention on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, O.J. L 299/32 (1972), amended by O.J. L 304/77 (1978), amended by O.J. L 258/1 (1989)).

¹¹⁵ See, *e.g.*, Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 243 (2006).

¹¹⁶ In the United States, the factual determination of infringement but not construction of the patent claims may raise the constitutional right to a trial by jury. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-88 (1996).

¹¹⁷ See *Unilin Beheer BV v. Berry Floor NV*, [2007] EWCA (Civ) 364, ¶¶ 37-88 (appeal taken from Eng.), *available at* <http://www.ipjur.com/data/070425-2007-EWCA-Civ-364.pdf> (discussing *res judicata* effects of litigated judgments on United Kingdom and European Patent Office, providing for estoppel of challenges to damages awards based on later invalidation, but noting that later invalidation will not estop challenges to injunctive relief).

geographical jurisdictional concerns involved. “In truth asking which tribunal is ‘top’ is simply not helpful – there is just the untidy compromise inherent in the EPC and one which cannot properly be resolved unless and until a rational patent litigation system for Europe is created.”¹¹⁸

It is beyond the scope of this article to resolve the issues regarding harmonization of administrative and judicial validity challenges. What is important here is that the presumption of validity will (even if implicitly by default to a unitary standard) need to be specified for both judicial and administrative systems and for each procedural context within those systems. Uniformity of the presumption of validity appears neither to be the current rule nor sound policy.¹¹⁹ Rather, it appears more important to tailor the presumption so as to obtain more accurate and predictable results.¹²⁰ Although the requisite degree of tailoring may not be forthcoming from legislatures, such specification is a job the judiciary has traditionally undertaken (even when reviewing administrative action) and to which it is well-suited.¹²¹

B. *The Presumption of Validity, Patent Life, and Variable Burdens*

The appellate court in *Bilcare* appears to have rejected a presumption of validity in regard to preliminary relief, basing its conclusion both on the statutory declaration that there is no guarantee of validity¹²² and on the fact that the patent was recently

¹¹⁸ *Id.* ¶ 26. See also Nick Beckett, *United Kingdom: Awards of Damages in UK Patent Cases Will Prevail Notwithstanding the Findings of EPO*, MONDAQ, May 14, 2007, available at <http://www.mondaq.com/article.asp?articleid=48492&print=1> (noting that patentees will seek to bring infringement actions as early as possible in jurisdictions where the procedure for doing so is quick and efficient, before an unfavorable EPO ruling could be issued, and that defendants will seek stays of such litigation, with the result being even less uniformity across Europe).

¹¹⁹ See, e.g., Sag & Rohde, *supra* note 20, at 78-9 (recommending a general preponderance of evidence presumption of validity, which would be raised following post-grant review that sustains validity and would be replaced with a presumption of invalidity following post-grant review, so as to make more fair the comparative lack of procedural safeguards in such review).

¹²⁰ See Carroll, *supra* note 22, at 429-30 (noting concerns raised by the Chief Justice in concurrence in *eBay* regarding predictability of outcomes and “the basic principle of justice that like cases should be decided alike” (citing *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1841-42 (2006) (Roberts, C.J., concurring) (quoting *Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 710 (2005))).

¹²¹ *Cf. eBay*, 126 S. Ct. at 1841 (“[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts.”).

¹²² See *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, No. FAO 70/2007, ¶ 16 (Mar. 20, 2007) (citing Section 13(4) of the Indian Patents Act 1970) available at <http://www.delhicourts.nic.in/Mar07/BILCARE%20VS.%20THE%20SUPREME%20INDUSTRIES.pdf> (last visited June 30, 2007); *id.*, ¶ 20 (citing *M/S Standipack Pvt. Ltd. v. M/S Oswal Trading Co. Ltd.* [AIR 2000 Delhi 23], ¶ 15 (noting the lack of a presumption of validity from grant, notwithstanding examination and investigation under Sections 12 and

granted (compared to a substantive rule favoring a presumption in regard to a worked patent of long standing).¹²³ The premise of conditioning the existence of a presumption of validity on the length of time since the patent was issued is highly suspect. The timing of the lawsuit assessing validity may reflect the degree of opportunity for competitors to have sought earlier invalidation. But it seems an extremely poor proxy for the likelihood that the patent was granted correctly and is valid. As many commentators have noted in regard to United States law, where a determination of invalidity in one action will bar enforcement in another but not vice-versa, the incentives for bringing challenges to validity are substantially inadequate.¹²⁴ Thus, the timing of making such a challenge (based on the patent holder's or challenger's choices to litigate) may have relatively little to do with the strength of arguments regarding validity.¹²⁵ And until recently, licensees of the patent in good standing were thought to lack standing to bring declaratory challenges to the validity of the patent.¹²⁶

Similarly, the fact that time has gone by should not directly affect the three-factor (or four-factor) test for preliminary relief,

13 of the Indian Patents Act)).

¹²³ See *Bilcare*, No. FAO 70/2007, ¶ 21; *id.* ¶ 23 ((quoting *Hindustan Lever Ltd. v. Godrej Soaps Ltd. and Others*, [1997 PTC (17) 756], ¶ 29

[I]f the patent is a new one, a mere challenge at the Bar would be quite sufficient for the refusal of a temporary injunction, but if the patent is sufficiently old and has been worked, the Court would, for the purpose of a temporary injunction, presume the patent to be a valid one.

See also *supra* note 76 and accompanying text; Lichtman & Lemley, *supra* note 20, at 51 (recommending a heightened presumption of validity based on passage of time between issuance and evaluation, because "delay means that there was more opportunity for reliable outsider evaluations to come to light").

¹²⁴ See, e.g., Kesan & Ball, *supra* note 115, at 244 & n.49 (explaining inadequate incentives for provision of validity challenges, based on private costs exceeding public benefits and on free riding and collective action problems (citing Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 948-60 (2004))); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75 (2005) (explaining why private parties lack incentives to challenge patents in courts); Jay P. Kesan & Andres A. Gallo, *Why "Bad" Patents Survive in the Market and How Should We Change? – The Private and Social Costs of Patents*, 55 EMORY L.J. 61, 85 (2006) (same); Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667 (2004) (discussing new incentives for challenging invalid patents). The collective action problems with incentives for challenging patents may reflect in part the rule that patent holders are estopped from asserting validity if a patent has been declared invalid in a prior suit affording a full and fair opportunity for the patent holder to litigate validity. See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 317-49 (1971). Cf. The India Patents Act, No. 39 of 1970 § 151, as amended by The Patents (Amendment) Act of 2005, No. 15, Acts of Parliament, 2005 (stating that where a court has found a claim invalid, "the court shall transmit a copy of its judgment and decree to the Controller who shall on receipt thereof cause an entry in relation to such proceeding to be made in the prescribed manner in a supplemental record").

¹²⁵ Cf. Sag & Rohde, *supra* note 20, at 22-23 (noting that litigation costs, rather than validity of claims, may determine whether a prospective licensee will pay the demand or seek to litigate validity).

¹²⁶ See *Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).

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or at least not in the way the Indian rule of practice suggests. The length of time since the patent issued may actually decrease the likelihood of irreparable harm or of success on the merits of proving infringement and validity (or of overcoming invalidity challenges). Patents are more likely to be valuable and damages harder to calculate during their early years.¹²⁷ Similarly, the amount of time since the patent has issued may be a weak proxy for assessing the balance of hardships (or the “balance of convenience”).¹²⁸ If significant time has gone by, both the patent holder and the alleged infringer may have made extensive investments and may have significant reliance interests. Nor is it clear how additional time would affect public interests in assuring protection of incentives for valid patents and protection from market harms where invalid patents are asserted.¹²⁹ Substantial additional empirical and policy analysis is required before time should be treated as a relevant variable.

The more difficult presumption of validity questions raised by *Bilcare* relate to likelihood of success on the merits, particularly given the scant record that was before the appellate court and its citation to “settled law” in India that an injunction should not issue when an administrative revocation proceeding had been filed.¹³⁰ It may have been entirely unnecessary to assess validity to

¹²⁷ See Carroll, *supra* note 22, at 432-33 (stating that as litigated patents tend to be recently granted, and for new inventions market values are much less certain— and given that most inventions prove to have little or no market value as their patents mature— “damages will tend to be inadequate for infringements of recently-granted patent[s]” (citing John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 460 (2004) and Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521 (2006))). See also John R. Allison & Thomas W. Sager, *Valuable Patents Redux: On the Enduring Merit of Using Patent Characteristics to Identify Valuable Patents*, 85 TEX. L. REV. 1769 (2007) (updating the *Valuable Patents* analysis with additional tests and responding to criticisms of that analysis in David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677 (2007)).

¹²⁸ See, e.g., Carroll, *supra* note 22 at 433-37 (discussing how post-grant licensing and working behaviors by the patent holder will affect the harm of infringing conduct and how the nature of the patent relative to the infringer’s activities affects the balance of hardships).

¹²⁹ See, e.g., *id.* at 440-41 (noting uncertainties in trading off short-term and long-term interests).

¹³⁰ *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, No. FAO 70/2007, ¶ 20 (Mar. 20, 2007) (quoting *M/S Standipack Pvt. Ltd. v. M/S Oswal Trading Co. Ltd.*, [AIR 2000 Delhi 23], ¶ 16), available at <http://www.delhicourts.nic.in/Mar07/BILCARE%20VS.%20THE%20SUPREME%20INDUSTRIES.pdf>. See *supra* note 113-21 and accompanying text. In contrast, courts in the United States may issue injunctions while reexamination proceedings are pending. See, e.g., *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1287, 1291 & n.3 (Fed. Cir. 2005) (reviewing damages award and permanent injunction that the District Court stayed pending appeal, and noting that the Patent Office granted reexamination after the jury verdict). Cf. *MercExchange, L.L.C. v. eBay, Inc.*, 500 F.Supp.2d 556 (E.D. Va. 2007) (denying renewed motion for permanent injunction following remand from the Supreme Court and noting the potential for eBay to suffer irreparable harm if an injunction issued but the Patent Office later invalidated the patent at issue, which is currently in

justify upholding the vacatur of the *ex parte* injunctions, given that the burden of proving infringement was on the patent holder and that a significant question of non-infringement was demonstrated by the respondents.¹³¹ Further, it does not seem likely that the appellate court simply rejected the grounds for injunctive relief based on pendency of the administrative opposition, as it would have then had no reason to opine that the traditional equitable factors all inclined against the injunctions (and thus in favor of upholding their vacatur).¹³²

In the United States., the decision to commence an *ex parte* or an *inter partes* reexamination proceeding requires an initial finding by the Patent Office of a “substantial new question of patentability.”¹³³ Such a finding arguably should eliminate the presumption of validity once made, not only for the administrative proceeding but also for judicial actions (unless and until a decision is reached). After all, if the presumption arises from the inference of correct process in the Patent Office (even if it serves additional purposes), the reexamination order reflects a preliminary determination that calls its earlier determination of a correct process into question.¹³⁴ What court would then believe (much less believe strongly) in the factual inference provided by the initial determination from the grant to the validity? Formally eliminating the presumption of validity and thus changing the standard for proof may not necessarily lead to different outcomes in administrative and judicial decision-making, given that deference to the initial administrative judgment may nevertheless be supplied.¹³⁵

In contrast, once a patent issues from an *ex parte* or *inter partes* reexamination, the factual inference from the grant to its validity

reexamination).

¹³¹ See Postings of Mrinalini Kochupillai and Shamnad Basheer to SPICY IP, <https://www.blogger.com/comment.g?blogID=17664472&postID=3538153164842343905&isPopup=true> (May 2007) (noting the relative ease of proving lack of infringement in the case, if the claims covered three-layer films given that the defendants used two-layer films).

¹³² See *Bilcare*, No. FAO 70/2007, ¶ 25.

¹³³ 35 U.S.C. §§ 303(a), 304, 312(a), 313 (2007).

¹³⁴ Cf. Benjamin & Rai, *supra* note 20, 297-99 (arguing that Patent Office determinations of validity are likely entitled only to *Skidmore* deference); see also *id.* at 296 (stating that *Skidmore* deference considers, among other factors, “the thoroughness evident in [the agency’s] consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements” (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

¹³⁵ See, e.g., Benjamin & Rai, *supra* note 20, at 330-34 (discussing changes in appellate and administrative review deference standards and their effects on judicial decisionmaking) (citing, *inter alia*, Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1029-32 and John Allison & Mark Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745, 755 (2000)).

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may be significantly stronger than from the initial grant. The claims at issue may have been determined valid not once but twice and by a different set of decision makers, or may (except in rare *sua sponte ex parte* reexaminations¹³⁶) have been determined valid notwithstanding both third-party and administrative efforts to demonstrate invalidity. Thus, various commentators have suggested heightened presumptions of validity for patents that have successfully been subjected to reexaminations.¹³⁷ The same would apply to administrative pre-grant or post-grant oppositions. Even successful survival of a reexamination or opposition proceeding does not guarantee validity, and the heightened presumption still might not apply to evidence of invalidity not considered in the reexamination or opposition proceeding.

The analysis again suggests that specification of the nature and scope of the presumption of validity is required, that uniformity may not be the best policy, and that other presumptions or substantive rules regarding validity may supersede the presumption of validity that arises from the grant of a patent. This only returns us to the question of the deference to be accorded to prior administrative judgments (and reliance on agency technical expertise and reasoning) in contexts other than direct judicial review. One potential policy prescription would be to require detailed findings of the basis for patent grants, initially and following reexaminations.¹³⁸ Such an approach would likely significantly raise the costs of administering examination systems but also might significantly reduce the costs of judicially evaluating patents. However, it accords well with developments in both patent law and administrative law that emphasize reasoned decision making documented in the administrative record.¹³⁹

¹³⁶ See 35 U.S.C. § 303(a).

¹³⁷ See, e.g., Sag & Rohde, *supra* note 20, at 77-79 (suggesting a higher presumption of validity for patents upheld in post-grant review); Lichtman & Lemley, *supra* note 21, at 117-21 (suggesting a higher presumption of validity for “gold-plated” initial review and post-grant reviews not limited to the Patent Office).

¹³⁸ Cf., e.g., Ravicher, *supra* note 19, at 14 (recommending that examiners document in the record of the patent grant their claim constructions, which should not impose additional burdens as they are already required to adopt such constructions in order to perform examinations); Joseph Scott Miller & James A. Hilsenteger, *The Proven Key: Roles and Rules for Dictionaries at the Patent Office and the Courts*, 54 AM. U. L. REV. 829, 896-901 (2005) (recommending that the Patent Office require applicants to specify during examination the choice of dictionaries to be used when construing their claims, and noting the relatively low additional costs of doing so and substantial systemic cost savings that would result).

¹³⁹ See *supra* notes 30, 34, 71-73 and accompanying text.

IV. KSR AND SUBSTANTIVE RULES REGARDING INVALIDITY

A. KSR, *Proof of Obviousness, and the Presumption of Validity*

In contrast to the complex procedural considerations raised by *Bilcare*, the recent decision in *KSR International Co. v. Teleflex, Inc.*¹⁴⁰ raises complex substantive considerations regarding when the presumption of validity should be superseded by competing presumptions or by substantive legal rules that may shift the burdens of persuasion and proof, and that may limit the scope of relevant evidence. As discussed below, the *KSR* decision reaffirmed earlier United States Supreme Court precedents that imposed such substantive rules regarding the obviousness of particular categories of inventions (combination patents).¹⁴¹ That superseding presumptions of invalidity of granted patents could be adopted should not be a surprise, much less a cause for concern.¹⁴² For example, legislation was recently introduced in the United States that would have adopted a rebuttable, preponderance-of-the-evidence presumption of obviousness in regard to patents for business method inventions.¹⁴³ Nor should it be a surprise that legal rules may shift burdens of production and persuasion or may limit the scope of relevant evidence. For example, in the employment discrimination context, courts have adopted rules that shift the burden of persuasion to the defendant to produce evidence of a non-discriminatory motive, once the plaintiff presents a prima facie case of disparate treatment.¹⁴⁴ The Federal Rules of Evidence expressly permit exclusion of certain types of evidence having some logically probative force on substantive policy grounds (including that it would lead to “confusion of the issues” or “waste of time”),¹⁴⁵ and numerous

¹⁴⁰ *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

¹⁴¹ *See id.* at 1837-41.

¹⁴² *See, e.g.*, Philippe Signore, *There is Something Fishy About a Presumption of Obviousness*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 148 (2002).

¹⁴³ *See* John H. Barton, *Non-Obviousness*, 43 IDEA 475, 501 & n.119 (2003) (citing H.R. 1332, 107th Cong. (Apr. 3, 2001), which would have created a rebuttable presumption of obviousness, using a preponderance of evidence standard, for “a business method invention . . . if the only significant difference between the combined teachings of the prior art and the claimed invention is that the claimed invention is appropriate for use with a computer technology,” with two specified exceptions).

¹⁴⁴ *See, e.g.*, *Tex. Dept. of Cmty. Affairs v. Burdine*, 450 U.S. 248, 253-57 (1981) (clarifying the shifting burdens of production and persuasion established by *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973)). *Cf. Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 510-11 (2002) (establishing that the prima facie case required to make out a disparate impact claim is an evidentiary standard that does not apply to pleading and motions to dismiss).

¹⁴⁵ FED. R. EVID. 403. *See, e.g.*, *Old Chief v. United States*, 519 U.S. 172, 180-84 (1997) (discussing the factors to consider when balancing the probative value of evidence with

substantive legal rules (or conclusive presumptions) may prevent consideration of evidence regarding what would otherwise be highly relevant facts.¹⁴⁶

Determining whether and when such substantive rules regarding invalidity should supersede the presumption of validity from the grant of the patent will require further legislative or judicial elaboration and resolution. To the extent that such substantive rules have been adopted, they should also be applied by the Patent Office, and thus may shift the burdens of production (and persuasion) in the administrative as well as the judicial context.¹⁴⁷ Even if the burden of producing a prima facie case is placed initially on the Patent Office,¹⁴⁸ it may be relatively simple to produce evidence that would trigger such a presumption of invalidity. In that case, the grant of the patent may reflect an administrative determination based on applying the same presumptions and legal rules as would be applied by the courts. This returns us to the question of the deference to be accorded to administrative decisions in regard to evaluation of similar and of new evidence.

What then did *KSR* establish in regard to the legal rules for proving obviousness? The patented invention at issue addressed an adjustable-position pedal assembly with an electronic sensor for controlling a vehicle engine's throttle. The trial court granted summary judgment of obviousness of the invention (considering

unfair prejudice it may cause). See generally Edward J. Imwinkelried, *The Meaning of Probative Value and Prejudice in Federal Rule of Evidence 403: Can Rule 403 Be Used to Resurrect the Common Law of Evidence?*, 41 VAND. L. REV. 879 (1988).

¹⁴⁶ See, e.g., *Michael D. v. Gerald H.*, 491 U.S. 110 (1989) (discussing substantive rule of law – framed as a conclusive presumption – that declared evidence of actual paternity irrelevant except in limited circumstances and thus precluded putative natural father from presenting evidence of paternity). Cf. RICE & KATRIEL, *supra* note 35, at 1311 (“[S]o-called ‘conclusive presumptions’ . . . are not presumptions at all. They are simply rules of law that conclusively establish certain facts in a cause of action.”); Daniel A. Richman, *Applying the Constitutional Doctrine of Irrebuttable Presumption to the Handicapped – Gurmankin v. Costanzo*, 27 DEPAUL L. REV. 1199, 1199 & n.4 (1978) (noting Due Process concerns with irrebuttable presumptions and citing 2 MCCORMICK ON EVIDENCE, § 342, at 802-04 (2d ed. E. Cleary 1972)).

¹⁴⁷ See Barton, *supra* note 143, at 497-99 (arguing that the substantive standard for obviousness adopted by the Patent Office is wrong, and results in a wrong allocation of the burden of producing a prima facie case to examiners. The burden of production for practical reasons should be placed on the applicant given the frequency of rejections under the proper standard and given that the “kind of evidence needed, a comparison with industry practice, is probably better known to the applicant—indeed many patents already include information on the reasons why the proffered invention is much better than what was happening in the industry” (quoting Manual of Patent Examining Procedure (orig. 8th ed. 2001) §§ 2141-43 and *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992))).

¹⁴⁸ See Signore, *supra* note 142, at 149-50 (noting that the Patent Office is supposed to bear the burden of producing a prima facie case of obviousness before any burden is imposed on the applicant to produce evidence of non-obviousness); see also *id.* at 153-56 (discussing support for the prima facie case approach under the 1836 Patent Act, the 1952 Patent Act, and subsequent cases).

the presumption of validity), based on the defendant's evidence that all of the elements of the claim were found in prior art references (including references not considered by the Patent Office) and that the references also supplied a motivation for a person skilled in the art to make the combination.¹⁴⁹ The Court of Appeals reversed the grant of summary judgment, holding that the trial court had failed to make sufficient factual findings regarding whether a person skilled in the art would have been motivated to make the combination, had misunderstood the legal test for finding such a motivation, and had failed to recognize the presence of disputed material facts from expert affidavits concluding that the invention was non-obvious.¹⁵⁰

The Supreme Court began its discussion of the applicable legal standards by expressly reaffirming its earlier precedents regarding "patent[s] based on the combination of elements found in the prior art," which were issued in light of the 1952 Patent Act and the 1966 methodology for determining obviousness articulated in *Graham v. John Deere Co. of Kansas City*.¹⁵¹ The Supreme Court thus reiterated "the need for caution [by the Patent Office] in granting a patent based on [such a] combination,"¹⁵² implicitly questioning the strength of the presumption of validity in regard to such patents (to the extent that such caution was not previously exercised).

Graham appears to have adopted a presumption-shifting approach to determining obviousness, without specifying the comparative legal weight to be placed on the competing factual evidence and inferences at issue. *Graham* required an initial assessment of obviousness by making factual findings regarding: (1) the scope and content of the prior art; (2) the differences of such art from the claims; and (3) the level of ordinary skill in the pertinent art, "against [which] background the obviousness or nonobviousness of the subject matter is determined" as a question of law.¹⁵³ However, the factual inferences leading to a legal conclusion of obviousness may be rebutted by additional evidence. "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."¹⁵⁴ *KSR* affirmed the *Graham*

¹⁴⁹ See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734, 1737-8 (2007).

¹⁵⁰ *Id.* at 1738-39.

¹⁵¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). See *KSR Int'l Co.*, 127 S. Ct. at 1739.

¹⁵² *KSR Int'l Co.*, 127 S. Ct. at 1739.

¹⁵³ *Graham*, 383 U.S. at 17-18.

¹⁵⁴ *Id.* at 18.

approach, describing its “framework for applying the statutory language of § 103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*¹⁵⁵ . . . and its progeny” as an “objective” analysis.¹⁵⁶ *KSR* noted, however, that “[w]hile the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry.”¹⁵⁷ Thus, *KSR* may have altered *Graham*’s approach of considering technological factors first and of shifting the burden (at least of production) to rebut the inferences of obviousness with secondary consideration evidence.

KSR went much further than *Graham* in discussing the standards for proving obviousness in regard to combination inventions. *KSR* described the Court’s earlier combination patent cases in terms that suggest a legal rule that shifts the burdens of production and persuasion to the patent holder and (for at least a subset of such inventions) limits the evidence that may be used to rebut the inference of obviousness. First, in describing *Sakraida v. Ag Pro, Inc.*,¹⁵⁸ the *KSR* decision states that “the Court [had] derived from the precedents the conclusion that when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination *is* obvious.”¹⁵⁹ The use of the word “is” is highly significant, as it suggests a conclusive legal rule of obviousness. If all of the elements of the combination were in the prior art, the invention can be proved non-obvious only by evidence that the elements perform different functions in the combination or that the combination yields more than one would expect.¹⁶⁰ No other evidence regarding obviousness would seem to be relevant, whether it relates to skill in the art or to secondary considerations.

The Supreme Court’s choice of mandatory (conclusive) language is reinforced by its discussion of *United States v. Adams*.¹⁶¹ *Adams* was the companion case to *Graham*, and is the only case under the 1952 Act where the Court has found an invention to be

¹⁵⁵ *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850).

¹⁵⁶ *KSR Int’l Co.*, 127 S. Ct. at 1734.

¹⁵⁷ *Id.* at 1735.

¹⁵⁸ *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976).

¹⁵⁹ *KSR Int’l Co.*, 127 S. Ct. at 1740 (quoting *Sakraida*, 425 U.S. at 282) (emphasis added).

¹⁶⁰ Evidence also might rebut the showing that all the elements of the combination were in the prior art, which triggers the legal rule. It is unclear whether the legal rule is triggered merely by a prima facie showing that all of the elements were in the prior art, or whether the challenger must introduce some evidence of the lack of novel functions or unexpected results.

¹⁶¹ *Graham v. John Deere Co.*, 383 U.S. 1, 39 (1966).

non-obvious.¹⁶² The *KSR* decision states that “[t]he Court [in *Adams*] recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination *must* do more than yield a predictable result.”¹⁶³ Similarly, the Court suggested a conclusive legal rule of invalidity when summarizing its discussion of the combination cases. The Court noted that the principles articulated by the cases were “instructive” and held that “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique *is* obvious unless its actual application is beyond [his or her] skill.”¹⁶⁴ Absent proof by the patent holder that the improved function was beyond the skill of the ordinary artisan, or that the invention possess a new (and not just an improved) function,¹⁶⁵ the legal question of obviousness is fully determined.

At other points the Court seems to limit its legal rule to shifting the burdens of production and persuasion, without limiting the evidence that can be used to prove non-obviousness. When introducing its discussion of the combination cases, and after noting the “principal purpose” of the obviousness inquiry to avoid withdrawing prior art from the public domain articulated by *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*,¹⁶⁶ the Court stated that “[t]he combination of familiar elements according to known methods *is likely to be* obvious when it does no more than yield predictable results.”¹⁶⁷ Similarly, after discussing *Sakraida*, the Court states that “[i]f a person of ordinary skill . . . can implement a predictable variation, § 103 *likely* bars its patentability.”¹⁶⁸ Use of the term “likely” suggests that a burden-shifting approach to proving obviousness is warranted; once the invention is proved to be a combination of prior art elements that produce no new or unexpected functions, the burden shifts to the patent holder to prove the invention was nevertheless obvious

¹⁶² *See id.* at 50-52.

¹⁶³ *KSR Int'l Co.*, 127 S. Ct. at 1740 (emphasis added). However, the Court also described the holding in *Adams* as based on “the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious[.]” suggesting a competing (but not clearly superseding) presumption. *Id.*

¹⁶⁴ *Id.* (emphasis added).

¹⁶⁵ *See Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976) (“Though doubtless a matter of great convenience, producing a desired result in a cheaper and faster way, and enjoying commercial success, Dairy Establishment ‘did not produce a “new or different function” . . . within the test of validity of combination patents.”) (quoting *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 60 (1969)).

¹⁶⁶ *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950).

¹⁶⁷ *KSR Int'l Co.*, 127 S. Ct. at 1739 (emphasis added).

¹⁶⁸ *Id.* at 1740 (emphasis added).

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because a person skilled in the art would not have had an apparent reason to make the combination.¹⁶⁹

The Court further suggested that different substantive legal rules for obviousness may apply depending on the nature of the combination invention. “Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement”¹⁷⁰ The Court thus implied that the substantive rules limiting evidence of non-obviousness should be reserved for these special cases (simple substitution and mere application of a known technique), with the remaining categories of combination inventions subject to less stringent evidentiary requirements. In these other cases, “[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, *all in order to determine whether there was an apparent reason to combine the known elements* in the fashion claimed by the patent at issue.”¹⁷¹ But for all cases, the Supreme Court expressly directed lower courts to evaluate obviousness by determining if the invention triggers the legal rules applicable to combination inventions.¹⁷² In some cases, the combination invention rules will not apply, because the evidence will not be sufficient to prove that all of the elements of the invention were in the prior art.

The Supreme Court apparently analyzed the facts of the invention at issue in *KSR* as if it fell into the latter category of combination inventions. The Court first found legal error in the Federal Circuit’s excessively “narrow conception of the

¹⁶⁹ One of the amicus briefs in *KSR* proposed a similar, burden-shifting approach based on whether the elements of the invention were in the analogous art, creating a rebuttable presumption of a motivation to combine them. See Brief for International Business Machines Corp. as Amicus Curiae in Support of Neither Party, *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 18-26 (also noting that the presumption gives meaning to the level of ordinary skill in the art and thus is consistent with both the statutory language and the *Graham* test).

¹⁷⁰ *KSR Int’l Co.*, 127 S. Ct. at 1740.

¹⁷¹ *Id.* at 1740-41 (emphasis added). See *id.* at 1741

Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, *it can be important to identify* a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

(emphasis added).

¹⁷² See *id.* (“[A] court *must* ask whether the improvement is more than the predictable use of prio-art elements according to their established functions.”) (emphasis added).

obviousness inquiry [reflected] in its application of the TSM test[.]” which had created “a rigid rule that limits the obviousness inquiry[.]”¹⁷³ In contrast, the original TSM test had been introduced by the Federal Circuit’s predecessor and “captured a helpful insight.”¹⁷⁴ The Court noted four errors in the legal standard applied by the Federal Circuit when determining whether an “apparent reason to combine” prior art elements existed: (1) looking only to the problem that the patentee was trying to solve; (2) assuming the persons having ordinary skill in the art will look only to prior art designed to solve the same problem; (3) concluding that an invention cannot be proved obvious “merely by showing that the combination of elements was ‘obvious to try,’” at least when there is a design or market need and limited alternatives; and (4) seeking to prevent hindsight bias by adopting “[r]igid preventative rules that deny factfinders recourse to common sense.”¹⁷⁵ The Court then discussed in detail why an apparent reason to combine should be found from the evidence that had been produced by the defendant, in light of the contrary evidence supplied by the patent holder.¹⁷⁶ The Court implicitly affirmed the trial judge’s grant of summary judgment, dismissing arguments regarding factual disputes raised by an expert affidavit and suggesting that there was no factual dispute material to determining that the invention at issue was obvious.¹⁷⁷ The Court also held that the secondary consideration evidence that the patent holder had introduced was insufficient as a matter of law to alter its legal conclusion of obviousness or to create a triable issue of fact.¹⁷⁸ It appears that the Court considered such evidence to be legally relevant but legally insufficient to rebut the inferences of obviousness otherwise established.¹⁷⁹

In reaching its decision, the Supreme Court did not address the burdens of production and proof, and did not expressly state

¹⁷³ *Id.* at 1741.

¹⁷⁴ *Id.* (citing *Application of Bergel*, 292 F.2d 955, 956-57 (C.C.P.A. 1961)).

¹⁷⁵ *Id.* at 1742-43.

¹⁷⁶ *Id.* at 1743-46.

¹⁷⁷ *See id.* at 1743 (“When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court’s recitation of the relevant prior art and its determination of the level of ordinary skill in the field.”); *see also id.* at 1745-56 (noting that the ultimate judgment of obviousness is a legal question and “the obviousness of the claims is apparent” in light of the undisputed facts regarding the prior art, the scope of the claim, and the level of ordinary skill).

¹⁷⁸ *See id.* at 1745 (“Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious.”).

¹⁷⁹ The patent holder had offered evidence regarding commercial success, but had not provided sufficient evidence to demonstrate the amount of success or the required nexus of such success to the patented invention, and had not introduced any other secondary consideration evidence (such as a long-felt but unsatisfied need for the invention). *See Teleflex, Inc. v. KSR Int’l, Co.*, 298 F.Supp.2d 581, 596 (E.D. Mich. 2003).

whether any heightened evidentiary standard of persuasion should apply. In contrast, the Court expressly refused to decide whether or not the “presumption of validity given to issue patents” should apply, given that the most pertinent prior art reference was not considered by the Patent Office, and held that the claimed invention “is obvious despite the presumption.”¹⁸⁰ Nevertheless, the Court may have implicitly suggested the existence of such a heightened burden of persuasion (placed on the party challenging validity). There would have been no need to find obviousness “despite” the presumption of validity if it were only a bursting bubble (in which case it would have disappeared entirely given the introduction of evidence by the defendant) or if it only supplied a preponderance of the evidence burden of persuasion (given that the defendant had clearly made a prima facie case exceeding a preponderance of evidence until the patent holders’ evidence was considered).

The Court was aware that its decision in *KSR* might create evidentiary presumptions or legal rules regarding proof of obviousness, given the various amicus briefs raising these issues. For example, one law professor filed a brief that focused almost entirely on the presumption of validity and the lack of basis for a clear and convincing evidence standard in regard to prior art not considered by the Patent Office, urging the Court to adopt different strength presumptions depending on the art.¹⁸¹ The United States Government brief argued that a weaker presumption of validity might apply to the case, given that not all the prior art had been considered by the Patent Office, but that there was no dispute of material fact and thus the Court need not resolve the question.¹⁸² In contrast, various companies that trade in patents and various universities and research institutions argued that objective facts fully determine the legal conclusion of obviousness and thus changing the legal standard by eliminating the TSM test (thereby making summary judgment easier to obtain) would alter the statutory presumption of validity (shifting the burden to patent holders to provide objective evidence of non-obviousness) and would diminish predictability and lead to arbitrary decision-making.¹⁸³ In contrast, various businesses and

¹⁸⁰ *KSR Int'l Co.*, 127 S. Ct. at 1745.

¹⁸¹ See Brief of Professor Lee A. Hollaar as Amicus Curiae Urging Affirming in Part and Vacating in Part, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 2-29.

¹⁸² See Brief for the United States as Amicus Curiae Supporting Petitioner, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 27 & n.13.

¹⁸³ See Brief of Altitude Capital Partners et al. as Amici Curiae in Support of Respondents, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 26-27; Brief of Wisconsin Alumni Research Foundation et al. as Amici Curiae In Support of

law professors argued that obviousness is a legal issue which the TSM test improperly treats as a question of fact, thereby eliminating the “analytic step” of determining obviousness and “effectively replac[ing] the broad legal and policy considerations properly embodied in the obviousness determination with a factual inquiry into what is already available in the prior art.”¹⁸⁴

The Supreme Court declined the opportunity to clarify the law of obviousness and the presumption of validity further, particularly regarding the nature of the ultimate legal conclusion of obviousness. Given the extensive briefing, the Court could readily have supplied some definition of what Congress had intended by the term “obvious” as adopted in Section 103(a), but the Court did not do so. The Court only hinted at the character of the legal question. The Court quoted with approval both the “functional approach” of the *Hotchkiss* decision (and its requirement for an invention of more than mechanical skill)¹⁸⁵ and the language of *Great Atlantic* (that patents on obvious inventions withdraw prior knowledge from the public domain)¹⁸⁶ as the “principal reason” for the obviousness standard,¹⁸⁷ and stated that “as progress beginning from higher levels of achievement is expected in the normal course, the results of

Respondents, *KSR Int’l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 18-20.

¹⁸⁴ Brief of Cisco Systems, Inc. et al. as Amici Curiae in Support of Reversal, *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 9; Brief of Intellectual Property Law Professors as Amici Curiae in Support of Petitioner, *KSR Int’l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 9. Although obviousness is a question of law, the ultimate legal question of validity is now decided by jurors rather than judges, except where summary judgment (or judgment as a matter of law) is appropriate. See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (discussing “factual underpinnings implicit in the jury’s verdict” as sufficient to support the jury’s verdict of obviousness).

As one of the amici argued, however, courts, not juries, determined obviousness prior to the Federal Circuit. See Brief of Cisco Systems, Inc. et al., *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) No. 04-1350, at 9.

KSR may alter this allocation of functions, as well as making clear that the ultimate legal conclusion regarding obviousness in reviews of patent office denials is made *de novo*. See, e.g., Constantine L. Trella, Jr., *An Afteward To: A Panel Discussion on Obviousness in Patent Law: KSR International v. Teleflex*, 6 J. MARSHALL REV. INTEL. PROP. L. 633, 634 (2007) (noting that *KSR* suggests that “permitting the jury to decide the ultimate question of obviousness is wrong,” that *KSR*’s references to examination suggest that the Court did not limit its holding to the summary judgment context, and that jury interrogatories therefore should be specific to the underlying factual questions); John F. Duffy, *KSR v. Teleflex: Predictable Reform of Patent Substance and Procedure in the Judiciary*, 106 MICH. L. REV. First Impressions 34, 37 (2007) (noting the “sea change” in procedure that will result from obviousness determinations becoming “the exclusive province of the judge”), <http://www.michiganlawreview.org/firstimpressions/voll106/duffy.pdf>.

¹⁸⁵ See *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 265 (1851); *supra* note 32 and accompanying text.

¹⁸⁶ See *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950); *supra* note 166 and accompanying text.

¹⁸⁷ *KSR Int’l Co.*, 127 S. Ct. at 1739.

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ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.”¹⁸⁸ Given the Court’s express holding that obviousness is a question of law, moreover, the Court implied that the question of whether more than mechanical skill or ordinary innovation was required to produce the invention at the relevant time is not merely a factual question. It cannot be resolved by perfunctorily determining the level of ordinary skill and applying that factual finding to the factual finding of the differences between the claimed invention and the prior art.

As I argued to the Court, in a brief on behalf of economists and legal historians, obviousness reflects a policy decision regarding the level of inventive contribution that warrants a patent (which historically was set at a substantial threshold that combination inventions generally did not cross).¹⁸⁹ As the United States Government put it in its *KSR* brief, the Supreme Court “has applied the *Graham* framework in a variety of context to resolve the core issue: Whether the claimed invention manifests the *extraordinary level of innovation* that justifies the award of congressionally prescribed rights to exclude others from practicing the invention.”¹⁹⁰ There are sound historical reasons to believe that this legal question of the obviousness threshold reflects discretionary policy judgments made by the judiciary.¹⁹¹

¹⁸⁸ *Id.* at 1746.

¹⁸⁹ See Brief of Economists and Legal Historians as Amicus Curiae in Support of Petitioner, *KSR Int’l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 1-15. Cf. U.S. NATIONAL PATENT PLANNING COMM’N, THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 239, 78th CONG., 1st Sess. 5 (1945) (recommending to Congress that “patentability be determined objectively by the nature of the contribution to the advancement of the art”).

¹⁹⁰ Brief for the United States as Amicus Curiae Supporting Petitioner, *KSR Int’l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 9-10 (emphasis added).

¹⁹¹ The 1790 Patent Act originally vested discretionary authority in the Patent Board to grant patents when it deemed them to be “sufficiently useful and important.” Patent Act of April 10, 1790, ch. 7, § 1, 1 Stat. 109, 110 (1790) (repealed 1793). The 1793 Patent Act eliminated this authority when changing to a registration system. In *Grant v. Raymond*, 31 U.S. 218 (1832), the Supreme Court held that the Secretary of State had the power to grant a patent for the unexpired term of a surrendered patent, in the process stating that he acts as “a ministerial officer [and i]f the prerequisites of the law be complied with, he can exercise no judgment on the question whether the patent shall be issued.” *Id.* at 241. Nevertheless, Congress in the 1836 Act restored the discretionary authority to the Commissioner to “deem” inventions “sufficiently useful and important” to issue the patent, when reinstating an examination system. Patent Act of July 4, 1836, ch. 357, § 7, 5 Stat. 117, 121 (1836) (repealed 1870 with relevant language preserved in new Section 31). In doing so, Congress noted the failure of the Secretary to refuse patents for inventions that lacked novelty or utility but met formal application requirements. See S. REP. NO. 24-338, at 2 (1st Sess. 1836). Following the 1836 Act, Congress failed to appropriate sufficient funds to hire examiners, which resulted in a backlog of applications; following a political campaign against the rigid examination standards that were being applied, scientists were replaced with political appointees who applied less stringent examination standards, fueling an explosion of patenting beginning in 1850. See Robert C. Post, “*Liberalizers*” versus “*Scientific Men*” in the Antebellum Patent Office, 17 TECH. AND CULTURE 24, 33-52 (1976); Steven Lubar, *The Transformation of Antebellum Patent Law*, 32 TECH. AND

The brief thus suggested that the Court clarify the legal standard to better accomplish the functional purpose articulated by the Court in *Graham* (“to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent”¹⁹²), by holding that “the obviousness inquiry is designed to prohibit patents on inventions that could have been made by those skilled in the art within a reasonable period of time (following the time that the invention at issue was actually made) and within reasonable budgetary constraints.”¹⁹³

B. *Effects of KSR on Proving Obviousness*

Whatever the legal or factual status of the obviousness inquiry, *KSR* has enormous importance as it has clearly raised the bar for determining when inventions are non-obvious and thus patentable. Consider, for example, a decision that closely antedated the Supreme Court’s *KSR* decision, *Pfizer, Inc. v. Apotex, Inc.*¹⁹⁴ In *Pfizer*, the Federal Circuit reversed a judgment of infringement and an injunction delaying regulatory approval and prohibiting making, using, selling or importing of a generic manufacturer’s hypertension drug amlodipine besylate (sold in the United States by the patent holder under the trade name Norvasc®), because the infringer had proved obviousness below by clear and convincing evidence.¹⁹⁵ The trial court had rejected the showing of obviousness, based on another patent and other prior art (that the Patent Office most likely had considered)¹⁹⁶ that arguably taught away from the besylate salt and failed to suggest the unexpectedly superior function of that salt, and on secondary evidence of the costs of switching research from a maleate salt to a

CULTURE 932, 941-45 (1991). In this context, the Court decided *Hotchkiss* and adopted the requirement for inventions to reflect more than mechanical skill. Nothing in *Hotchkiss* suggests that the Court actually relied on Section 7 of the 1836 Act to adopt the obviousness standard, and thus that the judiciary substituted its policy judgments for those of the administration. Nevertheless, Congress ultimately eliminated the “sufficiently useful and important” discretionary authority of the Patent Office only in 1952, because it was “unnecessary” in light of the simultaneous codification of the obviousness standard. Giles S. Rich, *The Principles of Patentability*, 42 J. PAT. OFF. SOC’Y 75, 80-81 (1960) (quoting 35 U.S.C.A. § 131 revision note (1954)).

¹⁹² *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 11 (1966).

¹⁹³ Brief of Economists and Legal Historians as Amici Curiae in Support of Petitioner, *KSR Int’l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 17. If obviousness is a discretionary policy decision, moreover, concerns over hindsight bias may be overstated because such decisions may properly be retrospective in outlook. Cf. Mandel, *supra* note 29, at 1411 (“Ex post knowledge of invention deeply affected [study] participants’ conclusions regarding whether an invention was non-obvious ex ante.”).

¹⁹⁴ *Pfizer, Inc. v. Apotex, Inc.* 488 F.3d 1377, 1348 (Fed. Cir. 2007).

¹⁹⁵ *Id.* at 1352-53.

¹⁹⁶ *Id.* at 1356, 1357 n.4 (interpreting the District Court’s oral findings that the reference was cited in the patent and must have been considered).

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besylate salt.¹⁹⁷ The Federal Circuit first rejected the trial court's holding that the defendant could establish a prima facie case of obviousness based on an interim rejection of the claim for obviousness by the Patent Office. The presumption of validity places the burden on the challenger to prove facts demonstrating obviousness, does not require the patent holder to rebut the challenger's evidence with secondary evidence, and retains the burden of persuasion on the defendant (after any rebuttal evidence offered in response to the prima facie case).¹⁹⁸ The Federal Circuit also noted that there were not real disputes about the facts—including the level of ordinary skill in the art, that the relevant references were in the prior art, and that the claims of the prior art patent encompassed (but did not specifically recite) the amlodipine besylate salt – but only about the motivation to combine references to substitute the besylate salt and the expectation of successful results in doing so.¹⁹⁹

The Federal Circuit found sufficiently clear and convincing evidence of motivation to combine from the nature of the problem and from expert evidence suggesting such motivation, because: (1) maleate, an acyclic anion with a double bond, did not work, and a skilled artisan would have been motivated to look for a different, cyclic anion without a double bond such as besylate; (2) pharmaceutical chemists would have been motivated to use anions such as besylate that had previously been used in pharmaceuticals; and (3) additional prior art references described useful pharmaceutical properties of using besylate anions, such as stability and solubility.²⁰⁰ The trial court erred by finding these motivating factors insufficient because they were not specifically addressed to the problem the patent holder was seeking to solve—pharmaceutical compounds for hypertension or angina (particularly given that the anion has no direct therapeutic effect).²⁰¹ Given the evidence, the Federal Circuit held that a reasonable factfinder could only conclude that clear and convincing evidence demonstrated a motivation to combine.²⁰²

Similarly, the Federal Circuit found error in the trial court's holding that the facts that the formation of a salt and the determination of its properties are unpredictable precluded a sufficient expectation of success that the specific combination would work for its intended purpose. Expert testimony indicated

¹⁹⁷ *Id.* at 1356-58.

¹⁹⁸ *Id.* at 1359.

¹⁹⁹ *Id.* at 1360-61.

²⁰⁰ *See id.* at 1361-63.

²⁰¹ *See id.* at 1363.

²⁰² *See id.* at 1364.

that various salts, including besylate, would form improved compounds over maleate, and suggestions in the prior art patent and prior statements of the patent holder suggested the interchangeability of salts.²⁰³ Finally, the Federal Circuit rejected the patent holder's argument that the combination was only "obvious to try," because of the limited number of parameters to test, the patent holder's prior statements, and publications suggesting the besylate salt for other pharmaceuticals.²⁰⁴ Accordingly the Federal Circuit found the case "analogous to the optimization of a range or other variable within the claims that flows from the 'normal desire of scientists or artisans to improve upon what is already generally known.'"²⁰⁵

In regard to secondary considerations, the Federal Circuit first found the trial court's findings of fact clearly erroneous, because there was no evidence that the patent holder would have abandoned a search for useful amlodipine salts or stood to lose time and money by switching research strategies.²⁰⁶ It then rejected arguments regarding unexpected success for various properties, either because: (1) the evidence did not support some factual findings of unexpectedly improved function; (2) the evidence did not compare the closest prior art compounds; and (3) given evidence of unpredictable ranges of behavior of various compounds, the improved performance of the compound at issue could not be unexpected.²⁰⁷ Finally, it held that even if the functions of the combination were unexpectedly superior, that fact was insufficient as a matter of law (on de novo review) to alter the conclusion of obviousness based on inferences from the other evidence.²⁰⁸

Following *KSR*, the Federal Circuit refused to reconsider the panel decision as an en banc court. One dissent to this decision challenged the panel's holding that the combination was not merely obvious to try (questioning that skill in the art and prior art references would have directed the search to besylate salts), and argued that the panel erred by failing to give weight to the secondary evidence of improved manufacturing (rather than therapeutic) properties.²⁰⁹ Another dissent focused on confusion the panel decision would cause regarding rebuttal of a prima facie

²⁰³ See *id.* at 1365-66.

²⁰⁴ *Id.* at 1366.

²⁰⁵ *Id.* at 1368 (quoting *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)).

²⁰⁶ See *id.* at 1369.

²⁰⁷ See *id.* at 1369-71.

²⁰⁸ *Id.* at 1372.

²⁰⁹ See *Pfizer, Inc. v. Apotex, Inc.* 488 F.3d 1377, 1379-81 (Fed. Cir. 2007) (Newman, J., dissenting from denial of rehearing en banc).

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case of chemical obviousness, by failing to defer to the trial court's not clearly erroneous factfinding, by substituting its own factual judgment regarding the expectation of success, by placing greater value on therapeutic than other properties in determining obviousness over the prior art, and by treating the experiments as mere verification rather than as discovery of the relevant properties.²¹⁰ A third dissent made similar points, also noting that most pharmaceutical invention involves routine screening of both active compounds and new formulations and salts.²¹¹ All emphasized the "exceptional importance" of the legal issues to the pharmaceutical and chemical industries and to their investments, and thus to society.²¹²

How does *KSR* affect these arguments, and thus affect arguments that will be made in the wide range of similar cases that will arise in the United States (and, if followed, worldwide)²¹³? The dissenting concerns in *Pfizer* regarding the "obvious to try" analysis are unlikely to find favor, given the Supreme Court's express holding in *KSR* that obviousness may be proved "merely by showing that the combination of elements was obvious to try," at least where there are limited options and a good reason to pursue the known options.²¹⁴ Similarly, the dissenting concerns that secondary considerations were unfairly discounted by the panel are also undermined by *KSR*'s dismissal of the argument that secondary consideration evidence dictated a legal conclusion of obviousness or at least precluded summary judgment, given *KSR*'s reiteration that obviousness is a legal conclusion and not a factual question.²¹⁵

²¹⁰ See *id.* at 1381-82 (Lourie, J., dissenting) (citing *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)). See generally Harold C. Wegner, Chemical Obviousness in a State of Flux (June 22, 2007) (unpublished draft, on file with author).

²¹¹ See *Pfizer*, 488 F.3d at 1383-84 (Rader, J., dissenting).

²¹² *Id.* at 1381-82 (Lourie, J., dissenting). See *id.* at 1379-80 (Newman, J., dissenting); *id.* at 1384 (Rader, J., dissenting).

²¹³ See, e.g., *Angiotech Pharms. & ANR v. Conor Medsystems, Inc.*, [2007] EWCA (Civ) 5, [31] leave to appeal to the House of Lords granted, Minutes of June 7, 2007 (rejecting appeal from conclusion of obviousness because "[j]ust to name one 'other' [specific compound having the identified property but not expressly enumerated] which, on the information given in the patent, is no more and no less likely to be found to work in practice is not to make an invention").

²¹⁴ See *KSR Int'l, Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1742 (2007).

²¹⁵ See *id.* at 1745; *supra* notes 28, 180-83 and accompanying text. See also *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976) ("The ultimate test of patent validity is one of law . . . but resolution of the obviousness issue necessarily entails several basic factual inquiries."). For another example of the significance of the changed focus from fact to law, compare *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1321

In determining whether a combination of old elements is non-obvious, the court must assess whether, *in fact*, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference.

Perhaps the greatest effect of *KSR* will be to shift the burdens of production and persuasion to the patent holder (and possibly limit the relevant evidence for rebuttal) once a prima facie case is made by the party challenging validity that the invention is merely a combination of prior art elements performing their expected (even if significantly improved) functions.²¹⁶ The panel decision in *Pfizer* took pains to reiterate the high burden of persuasion throughout its decision,²¹⁷ and would likely have reached its result much more easily if the ultimate burden of persuasion had been shifted as required by *KSR*. Using the *KSR* approach, the *Pfizer* decision is virtually a foregone conclusion, since it was undisputed that the properties at most were unexpectedly better than the prior art; rather, they were not wholly new functions but those typical of and desirable for pharmaceutical products.²¹⁸ The dissenting concerns that the panel had improperly emphasized certain properties that would have become moot. But even if they had not become moot, *KSR* suggests that the policy discretion remaining in the legal conclusion of obviousness would have permitted the judiciary to privilege therapeutic properties over other properties when determining whether the inventive contribution warrants the grant of a patent.²¹⁹

Similarly, as the *Pfizer* panel concluded, the demonstration through scientific research of hoped-for properties (where there is a reasonable expectation of success) will not be enough to make an invention patentable. Relying on both *KSR* and *Pfizer* as authority, the Federal Circuit in a more recent (split) decision reversed a jury verdict of non-obviousness in a case addressing a transplantation invention that used hematopoietic stem cells. The majority opinion concluded that “the inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention.”²²⁰

(emphasis added) (citing *In re Fulton*, 391 F.3d 1195, 1200-02 (Fed. Cir. 2004)) with *KSR Int'l. Co.*, 127 S. Ct. at 1744

The consequent *legal* question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both *KSR* and Engelgau put it would have been obvious to a person of ordinary skill.

(emphasis added).

²¹⁶ See *KSR Int'l. Co.*, 127 S. Ct. at 1739-41; *supra* notes 152-72 and accompanying text.

²¹⁷ The panel decision referred to the “clear and convincing” standard no less than nineteen times. See *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007).

²¹⁸ See *supra* note 165 and accompanying text.

²¹⁹ See *supra* notes 183-90 and accompanying text.

²²⁰ *Pharmastem Therapeutics, Inc. v. Viacell*, 491 F.3d 1342, 1363-64 (Fed. Cir. 2007) (“[A]dvances that would occur in the ordinary course without real innovation retards

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KSR truly will have important implications not just for pharmaceutical patents but also for information technologies, business methods, and other patents.²²¹ These implications will emanate far beyond United States borders, including but not limited to India and other countries seeking to limit follow-on pharmaceutical patents and focusing on their therapeutic (as opposed to other) improvements.²²² Of course, other countries

progress" (quoting *KSR Int'l Co.*, 127 S. Ct. at 1732); *id.* at 1364 (noting that verification of new properties through testing does not satisfy the test for patentability, as "the expectation of success need only be reasonable, not absolute" (citing *Pfizer, Inc.*, 480 F.3d at 1367-69)). See *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1300-03 (Fed. Cir. 2007) (noting that *KSR* supports the obviousness of isolated, concentrated, or purified ingredients and of structurally similar compounds that do not have unexpected functions, even without a specific teaching or suggestion) (citing, *inter alia*, *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc), *In re Papesich*, 315 F.2d 381 (C.C.P.A. 1963), and *In re Adamson*, 275 F.2d 952, 954-55 (C.C.P.A. 1960)). Cf. *McNeil-PPC, Inc. v. Perrigo Co.*, 2007 WL 1624764, at *8-9 (S.D.N.Y. June 5, 2007) (rejecting arguments that costs of coating processes would have dissuaded skilled practitioners from combining references and noting that "*KSR* casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness"). *But cf.* *Takeda Chem. Indus. Ltd. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (affirming district court holding of nonobviousness and the absence of a prima facie case of a reason to combine structurally similar compounds in the absence of evidence showing that the "prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention") (quoting *In re Deuel*, 51 F.3d 1552, 1558 (Fed.Cir.1995), and citing, *inter alia*, *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992)); *id.* at 1356-57 (holding that this standard is consistent with *KSR*); *id.* at 1364 (Dyk, J., concurring) (concurring as to a species claim, based on clearly demonstrated unexpected results, suggesting that two broader claims were obvious given that they covered a compound within the scope of a prior art patent genus claim that was acknowledged to have no unexpected results, but noting that the argument regarding overly broad claims had been waived).

²²¹ See, e.g., *Leapfrog Enterp., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) ("Accommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years."). In a trio of precedential opinions, the Patent Office signaled its view that *KSR* had dramatically changed the law of obviousness in regard to different industries, adopting *KSR*'s functional approach. See *Ex parte Kubin*, Appeal 2007-0819, at 7-10 (May 31, 2007) (biotechnological inventions); *Ex parte Catan*, Appeal 2007-0820, at 9-21 (July 3, 2007) (electronic inventions); *Ex parte Smith*, Appeal 2007-1925, at 12-21 (June 25, 2007) (mechanical inventions). The United States Patent Office has issued guidelines for examiners in light of *KSR* that will dramatically affect examination practice, by permitting consideration of predictability of the accomplished results without specific reference to prior art suggestions of the particular combination or to its ability to accomplish such results. See U.S. Patent and Trademark Office, *Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57526, 57529-34 (2007) (listing and discussing seven types of arguments for obviousness rejections, which focus on the predictability of the results achieved or a reasonable expectation of success in achieving desired results).

²²² For example, consider The India Patents Act, No. 39 of 1970 § 151, as amended by The Patents (Amendment) Act of 2005, No. 15, Acts of Parliament, 2005, Ch. II §3(d): the mere discovery of a new form of a known substance which does not result in increased efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.

See also A.J. Rajasekaran, *Indian Patent Law – Needed Proper Definition of “Inventive Step,”* THE HINDU BUSINESS LINE (Apr. 13, 2007), available at

will remain free to adopt different substantive policies regarding the level of inventive contribution that they wish to impose to warrant the grant of a patent.²²³

In summary, the Supreme Court in *KSR* has suggested that not all patented inventions are to be treated equally, and that the presumption of validity may be superseded by shifting burdens of production and persuasion when evidence regarding the nature of the inventive contribution at issue is introduced. Whatever the legal conclusion of obviousness means, a prima facie case of obviousness may be created for some claimed or patented inventions merely by showing that all of its elements were in the prior art (and perhaps also requiring some evidence from the challenger that it exhibits no new and unexpected functions). If this is the applicable legal standard, it should also apply to the Patent Office and examiners' demonstrations of the obviousness of claimed inventions. Finally, although the Court expressly did not resolve the issue, it confronted the question of whether the presumption of validity should vary depending on the evidence that was reviewed in the Patent Office.

The Patent Office in some cases may be able to perform the complete analysis contemplated by the Supreme Court in *KSR*, considering and evaluating the full range of evidence that may create a prima facie case and thus may weigh the inferences raised therein. But in other cases it may not be possible to do so, given that relevant evidence (such as testimony and secondary considerations) may not be permissible or may arise only after the grant of the patent.²²⁴ As noted by an Indian commentator:

[T]he question of obviousness or inventiveness has to be judged from the point of view of a man skilled in the art which requires evidence of experts. This question can be resolved only in opposition or revocation proceedings. But many patents are granted unopposed. The [Indian Patents] Act therefore does not guarantee the validity of the patent which can finally be

<http://www.blonnet.com/2007/04/13/stories/2007041300930800.htm> (discussing the high-profile challenge brought by Novartis Pharmaceuticals in the Madras High Court to Section 3(d) following denial of a patent for the beta-crystalline form of imatinib mesylate, based on alleged incompatibility with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1125 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

²²³ See, e.g., Indra Bhattacharya & Robert Cooper, *Australia High Court Locks in the Law on Obviousness*, 21 WORLD INTEL. PROP. REP. NO. 7 (July 2007) (noting that the Australian High Court recently "reinforced the long-standing principle that even a small advance may be inventive so long as it offers some material benefit to the existing state of the art" (citing *Lockwood Security Prods. Pty. Ltd. v. Doric Prods. Pty. Ltd.*, (2007) 235 A.L.R. 202 (Austl.)).

²²⁴ See, e.g., Barton, *supra* note 143, at 484.

decided only by the High Court in infringement or revocation proceedings.²²⁵

Government administrative officials— even highly trained patent examiners— simply may not be adequate substitutes for experts in the relevant technology. Thus, any heightened presumption of validity may be inappropriate in regard to grants of patents.²²⁶ Where the Patent Office has not evaluated or weighed all of the relevant evidence, significant questions remain as to whether a presumption of validity should apply at all.

V. PATENT LAW POLICIES, EXAMINATION, AND A WEAK PRESUMPTION OF VALIDITY

When Congress codified the statutory presumption of validity in 1952, it did so in response to calls from the business community concerned with uncertainty regarding the validity of patents resulting from the “ever-widening gulf” between the grant of patents in the Patent Office and their later invalidation (principally on obviousness grounds) in the courts.²²⁷ These concerns were and remain important. The smaller the gap between the grant of patents and their actual validity, the better. But these concerns do not affect the choice of where the standard of invention should be set, do not ultimately determine the strength of the evidentiary burdens that the presumption should impose, may require excessive expenditures, and do not outweigh competing concerns to avoid over-reliance on the granting processes of patent offices (particularly when their expertise has not been applied to the facts and policy judgments at issue).

There is no necessary reason why the Patent Office could not apply the same substantive standards to validity determinations as the courts, even if it may not be able to apply all of the same evidence. But current legal doctrines assure that different standards apply—particularly by providing different

²²⁵ NARAYANAN, *supra* note 5, ¶ 1-19.

²²⁶ Cf. Charles E. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 FED. CIR. B.J. 143, 143-44 (2000) (arguing that only the presumption of administrative correctness, and not 35 U.S.C. § 282, provides a basis for a heightened evidentiary standard and only for validity issues that are within examiners’ areas of expertise, excluding issues that examiners are not tasked to consider).

²²⁷ Riesenfeld, *supra* note 2, at 308 (noting recommendations of the National Planning Commission to make the obviousness inquiry more objective, for district courts to obtain advisory opinions on validity from the Patent Office, and for “greater observance of the presumption of validity of patents to be another road to patent security” (citing U.S. NAT’L PATENT PLANNING COMM’N, THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 239, 78th CONG., 1st Sess. 5, 6 (1945), and quoting U.S. NAT’L PATENT PLANNING COMM’N, THIRD REPORT ON THE AMERICAN PATENT SYSTEM, H.R. DOC. NO. 283, 79TH CONG., 1st Sess. 4 (1945))).

interpretations of the invention as claimed²²⁸ — and thus the gulf between the grant and validity filled by the presumption of validity is all the more inevitable. Having already discussed the substantive standard for obviousness, I discuss below policies and practical concerns regarding the administrative patent granting process that suggest the application of at most a weak presumption of validity.

A. *Policies Favoring Challenges to Validity and Invalidation of Invalid Patents*

Since at least *Lear v. Atkins*,²²⁹ patent law has affirmatively encouraged litigation challenges to the validity of granted patents. The United States Supreme Court's rationale is worth quoting at length:

Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued.

.....

It seems to us that such a [contractual] requirement [to continue paying royalties until a validity challenge is concluded] would be inconsistent with the aims of federal

²²⁸ The Patent Office supplies the "broadest reasonable construction" to the claims. *See Exxon Res. & Eng. Co. v. United States*, 265 F.3d 1371,1380 (Fed. Cir. 2001) (permitting applicants to clarify their claims so as to avoid invalidity). *Cf. id.* at 1375 (allowing for claims to be invalidated for indefiniteness if they are "insolubly ambiguous, and no narrowing construction can properly be adopted"). In theory, this approach to claim construction should best preclude invalid claims from being issued. In contrast, courts determine the meaning of claims following the methodology articulated by the Federal Circuit in *Phillips v. AWH Corp.*, under which courts may, if they find that interpretive uncertainties with granted patents remain after reviewing all the evidence, adopt narrowing constructions so as to preserve claim validity. 415 F.3d 1303, 1312-24, 1327-28 (Fed. Cir. 2005) (en banc) (adopting an approach starting with ordinary meaning of claim terms as understood by a person having ordinary skill in the art, and then looking to other claims, the specification, the prosecution history, and— if ambiguities remain— to extrinsic evidence— including dictionaries— of claim term meaning).

²²⁹ *Lear v. Atkins*, 395 U.S. 653 (1969).

patent policy. Enforcing this contractual provision would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning If a licensee has reason to believe that he will replace a patented idea with a new one in the near future, he will have little incentive to initiate lengthy court proceedings, unless he is freed from liability at least from the time he refuses to pay the contractual royalties. Lastly, enforcing this contractual provision would undermine the strong federal policy favoring the full and free use of ideas in the public domain.²³⁰

Lear thus identifies a strong public policy in invalidating invalid patents, which expressly overrides any contractual fairness interests that a patent holder would assert in seeking to bar challenges to the patent's validity.²³¹ *Lear* also overrode – on the same public policy grounds – the express language of the license that required payment of royalties until the validity of the patent had been conclusively adjudicated.²³² The policy favoring challenges to validity would seem to be even stronger where such contractual fairness concerns were not applicable.²³³

More recently, the Supreme Court held in *Medimmune, Inc. v. Genetech, Inc.*²³⁴ that licensees need not materially breach their contracts in order to have constitutional standing to sue²³⁵ (and thus Declaratory Judgment Act jurisdiction²³⁶) to raise contractual or patent validity challenges.²³⁷ Although it expressly refused to address the scope of *Lear*, or to determine whether a non-repudiating licensee is relieved during a challenge to patent validity of any express contractual obligation to pay royalties until the patent is determined invalid,²³⁸ the Court nevertheless called into question a long line of lower court cases limiting the

²³⁰ *Id.* at 670-74.

²³¹ *Lear* extended its holding to contracts negotiated before the patent issues, based on concerns that patent applicants would negotiate licenses precluding validity challenges by those having the strongest incentives “to show that a patent is worthless.” *Id.* at 672. *See id.* at 672-73 (“While the equities supporting Adkins’ position are somewhat more appealing than those supporting the typical licensor, we cannot say that there is enough of a difference to justify such a substantial impairment of overriding federal policy.”).

²³² *See id.* at 673-74 (overriding the contractual obligation “at least from the time [the licensee] refuses to pay the contractual royalties”).

²³³ *Cf. Yamashita v. Wilbur-Ellis Co.*, 2006 WL 1320470, at *8 (N.D.Cal. May 15, 2006) (noting, in the context of refusing a preliminary injunction, that the public interest “seems better served by having access to competitive products, being able to determine which products better suit their needs, and receiving reduced prices due to the availability of competing products”).

²³⁴ *Medimmune, Inc. v. Genetech, Inc.*, 127 S. Ct. 764 (2007).

²³⁵ *See* U.S. CONST. art. III (authorizing judicial power over “cases” and “controversies”).

²³⁶ *See* 28 U.S.C. § 2201(a) (2007) (providing federal court jurisdiction over an “actual controversy”).

²³⁷ *See Medimmune*, 127 S. Ct. at 770-77.

²³⁸ *See id.* at 769-70, 776.

application of *Lear* based on the idea that an assignor²³⁹ or licensee²⁴⁰ who reaps contractual benefits from a patent should be required to sow contractual compliance therewith.²⁴¹ The Supreme Court in *Medimmune* focused on the actual language of the contract and the nature of the contractual licensing bargain (which may not in fact provide the patent holder with an insurance policy against validity challenges).

To begin with, it is not clear where the prohibition against challenging the validity of the patents is to be found. It can hardly be implied from the mere promise to pay royalties on patents “which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken,” Promising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity. . . . Petitioner is not repudiating or impugning the contract while continuing to reap its benefits. Rather, it is asserting that the contract, properly interpreted, does not prevent it from challenging the patents, and does not require the payment of royalties because the patents do not cover its products and are invalid.²⁴²

Of course, *Lear* itself had implicitly rejected such reaping and sowing reasoning, and refused to make its decision applicable only prospectively so as to protect asserted reliance interests “[g]iven

²³⁹ See, e.g., *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224-25 (Fed. Cir. 1988)

To allow the assignor to make that representation [of the worth of the patent] at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee. . . . [D]espite the public policy encouraging people to challenge potentially invalid patents, there are still circumstances in which the equities of the contractual relationships between the parties should deprive one party . . . of the right to bring that challenge.

²⁴⁰ See, e.g., *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997)

[A]s in *Diamond Scientific*, Shell executed a contractual agreement which produced significant benefits for the corporation and attested to the worth of the patent. Under the agreement . . . Shell had the benefits of producing polypropylene insulated from unlicensed competition, insulated from investigations of infringement, and even insulated from royalties To these benefits, Shell now seeks to add the benefit of abrogating its agreement and avoiding its breach of the contract. . . . [T]his court must prevent the injustice of allowing Shell to exploit the protection of the contract and patent rights and then later to abandon conveniently its obligations under those same rights.

²⁴¹ See, e.g., Eric Belt & Keith Toms, *The Price of Admission: Licensee Challenges To Patents After Medimmune v. Genentech*, 51 BOSTON BAR J. 10, 10 (May/June 2007) (“The opinion upset a balance that had existed between patent owners and their licensees and . . . will not return until key issues of patent policy are resolved.”).

²⁴² *Medimmune*, 127 S. Ct. at 776. The Court also noted that any such contractual provision or common-law rule that might expressly preclude validity challenges would not raise a jurisdictional but only a merits question.

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the extent to which the estoppel principle had been eroded by [its] prior decisions.”²⁴³

The lower court cases limiting *Lear* also established that the payment of patent licensing royalties was required at least until notice was provided of the licensee’s belief in invalidity of the patent.²⁴⁴ These cases therefore precluded the recoupment of royalties that had been paid under the license once the patent was held invalid, even though the contractual licensing language may have contemplated royalty payments only for infringement of valid claims.²⁴⁵ Although the language from *Medimmune* quoted above might suggest the enforceability of express license terms that prohibit recoupment of royalties paid prior to finding a patent invalid, it does not actually determine that such contractual provisions are permissible in light of *Lear*.²⁴⁶ Express contractual provisions prohibiting validity challenges are more strongly suspect. Both kinds of contractual provisions would reduce incentives for licensees to challenge validity, and thus would conflict with the public policy of encouraging challenges by the parties having the greatest interest in doing so. *Lear* expressly refused to enforce contractual obligations to pay before invalidity had been determined (at least from the time that validity was challenged), without regard to whether the contractual terms required payment only in regard to infringement of valid claims.²⁴⁷

²⁴³ *Lear*, 395 U.S. at 674 n.19. *See id.* at 664-68 (discussing historic judicial treatment of the estoppel rule, in particular an early assignor-estoppel case holding “that it was improper both to “sell and keep the same thing” (quoting *Faulks v. Kamp*, 3 F. 898, 902 (2d Cir. 1880))).

²⁴⁴ *See, e.g.*, *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381-82 (Fed. Cir. 2004) (licensee is liable for unpaid royalties accrued under a license before invalidation of the patent, payment of royalties under protest precludes a declaratory judgment action to contest validity, and allowing such actions would defeat contractual covenants and discourage patent licensing) (citing *Studiengesellschaft Kohle, M.B.H.*, 112 F.3d at 1568); *see also id.* at 1568 (because failing to notify of contractual breach also may delay validity challenges, licensee is not relieved of its obligation to pay contractual royalties for infringing conduct until it actually ceases payment of royalties and notifies the licensor that the reason for doing so is a belief of invalidity of the patent).

²⁴⁵ *See, e.g.*, *Pony Pal, LLC v. Claire’s Boutiques, Inc.*, 2006 WL 846354, at *2 (S.D.N.Y. Mar.31, 2006) (construing a license imposing royalties on products “covered by . . . valid claims” as requiring payment until a patent is determined invalid, or at least until challenged as invalid (citing *Studiengesellschaft Kohle, M.B.H.*, 112 F.3d at 1568, and *Gen-Probe, Inc.*, 359 F.3d at 1378)). *Cf. Studiengesellschaft Kohle, M.B.H.*, 112 F.3d at 1567 (“Nothing in this license made payment of royalties contingent upon the validity [of the patent].”); *Gen-Probe, Inc.*, 359 F.3d at 1378 (discussing licensing terms imposing royalties for licensed methods and products, defined by reference to granted claims that have not been ruled invalid and from which all appeals have run).

²⁴⁶ Of course, where the license is not as explicit, *Medimmune* may suggest the alternate result as the contractual bargain may not itself contemplate payment if the patent is later held invalid. An agreement to pay royalties on claims that are valid and infringed does not necessarily entail an agreement to pay royalties on claims subsequently determined to be invalid or not-infringed, or to preclude recoupment of royalties erroneously paid once they have been determined to be invalid or not infringed.

²⁴⁷ *See Lear*, 395 U.S. at 672-73.

But other policies than providing incentives for challenges to validity are involved (including honoring express contractual bargains, even if made under the coercion created by patent law threats of treble damages²⁴⁸), and it is not clear that the Supreme Court would adopt the same public policies now that it did almost a half-century ago.

In refusing to extend *Lear*, however, lower courts have prioritized public policies of minimizing litigation and assuring the finality of judicial processes and of settlements.²⁴⁹ Although these cases articulate good reasons for emphasizing the finality of settlements and judgments, there is no necessary theoretical reason why finality should be considered the more important social policy. Other litigation-related policies also strongly favor allowing challenges to patent validity, notwithstanding the grant of the patent and the patent holder's interests in enforcing it. As the Supreme Court has held in *Cardinal Chemical Co. v. Morton Int'l, Inc.*,²⁵⁰ patent validity and infringement are separate issues, and a challenger not only may seek a declaratory judgment of invalidity independent of the question of infringement, but also "of the two questions, validity has the greater public importance."²⁵¹ For this reason, a finding of non-infringement does not render a claim of invalidity moot, and thus courts *must* adjudicate and resolve validity claims when properly filed.²⁵² Nor is an invalidity defense waived by failing to advance it in the context of preliminary

²⁴⁸ See *Medimmune, Inc. v. Genetech, Inc.*, 127 S. Ct. 764 772-75 (2007) (noting that constitutional standing and declaratory judgment jurisdiction are present even when private conduct eliminates the risk of a lawsuit, so long as that conduct was coerced by threatened enforcement action of a government or of a private party). See also *Seymour v. McCormick*, 57 U.S. 480, 488-89 (1853) (holding that enhanced patent damages are punitive in nature and should be imposed only on proof that the defendant "deliberately and wantonly infringed what it knew to be a valid patent").

²⁴⁹ See, e.g., *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476-77 (Fed. Cir. 1991) (finding a strong public interest in favor of early resolution of litigation by consent judgments, and suggesting that such judgments have *res judicata* effect as to the litigated matter and are enforceable when they contain express provisions precluding further validity litigation); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1367-70 (Fed. Cir. 2001) (finding that settlement agreement containing express preclusion of subsequent validity challenges, followed by dismissal with prejudice, was enforceable as a contractual estoppel even though it did not create a collateral estoppel, distinguishing *Lear* as it did not involve a settlement and as the contract in *Lear* did not contain an express provision precluding challenges to validity, and noting that "settlement of litigation is more strongly favored by the law") (citing *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 349-51 (Fed. Cir. 1988)).

²⁵⁰ *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993).

²⁵¹ *Id.* at 100. See *id.* at 96.

²⁵² See *id.* at 102-03; *Altwater v. Freeman*, 319 U.S. 359, 365-66 (1943). However, declaratory jurisdiction may be rendered moot by dismissing infringement claims and covenanting not to sue before an infringement determination. See *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344-49, (Fed. Cir. 2007). Cf. *id.* at 1350-4 (Dyk, J., dissenting) (arguing that *Cardinal Chemical* shifts the burden of establishing mootness to the party challenging validity, to prove "there is no reasonable likelihood that the controversy over the patent's validity and enforceability will recur").

litigation matters addressing infringement questions.²⁵³

This returns us to the earlier theme, discussed in regard to preliminary relief, that challenges to validity should not be precluded (regardless of the social costs of administering them) absent very strong policy grounds. Even if public policies of minimizing litigation and assuring finality are considered grounds sufficient to supersede the public interest in promoting challenges to patent validity, the terms of a settlement agreement or judgment may be construed strictly to avoid preclusion of subsequent validity challenges unless expressly stated.²⁵⁴ Further, there may be reasons to distinguish between settlement agreements, which are private contracts, and consent judgments, which are public decisions with the force of law. The only (relatively) clear line to be drawn is *res judicata*.²⁵⁵

Finally, some lower courts in declining to extend *Lear* have looked to the presumption of patent validity to construe ambiguous licensing language to avoid having royalty payments conditioned on litigation to prove validity,²⁵⁶ but relying on the presumption of validity in this context puts the cart before the horse. The *Lear* and *Cardinal Chemical* policies favoring challenges

²⁵³ See, e.g., *Pandrol USA, LP v. Airboss Prods. Rv., Inc.*, 320 F.3d 1354, 1364-66 (Fed. Cir. 2003) (a party does not waive invalidity defense and counterclaim by failing to raise it in opposition to cross motions for summary judgment of infringement); *Scosche Indus. v. Visor Gear, Inc.*, 121 F.3d 675, 679 (Fed. Cir. 1997) (a party does not waive invalidity defense by making an offer of judgment under Fed. R. Civ. P. 68, whereby it admits infringement).

²⁵⁴ See, e.g., *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 472, 481-82 (Fed. Cir. 1991) (holding that strict construction fosters the policies of both finality and of *Lear*, and that a consent judgment that merely stated the asserted patents were “valid and enforceable in all respects” did not surrender invalidity defense as to future accused products that were not essentially the same); *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002) (refusing to bar future suits with new products when consent judgment decree merely recited that the patent “is a valid patent,” and finding that the newly challenged products were not essentially the same). Cf. *Diversey Lever, Inc. v. Ecolab, Inc.*, 191 F.3d 1350, 1352 (Fed.Cir.1999) (finding that a consent judgment precluded subsequent validity challenges involving new accused products given that it “manifest[ed] an intent to be bound” by language prohibiting aid in “any action contesting the validity” of the patents).

²⁵⁵ See *Foster*, 947 F.2d at 475-76 (discussing *res judicata* principles and noting earlier cases distinguishing consent judgments from imposed judgments, based “on the theory that *Lear* precludes parties from removing possible challenges to validity merely by their agreement”). Cf. *Flex-Foot*, 238 F.3d at 1369 (noting that settlement agreement of a challenge to validity that provided the opportunity for discovery and was followed by dismissal with prejudice barred subsequent challenges “whether or not the settlement order and dismissal actually adjudicated patent validity to create *res judicata*”). Thanks to Mark Lemley for having suggested this point.

²⁵⁶ See, e.g., *Pony Pal, LLC v. Claire’s Boutiques, Inc.*, 2006 WL 846354, at *2 (S.D.N.Y. Mar.31, 2006)

[A]s federal patent law, against which background the parties entered into the Agreement, provides a presumption of patent validity . . . it seems counterintuitive and needlessly litigious to construe the Agreement to require Plaintiff to prove validity of the claims of the Patent before Defendant would have any obligation to pay royalties under the Agreement.

to validity cannot be overcome by the presumption of validity or by the strength of the inference regarding whether the granted patent is valid. Rather, these policies are *premised* on the presumption of validity resulting from the grant of patents, which creates the need to assess the truth of validity to protect the public domain. After all, it was precisely such policies regarding *res judicata* and stability of prior litigated determinations of priority in creating patented inventions that led courts to adopt a presumption of validity in the first place.²⁵⁷

The presumption of validity thus can only affect how the burdens of production and persuasion should apply in challenges to patent validity, not whether such challenges should occur. So long as challenges are not precluded, and absent strong policy grounds such as stability of litigation, the force of these policies counsels against any heightened burdens of proof. Even then, analysis of competing policies and granting conditions suggests that a weak presumption or none at all may be more appropriate.

B. *Social Costs of Assuring High Levels of Administrative Accuracy*

As Professor John Thomas recently remarked, there are two general types of errors at the Patent Office, wrongful grants and wrongful denials, and we currently “have only the first sort of error in the patent system.”²⁵⁸ Although the statement may be hyperbolic, given the existence of appeals of a small percentage of rejected applications to the Board of Patent Appeals and Interferences²⁵⁹ and from there to the Federal Circuit,²⁶⁰ it may be

²⁵⁷ *Radio Corp. of America v. Radio Eng'g Labs.*, 293, U.S. 1, 2 (1934)

For the purpose of any controversy between [rival claimants to the same invention], the validity of the patents must be accepted as a datum. Even for the purpose of a controversy with strangers, there is a presumption of validity, a presumption not to be overthrown except by clear and cogent evidence. The question is whether the respondent has sustained that heavy burden.

²⁵⁸ Symposium, *Panel I: KSR v. Teleflex: The Nonobviousness Requirement of Patentability*, 17 *FORDHAM INTELL. PROP. MEDIA & ENTER. L.J.* 875, 896 (2007). Cf. Amitrajeet A. Batabyal & Peter Nijkamp, *Is There a Tradeoff Between Average Patent Pendancy and Examination Errors* 3-5 (Social Science Research Network, Working Paper No. 908579), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=908579 (last visited Dec. 25, 2007) (noting both types of errors, the potential to diminish both times of errors by increasing examination time, and discussing the tradeoff between the costs of such errors and social costs of increasing examination times so as to determine – assuming fixed resources – whether to have smaller numbers of examiners evaluate for longer times or vice-versa, which depends on the costs that are to be emphasized) (citing P.H. Jensen & E. Webster, *Achieving the Optimal Power of Patent Rights*, 37 *AUSTRAL. ECON. REV.* 419-426 (2004)).

²⁵⁹ See, e.g., Posting of Dennis Crouch to Patently-O Blog, http://www.patentlyo.com/patent/2007/03/bpai_appeal_sta.html (Mar. 4, 2007) (in a sample of 10,000 applications published in 2003, less than one percent ended up filing an appeal, and less than half of these filed a brief given that filing a notice of appeal is a way to obtain more time to file a continuing application); U.S. PATENT AND TRADEMARK OFFICE, *PROCESS PRODUCTION REPORT FISCAL YEAR 2006*,

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true in spirit given the extremely high rate of granting patents on continuations where the patent holder persists in seeking the grant. According to two studies, the Patent Office ultimately issues patents from 85% of all applications, which is a rate much higher than in either the European Patent Office (72.5% of corresponding United States applications) or the Japanese Patent Office (44.5% of same).²⁶¹ As discussed below, there is little reason to think that the American patent examiners are doing a better job than their international colleagues,²⁶² although some of the difference may be accounted for by more stringent patentability legal standards applied overseas. The current rates of judicial invalidation of patents after they have been granted (even considering the heightened presumption of validity) seem extremely high.²⁶³

<http://www.uspto.gov/web/offices/dcom/bpai/docs/process/fy2006.htm> (last visited Dec 25, 2007) (in 2006, there were under 3,000 ex parte appeals filed). Cf. Posting of Peter Zura to The 271 Patent Blog, <http://271patent.blogspot.com/2007/06/is-ksr-actually-helping-applicants-at.html> (June 27, 2007) (discussing unexpected, increased reversal rates in the BPAI of initial obviousness rejections following KSR).

²⁶⁰ See, e.g., U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT, APPEALS FILED, TERMINATED, AND PENDING DURING THE TWELVE MONTH PERIOD ENDED SEPTEMBER 30, 2006 <http://www.fedcir.gov/pdf/ao0906.pdf> (last visited Dec. 25, 2007) (noting seventy-two appeals from the Patent Office in twelve months).

²⁶¹ See, e.g., Ravicher, *supra* note 19, at 8 (citing Cecil D. Quillen, Ogden D. Webster & Richard Eichman, *Continuing Patent Applications and Performance at the U.S. Patent and Trademark Office-Extended*, 12 FED. CIR. B.J. 35 (2002), and Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*, 16 FED. CIR. B.J. 679 (2006)). See also Buchanan, *supra* note 19, at 37-38 (additional studies provide similar results, ranging from 75% to 97% of applications are ultimately issued, and the Patent Office's own analyses concluded that at least 4% to 6% of issued patents subjected to a performance review had at least one invalid claim) (citations omitted). Cf. U.S. Patent and Trademark Office Working to Improve System, *Pinkos Says*, VIRGINIA LAW NEWS AND EVENTS, Apr. 11, 2007, http://www.law.virginia.edu/html/news/2007_spr/pinkos.htm (noting comments from the Patent Office Deputy Director that in the last year there was "about a 52 percent approval rate"). But see Lawrence B. Ebert, *On Patent Quality and Patent Reform*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 1068, 1074-75 (2006) (noting that, since claims define the invention, use of continuing applications to measure grant rates is suspect).

²⁶² Cf. Kesan & Ball, *supra* note 115, at 242 (noting data suggesting a relative paucity of challenges in United States reexaminations compared to foreign oppositions regarding similar patents, so that unless United States examiners do a better job of examination – which is a questionable assumption – courts in the United States are more likely to confront invalid patents than courts in other countries).

²⁶³ See *supra* note 19 and accompanying text. These litigated patents, moreover, reflect patents whose value warrants the expense of litigation (after considering the likelihood of success in challenging validity). See *supra* note 27; Buchanan, *supra* note 19, at 39 (noting differing views of the high rate for a "small but economically important subset of patents"). Cf. Allison et al., *supra* note 127, at 437 (stating their assumption for analysis that there is "no reason to believe that valuable patents that are not litigated differ in any systematic ways from valuable litigated patents"); Allison & Sager, *supra* note 127, at 1787-88 (discussing factors that will be practically considered to assess whether patents are "substantially more valuable than the average and are substantially more likely to be enforced through litigation" and noting that the average age of litigated patents is significantly lower than the average patent). Separate efforts have been made to link various metrics to patent validity, including prior art citations (and whether they were reviewed by the Patent Office), elapsed time from patent grant, and whether patents that

There is no necessary reason to think that the two kinds of errors of administrative evaluation should have the same social consequences and thus should be treated equally.²⁶⁴ In fact, they are not treated equally, although the applicable legal doctrines may impose the wrong burdens of production and persuasion given the policies articulated above that challenges to invalid patents reflect the paramount social policy (except when stability of litigation results is at issue). In regard to proving the same factual validity issue – e.g., whether a reference is sufficient to qualify as prior art – burdens of production and persuasion for rejections are initially placed on the Patent Office but then are shifted to applicants (under deferential administrative review standards) in direct appeals from the Patent Office, whereas the clear and convincing evidentiary burdens placed on challengers apply after the grant.²⁶⁵

As Professor Mark Lemley has cogently argued, moreover, it may be excessively costly to prevent high rates of granting errors,²⁶⁶ even if it might make sense to spend significantly more than we do at present to prevent the chilling social effects that

have survived administrative validity challenges, but these metrics may not relate directly to patent value. See Allison & Lemley, *supra* note 19, at 228-40; Allison et al., *supra* note 127, at 441 n.28, 443 n.32, 449-54 (citing, *inter alia*, Dietmar Harhoff et al., Citations, Family Size, Opposition and the Value of Patent Rights (Working Paper, 1999); GLORIA K. KOENIG, PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS (rev. ed. 1980); and Kimberly A. Moore, *Xenophobia in American Courts*, 97 NW. U. L. REV. 1497, 1538 (2003)). Cf. James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 20-22 (2005) (discussing endogeneity of validity of patents); Mathur, *supra* note 76, at 41-42 (noting that patents in India with increased citation to prior art and numbers of claims were more likely to result in litigation, and concluding that the high levels of settlements of the relatively few cases suggests “a lack of faith in the Judiciary”). Other studies suggest significant differences in litigation outcomes based on the nature of the parties involved and other factors, but which may not necessarily provide predictive value in regard to assessing validity of particular patents. See generally Moore, *supra*; Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1 (2006).

²⁶⁴ Cf. Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 7, 8 & n.27, 19-20 (2005) (noting cases rejecting antitrust claims based on anticompetitive pharmaceutical patent litigation settlements based on findings that such social harms do not extend beyond the exclusive rights that valid patents entail, and criticizing arguments that the presumption of validity should apply to such settlements in the absence of sham or baseless litigation, because the presumption itself has no evidentiary value and because it does not affect the character of the patent that results in such anticompetitive power) (citing, *inter alia*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 536 & n.1 (E.D.N.Y. 2005), and *In re Tamoxifen Citrate Antitrust Litig.*, No. 03-7641, 2005 WL 2864654, at *17 (2d Cir. Nov. 2, 2005)).

²⁶⁵ See, e.g., Jennifer L. Kisko & Mark Bosse, *Enablement and Anticipation*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 144, 147 (2007) (noting that the burden of proving lack of anticipation is on the applicant in patentability suits but on the challenger to prove anticipation in infringement suits, although the legal standard for determining the sufficiency of a reference as prior art should not change depending on the nature of the case).

²⁶⁶ See generally Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001).

wrongly granted patents produce.²⁶⁷ The growing number of patent applications in the United States and around the world²⁶⁸ and the increasing disparity between such applications and examination resources,²⁶⁹ however, makes the ever-widening gap between the grant of a patent and the presumption of validity unlikely to close soon.²⁷⁰ Thus, we are as a practical matter assured that there will be erroneous grants, and that the rates of such errors will be high. What kind of presumption should then apply?

C. *Practical Realities of Patent Examination*

Many commentators and the United States Federal Trade Commission have noted the failure of the Patent Office to provide patent examiners with sufficient time to perform the functions of search and examination well.²⁷¹ As the Patent Office itself has acknowledged, it cannot hire its way out of the current problem,

²⁶⁷ See, e.g., NATIONAL ACADEMIES OF SCIENCE, A PATENT SYSTEM FOR THE 21ST CENTURY 7 (2004), available at <http://www.nap.edu/html/patentsystem/0309089107.pdf> (last visited Dec. 25, 2007) (discussing the need to strengthen Patent Office capabilities by providing an adequate budget, increased financial resources to train examiners and develop electronic processing capabilities, and by developing multidisciplinary analytic capabilities); John R. Thomas, *Does Patent Quality Matter?*, 6-8, available at http://www.ipo.org/AM/Template.cfm?Section=IPO_Patent_Quality_Conference&Template=/CM/ContentDisplay.cfm&ContentID=8712 (last visited Dec. 25, 2007) (discussing social costs of invalid patents, which exceed annual examination budgets with regard to just a single patent).

²⁶⁸ See, e.g., World Intellectual Property Organization (WIPO), *Record Number of International Patent Filings in 2004*, available at http://www.wipo.int/edocs/prdocs/en/2005/wipo_pr_2005_403.html (last visited Dec. 25, 2007) (noting four percent overall increase in filings under the Patent Cooperation Treaty, and twenty-three percent for developing countries); WIPO PATENT REPORT 2006, STATISTICS ON WORLDWIDE PATENT ACTIVITIES 4 (2006), available at http://www.wipo.int/ipstats/en/statistics/patents/pdf/patent_report_2006.pdf (last visited Dec. 25, 2007) (indicating that patent applications have doubled in twenty years, consistent with growth in economic activity); U.S. PATENT AND TRADEMARK OFFICE, 2007-2012 STRATEGIC PLAN 13, available at <http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf> (last visited Dec. 25, 2007) [hereinafter 2007-2012 STRATEGIC PLAN] (noting that "the volume of patent applications continues to outpace our capacity to examine them"). See also Jeffrey E. Young, *Patent and Trademark Office/Business Method Patents: Growth Amidst Uncertainty Sums Up the Patent and Trademark Office's Business Method Partnership Meeting*, 74 BNA PAT., TRADEMARK & COPY. J. 322 (July 13, 2007) (noting that applications gradually increased from 2005 to 2006, then surged in 2006 to a level exceeding the 2001 level, with the increase attributed to applications on financial inventions).

²⁶⁹ See, e.g., Thomas, *supra* note 267 at 1-2 (discussing even larger per-examiner application burdens and delays for Japanese and European examiners than for United States examiners).

²⁷⁰ See, e.g., 2007-2012 STRATEGIC PLAN, *supra* note 268, at 13 (projecting an eight percent annual increase in patent filings through 2012). Cf. Lichtman & Lemley, *supra* note 20, at 103, 105 (recognizing the reality of poor examination conditions, but recommending revising the presumption of validity rather than improving overall examination quality).

²⁷¹ See, e.g., Buchanan, *supra* note 19, at 35; FTC INNOVATION REPORT 2003, *supra* note 13, at 8.

and adequate training and supervision will invariably be an issue in any large institution.²⁷² Of greater relevance, the Patent Office itself has recently suggested that applicants may need to assume a greater role in demonstrating patentability (and adopted currently-enjoined rules that required them to do so when filing more than a limited number of claims),²⁷³ which may shift the burdens of production and persuasion regarding validity during initial examination.²⁷⁴

²⁷² See, e.g., 2007-2012 STRATEGIC PLAN, *supra* note 268, at 13 (noting the increased numbers and complexity of applications and questioning whether increased hiring will adequately address them); see also *id.* at 16-17 (noting measures to be taken to assure high examination quality, including enhanced recruiting, recruiting and retention incentives for employees, and an enhanced training through a “Patent Training Academy” and other initiatives). See also FTC INNOVATION REPORT 2003, *supra* note 13, at 9-10 (estimating application increases at ten percent per year and discussing the constraints of evaluating applications with only “8 to 25 hours” to perform all required functions).

²⁷³ See, e.g., Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (Aug. 21, 2007) (adopting 37 C.F.R. § 1.75, requiring an “examination support document” in various circumstances); *Tafas v. Dudas*, No. 1:07cv1008(JCC) Memorandum Opinion (E.D. Va. Oct. 31, 2007) (enjoining effectuation of the entire set of revisions to the continuation and claim examination rules); 2007-2012 STRATEGIC PLAN, *supra* note 268, at 13 (articulating the need for assistance from other interested parties to be able to perform adequate examinations); Statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, Before the S. Comm. on the Judiciary, “*Patent Reform: The Future of American Innovation*” (June 6, 2007), http://judiciary.senate.gov/print_testimony.cfm?id=2803&wit_id=6506 (noting the need for applicants to provide better information to the Patent Office to assist proper examination through full disclosure and “quality submissions”); FTC INNOVATION REPORT 2003, *supra* note 13, at 9 (discussing how examination proceeds “with only the applicant’s submissions for assistance,” aided by the duty of candor but subject to limitations that “the PTO does not have facilities with which to test the accuracy or reliability of [applicant submitted] information.”). Cf. Beth S. Noveck, “*Peer to Patent*”: *Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J. L. & TECH. REV. 123 (2006) (proposing collective inputs from third parties to assist patent office examination).

The Patent Office is expected to promulgate soon new examination and continuation application rules – which will likely be challenged as beyond Patent Office rulemaking authority – that will shift some of these burdens of examination. See Posting of Dennis Crouch to Patently-O Blog, <http://www.patentlyo.com/patent/2007/07/continuation-ch.html> (July 11, 2007) (noting approval of the rules by the United States Office of Management and Budget). See generally Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63 (2004); Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO’s Proposed New Rules Undermine an Important Part of the U.S. Patent System With Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 556 (2006).

²⁷⁴ Whether the Patent Office can shift such burdens of production and persuasion by rule is questionable, particularly as it currently lacks substantive rulemaking authority. See Director, Office of Workers’ Comp. Programs, Dept. of Labor v. Greenwich Collieries, 512 U.S. 267, 271 (1994) (assigning burdens of proof is substantive lawmaking); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (the Patent Office lacks substantive rulemaking authority). Cf. Menell, *supra* note 37, at 16 (hypothetically and humorously claiming a new method of patent legislative reform, which would avoid adopting biased burdens of proving that patent protection should be available for all innovations in all fields without empirical rebuttal evidence to show that such protection would be harmful, and noting that “those possessing the best information” regarding public and private costs “may enjoy private benefits (such as exclusion of competition) that make them unwilling to reveal such information.” (citing Arnold Plant, *The Economic Theory Concerning Patents for Inventions*, 1 ECONOMICA 30 (1934))).

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In addition, existing incentives for examiners “provide a bias towards allowing claims rather than continuing to reject them Patent Office productivity metrics and examination procedures thus favor allowance over continued rejection.”²⁷⁵ These incentives, as well as the burdens of production and persuasion placed on examiners to search for evidence and provide reasoned explanations,²⁷⁶ further call into question that the presumption of correctness that forms the basis for the presumption of validity. Because of these practical realities, moreover, the Patent Office may not properly apply its prophylactic measure of adopting the broadest reasonable construction of claims so as to better assure that issued patents are valid.²⁷⁷ Recent analyses suggest that uncertainty regarding patent scope and claim boundaries is the principle driver of increased patent litigation,²⁷⁸ leading to the patent system exerting a net tax on innovation (particularly for the information technology industry),²⁷⁹ which calls into question applying any presumption of validity (particularly when a claim construction is applied to validity questions that differs significantly from the understanding of the invention applied in the Patent Office).²⁸⁰

²⁷⁵ Buchanan, *supra* note 19, at 36. *See also id.* (discussing “disposal counts” and how they are accrued, and the need for time-consuming explanation when making rejections); Ravicher, *supra* note 19, at 7-9 (noting financial incentives for the Patent Office to generate fees by granting patents, leading to a culture of treating applicants as “customers,” and incentives for examiners who “should be rewarded, not penalized, for improving patent quality”). *Cf. supra* note 138 (recommending documentation of reasons for grants).

²⁷⁶ *See supra* notes 13, 148 and accompanying text.

²⁷⁷ *See supra* notes 66, 114, 139 and accompanying text.

²⁷⁸ *See* James Bessen & Michael J. Meurer, *What’s Wrong with the Patent System? Fuzzy Boundaries and the Patent Tax*, FIRST MONDAY, June 2007, http://www.firstmonday.org/issues/issue12_6/bessen/index.html, available at <http://www.researchoninnovation.org/dopatentswork> (last visited Dec. 25, 2007) (citing their forthcoming book, *Do Patents Work?*, which contains extensive empirical analysis, draft portions).

²⁷⁹ *See id.*; Michael Fitzgerald, *A Patent Is Worth Having, Right? Well Maybe Not*, N.Y. TIMES (July 15, 2007), available at http://www.nytimes.com/2007/07/15/business/yourmoney/15proto.html?_r=2&oref=slogin&pagewanted=print (“Today, over all, patents don’t work; for the information technology industry especially, they don’t work.” (quoting James Bessen)).

²⁸⁰ This problem may be even more significant than has been previously realized, given that patent claim terms may expand their application – if not also their meaning – over time, not just for infringement analysis but also for validity analysis. *See, e.g., In re Hogan*, 559 F.2d 595, 604-06 (C.C.P.A. 1977) (enablement is determined solely by reference to the meaning of claim terms as of their filing date, but that meaning may encompass later-arising equivalents not known on the filing date); *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 878 (Fed. Cir. 2004) (method and apparatus claims can include later-arising technology within their literal scope, because (unlike means-plus-function claims), they “are defined by the language of the claims themselves”). *But cf. Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254-55 (Fed. Cir. 2004) (noting that claim meaning that includes later-arising technology must be held invalid for lack of written description, but not necessarily for lack of enablement, because applicants would not be able to “possess and disclose” that scope); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313,

In summary, a presumption of validity based on Patent Office determinations to grant patents would remain suspect even if we were: (1) to increase the number of examiners, expand the amount of time spent by them, revise the incentives for them to make rejections, and improve their training and expertise; (2) to alter the legal standards to better assure that proper examination occurs under the same legal standards that apply after grant; and (3) to revise incentives for administrative challenges to invalidate patents before litigation.²⁸¹ Nor are patent holders likely to be deterred from asserting their patents even when they know that the patents are invalid, given that the costs of proving invalidity may make such challenges unlikely.²⁸² For these and other reasons, public policy favors challenges to validity, and does not suggest imposing any (much less heightened) burdens of production and persuasion on challengers based on the mere fact that the patent was granted. As the United States Federal Trade Commission put it, “[t]hese circumstances suggest that an overly strong presumption of a patent’s validity is inappropriate. Rather, courts should require only a ‘preponderance of the evidence’ to rebut the presumption of validity.”²⁸³

Nevertheless, we are confronted with an express statutory decision to place the burden of persuasion on a challenger to validity, which therefore also places on the challenger the burden of producing evidence of invalidity.²⁸⁴ Although there may be good reasons to think that the burdens should be altered given the limitations of examination procedures, it would be difficult to repeal the existing presumption and it may not be necessary to do so. All that is required is for the judiciary to acknowledge the

1330 (Fed. Cir. 2003) (noting that the written description is focused on preventing an applicant from later “asserting that he invented that which he did not”). See generally Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101 (2005); Christopher A. Cotropia, *“After-Arising” Technologies and Tailoring Patent Scope*, 61 N.Y.U. Ann. Surv. Am. L. 151 (2005).

²⁸¹ See, e.g., Sag & Rohde, *supra* note 20, at 43

[T]he [challenger-focused] model shows that the alleged infringer’s prospects of success are often not significant in deciding whether to challenge a patent. Furthermore, even where the prospects of success are a significant factor in the alleged infringer’s decision making process, they are only indirectly related to the validity of the underlying patent because of the uncertainties of patent litigation and information asymmetries.

²⁸² Cf. *id.* at 47-48

The [assertion-focused] model predicts that where targeting costs are low and the expected cost of retaliation is small, a rational patent holder will broadly assert her patent, even where the probability that a target will accept a license is low. The model also indicates that a patent holder’s incentive to assert her patent increases as the target’s probability of accepting a license increases.

Bessen & Meurer, *supra* note 263, at 15 (discussing anti-competitive and opportunistic lawsuits that rely on weak patents to exclude competitors and to induce licensing).

²⁸³ FTC INNOVATION REPORT 2003, *supra* note 13, at 8.

²⁸⁴ See 35 U.S.C. § 282 (2007).

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realities of examination procedures and to avoid imposing any heightened evidentiary burdens of production or persuasion. In most cases, it will not be difficult for challengers to produce *some* evidence of invalidity (particularly prior art that had not been considered by the Patent Office²⁸⁵), which should then permit consideration afresh of the factual issues and the distinct legal conclusions that are required. Whether to grant any deference in doing so is a question of the strength of the Patent Office's analysis, which can only be evaluated if the judiciary first performs its own.²⁸⁶

CONCLUSION

Questions about the presumption of validity and its proper scope and application will continue to be at the heart of procedural and substantive patent law disputes. Hopefully, courts will give careful consideration in such disputes to the actual nature of the presumption, the grounds for its existence, the method of its operation, and the evidence that can overcome it. As noted above, it will be critically important for courts to recognize that there is no presumption against challenging validity. To the contrary public policy favors bringing such challenges and considering evidence of invalidity even in preliminary relief contexts. Further, the presumption only applies to the facts on which legal conclusions regarding validity operate. Courts will need to be careful not to wrongly infer that the presumption affects the weight to be accorded to competing factual inferences or legal factors when making such legal conclusions. Nor should they import from the presumption of validity public policies that do not exist, such as the idea that granted patents should somehow be preserved from invalidation in the face of factual inferences of invalidity.

²⁸⁵ But even in its absence, the challenger may rely on the evidence of invalidity considered by the Patent Office in seeking to demonstrate a prima facie case.

²⁸⁶ See *supra* note 72 and accompanying text. Because the strength of the Patent Office's analysis can only be evaluated if the judiciary considers the issue, I do not support recent suggestions to adopt irrebuttable presumptions of validity even after more extensive review. See, e.g., Lichtman & Lemley, *supra* note 20, at 118 (suggesting conclusive presumptions for previously considered prior art evidence reviewed by the Patent Office in more intensive examination or opposition proceedings). The public policy in favor of judicial review to assess validity is not lessened after such review, even if the likelihood of discovering errors is decreased. Cf. *supra* notes 229-57 and accompanying text.