the celebrity personality and its relevance to social identity formation. A more nuanced approach would consider how the First Amendment can incorporate these cultural practices that contribute to the marketplace of ideas into its jurisprudence.

An understanding of cultural studies can provide an invaluable guide that takes into account the myriad competing interests when moving from the bright lines to the gray zones of the right of publicity. Whether arguing for the legally permissible uses of the celebrity’s identity for communicating information and expressing ideas or for the prohibition of free-riding on the economic associative value of identity predominantly for proposing a commercial transaction, the extra-legal perspectives of cultural studies on the meaning, production and consumption of the celebrity personality certainly has much to offer in the formulation of better legal solutions in contemporary times.

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

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(forthcoming in Spanish as translated by Carlos Correa in 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 existence of some other fact or group of facts." 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.⁶ As explained in 1890 by Professor William C. Robinson in his seminal patent treatise:

[the 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.]

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.⁷ 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.⁸ 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

¹ See, e.g., 35 U.S.C. § 305(a) (2007) ("On his own initiative, and at any time, the Director may determine whether a substantial new question of patentability is raised.").
³ Cf. DAVIE HUME, A TREATISE OF HUMAN NATURE 246 (T. H. Green & T. H. Grose eds., Longmans, Green & Co. 1890). ("For as this ought, or ought not, expresses some new relation or affirmation, 'tis necessary that it should be observed and explained; 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.").
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. 190, 192-94 (1894) (citing 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").
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. 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 burden of production and persuasion may determine the outcome of countless challenges to patent validity.

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 Balsec Ltd. v. M/S The Supreme Industries Ltd., which addressed the presumption of patent validity in regard to preliminary relief. The Balsec decision upheld the vacatur of ex parte injunctions, based on traditional preliminary injunction considerations of a prima facie case, balance of convenience, and irreparable loss.

I then discuss (in Part IV) the recent United States Supreme Court decision in KSR International Co. v. Teleflex, Inc. The KSR decision addressed the legal standard for burden of persuasion.


t JURISDICTION).

See 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 burden of production is made – on the face of the evidence without considerations of credibility.").


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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). I conclude (in Part V) by discussing recent studies of patent granting conditions and validity rates that provide reasons to believe that the logical inference of invalidity 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.

In reviewing and discussing the Balsec case, I seek to highlight the importance of providing an opportunity for evidentiary rebuttal of the presumption of patent 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
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 Pharmcs., 452 F.3d 1351, 1354-45 (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 Gost, 15 MICH. TELECOMM. TEGIL. L. REV. 421, 439-34 (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"); Lichman & 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, Remarking on Obviousness, 16 TEXAS INT'L L.J. 101 (forthcoming 2007) (available at http://www.leckir.edu/faculty/jmillier/ (last visited Dec. 24, 2007) (arguing for a presumption of invalidity specific to combination claims similar to the presumption of obviousness for claimed range overlapping within a prior art range) (citing and rejecting persuasive 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. 1740, 1743 (2007)).

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 1267, 1275-76 (Fed. Cir. 1986) ("[P]rior invention is a question of law, requiring the other validity issues of fact by clear and convincing evidence in light of the presumption of validity in 35 U.S.C. § 282."); Liebenthal Co. v. Medrad, Inc., 482 F.3d 1371, 1377 (Fed. Cir. 2007) ("Whether a claim satisfies the enabling requirement . . . is a question of law . . . Anticipation is a question of fact, but validity is a question of law.") (citations omitted)); Class Action Litigation, Inc. 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).
27 See, e.g., Gratz v. Bollinck, No. 04-1250, (D.C. Cir. 2007) (discussing 15 U.S.C. § 1317, 1325 (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,” 58 and prescribed the TSM test to avoid uncertainties of legal judgment that may be supplied by hindsight analysis. 59 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.” 60 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. 61 Obviousness decisions therefore may require not only finding facts, but also the exercise of administrative and judicial policymaking discretion. 62 It would be better if the actual grounds

the party seeking to invalidate a patent must prove invalidity by clear and convincing evidence.” (citing SRI Int’l Equip. S.A. v. USITC, 714 F.2d 369, 379 (Fed. Cir. 1983)) (Legale v. Dann, 544 F.2d 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 law of the case.”) (citations omitted). (Cf. Lichtman & Lemley, infra 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)).

58 Dippin’ Dots, Inc. v. Mosey, 475 F.3d 1357, 1345 (Fed. Cir. 2007).

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

60 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 prescribed hindsight reasoning when determining the obviousness of an invention” (citing In re Kahn, 441 F.3d 980, and In re Fridolph, 154 F.2d 414 (C.C.P.A. 1945)). See generally Gregory N. Mandel, Patent Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational, 67 OHIO ST. L. J. 1991 (2005) (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).

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

62 Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 155-56 (1950). See also id. at 156 (Douglas, J., concurring) (“[I]t is the ‘standard of invention’ which controls, so ‘finding of fact’ can be a substitute for it in any case.”).


for such legal conclusions were explicitly articulated, 64 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. 65

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. 66 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 presumed facts of validity that the patent was issued. After all, if invalid patents are commonly granted, reliance on the presumption may routinely result in errors of holding valid 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, 67 non-uniformity also

ingenious 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.

64 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 980)).

65 Cf. Janus, 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”).


67 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 costs\(^{37}\) 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

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44 RICE & KATHEL, supra note 35, at 1309.
45 Id. at 1311-14 (citing JAMES B. THAYER, PRELIMINARY TREATISE ON EVIDENCE AT THE COMMON LAW 355-89 (1886)); J. WIGMORE, EVIDENCE § 2491 (Chadbourn rev. 1961).
47 See id. at 925-27.
48 See id. at 927-28.
49 See RICE & KATHEL, supra note 35, at 1309.
50 See 2 MCCORMICK ON EVIDENCE, supra note 35, § 357, at 414.
51 Id. § 357, at 415. See also id. § 340, at 424-27 (discussing reasons for adopting a "true and convincing" standard of proof rather than the traditional "preponderance of the evidence" standard).

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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
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. Thus, having dispensed with both presumptions, a disputed issue of fact remained (precluding summary judgment) regarding the balance of inferences from the competing evidence. 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."

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.

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.

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, and nevertheless permitted judges to instruct juries about rebutted presumptions.

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 application for heightened standards recognized by the judiciary but not expressly provided for by Congress. 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. 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 subject) 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.

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.

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51 See id. at 3-10.
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, § 501.
54 See FED. R. EVID. 201 (advisory committee's note) (adopting 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 55, § 388, 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 & KATHEL, supra note 55, at 134-47; Buchanan, supra note 19, at 15 (quoting published "scintilla," and particular difficulties when rebuttal evidence is circumstantial, and the need for judicial judgment regarding the inferences).
58 See JANIS, supra note 13, at 928-29 (citing, inter alia, Hobbs v. U.S. Atomic Energy Comm'n, 451 F.2d 849, 856 (6th Cir. 1971) and 2 DONALD S. CHISUM, PATENTS § 5.06 n.24 (2003)); Morgan v. Daniels, 155 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 importunate 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 "setting 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.'" In contrast, under the preponderance of evidence standard, disputed facts only must be proved more likely than not to be true. 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." 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. The

placement of the ultimate burden of persuasion of invalidity on the party asserting its clearly warranted by the statutory language. 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. 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." 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

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relatively strong presumption of validity) should apply to *direct* judicial review of agency denials (and of some grants) of patents. 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. Indeed, 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

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72 See Benjamin & Rai, supra note 20, at 284-84. See also id. at 284-85 (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).

73 See 35 U.S.C. § 141 (2007) (establishing an administrative record for an appeal under 35 U.S.C. § 141). Cf. American Hotel & Derrick Co., 725 F.2d at 1560 ("When new evidence touching validity of the patent not considered by the PTO is relied on, the substance of the claim is not facing with having a disagreement with the PTO or with denying its judgment or with taking its expertise into account."). Fraser added. Similarly this issue may be determined *de novo* with newly added evidence, *de novo* review. Standard review standards should not apply to trials following a patent denial, 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. Zuckb, 327 U.S. 150, 164 (1949) (rejecting arguments regarding inconsistency of review standards between district court challenges, based on new facts, (and other cases of new evidence).). Cf. 5 U.S.C. § 706(2)(F) (2007) (creating a category of APA "de novo" review for agency action "unwarrented by the facts to the extent that the facts are subject to trial by a judge on the record made by the agency in the proceeding."). But see 5 U.S.C. § 706(2)(A) (2007) (applying the APA review standards to all cases except those 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, the only 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 of 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 the 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).

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74 See American Hotel & Derrick Co., 725 F.2d at 1560. 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 expertise in interpreting the references and to be familiar 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 "eliminates[s], or at least reduces[ ], the element of deference due to the Patent Office").

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75 See 35 U.S.C. § 251(a) (2007) (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 denial should accord greater deference than *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., 535 U.S. 218, 220-30 (2001), Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944), Chevron, U.S.A., Inc. v. NRDC, Inc., 465 U.S. 837, 844-44 (1984), and Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Al-Fawzi 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 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'n, 322 U.S. 111 (1944) (articulating the pre-APA standard for applications of law to facts). Even if APA review standards were to apply to 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 519 (noting that APA deference cannot apply to facts finding where the agency has not passed on the question).

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77 See Bilcare, No. FAQ 07/2007, 211 U.S. 1, 2 (citing Indian Patent No. 197893). See also id. 5 (noting that the patent holder's disclaimer of invalidity, in light of prior art regarding such films dating to 1975, when applying for the corresponding United States patent).

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favour of patentee.” 56 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 [lay] in its favour, and (iii) it would suffer irreparable injury if [an] injunction [was] not granted. 57 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,” the appellate court nevertheless held that the trial court should consider the strength of the prima facie cases of validity and infringement, 58 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”, (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.”

The appellate court also quoted an earlier case holding,

57 Id. ¶ 6. See also id. ¶ 7. 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 50-51, 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)).
59 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., IRL 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 Balaram Radhakrishnam v. M/S Mahaa Elecs, IRL 1995 Karnataka 2010, ¶ 10-15). In a related case, Judge Sanjay K. Kasi of the Delhi High Court noted that Bilara had not established a prima facie case for preliminary relief given evidence raising doubts about validity. See M/S Bilara Ltd. v. M/S Amartas Private Ltd., IA NO 10848/2006, 1397/2006 and 11160/2006 IN CS(OS) No.1847/2006, ¶¶ 51-59 (Mar. 30, 2007).
59 Bilara, 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 Balaram Radhakrishnam, ¶ 155)) at id. ¶ 21
60 If 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 on the market for some time, it would be quite improper to deny an interlocutory order.
61 Bilara, No. FAO 70/2007, ¶ 21
62 [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.
63 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.” Interlocutory relief is “an exceptional remedy . . . for which exceptional cause [is] to be shown.” 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.” In conclusion, the appellate court considered that the suit was filed before the patent was six years old, and that there were tangible grounds for suspicion of the alleged invention [(there 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] on the side of the respondents. 80
64 In summary, the appellate court in Bilara 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 statute that elapsed since its grant (particularly given the language of the statute rejecting a

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 of the United States

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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, 55 AIPLA Q.J. 139, 134 (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 question for trial" and that "the balance of convenience favors the granting of an injunction") (citing Am. Cyanamid Co. v. Ethicon, (1975) A.C. 386 (H.L.) (U.K.)). But cf David W. Hill & Shinichi Murata, Patent Litigation in Japan, 1 AERIAL INTELL. PROP. J. 141, 141-142 (2007) (noting that provisional injunctions in Japan are decided in separate proceedings 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 a 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. Conrol Med. Equip., Inc., 821 F.2d 645, 647 (Fed. Cir. 1987) and Aronson/Bauer, Inc. v. PAC, Ltd., 229 F.3d 1543, 1548 (Fed. Cir. 2003)).


90 Daley et al., supra note 87, at 148-49 (citing T.J. Smith & Nephew Ltd v. Conrol Med. Equip., Inc., 821 F.2d 645, 647 (Fed. Cir. 1987) and Aronson/Bauer, Inc. v. PAC, Ltd., 229 F.3d 1543, 1548 (Fed. Cir. 2003)).


94 475 U.S. 527 (1986).

95 455 U.S. 392 (1982).

96 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, 55 AIPLA Q.J. 139, 134 (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 question for trial" and that "the balance of convenience favors the granting of an injunction") (citing Am. Cyanamid Co. v. Ethicon, (1975) A.C. 386 (H.L.) (U.K.)). But cf David W. Hill & Shinichi Murata, Patent Litigation in Japan, 1 AERIAL INTELL. PROP. J. 141, 141-142 (2007) (noting that provisional injunctions in Japan are decided in separate proceedings 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 a hardship of denying or granting the provisional injunction without hearing witnesses and without considering the amount of damages).


98 Daley et al., supra note 87, at 148-49 (citing T.J. Smith & Nephew Ltd v. Conrol Med. Equip., Inc., 821 F.2d 645, 647 (Fed. Cir. 1987) and Aronson/Bauer, Inc. v. PAC, Ltd., 229 F.3d 1543, 1548 (Fed. Cir. 2003)).

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 Bilicore 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 Bilicore 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 infringement and validity. 102

In regard to infringement, the appellate court in Bilicore 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 Bilicore 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

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 efficiency 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.").
100 Cf. supra note 79 and accompanying text.
102 See, e.g., Feldhaus, supra note 89, at 535.
104 See id. ¶ 20 (quoting M/S Standpack Pvt. Ltd. v. M/S Oswal Trading Co. Ltd., [AIR 2000 Delhi 231, ¶ 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 invalidity 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 danger 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. Andrex Pharm., Inc., 452 F.3d 1351, 1355 (Fed. Cir. 2006) (citing, inter alia, Amazon.com, Inc. v. Barnesandnoble.com, 259 F.3d 1343, 1350-59 (Fed. Cir. 2001), and Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1381, 1384 (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, 1363 (Fed. Cir. 2006) ("[In 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 União Do Vegetal, 545 U.S. 418, 428-431 (2005)). 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 1347-48.

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

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

111 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").

112 See, e.g., J. Steven Baughman, Resuscitating Reexaminations: A Fresh Look at the Ex parte and Inter partes Mechanisms for Reviewing Issued Patents, 69 J. PAT. & TRADEMARK OFF. SOCIETY 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. As courts may not be as efficient as administrative agencies in invalidating invalid patents, and administrative agencies typically are not authorized to determine infringement questions (and may lack enforcement powers), 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. 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 development 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 MINN 3088 (Sup. Ct., Apr. 11, 2000) and TURKISH H [Japanese Patent Law], Law No. 120 of 2004, art. 104-3, translated at http://www.easa.go.jp/jp/aisai/kousei/data/PA.pdf).

14 See e.g., Baughman, supra note 119, at 355 & n. 278 (noting the potential for stay of litigation when a reexamination is pending, depending on how much litigation activity has occurred, whether the reexamination is poised for proper purposes or delay, and noting provision of stay for preliminary rehearing). See also Bilkem, supra note 86, 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 if there is a decision of invalidity follows a judicial finding of validity but not when a determination of validity follows a judicial finding of invalidity); and Bay State & American International Insurance Co., 4 CASKIP Newsletter (2017) (noting the German rule that an injunction may be delayed 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 33/52 (1972), amended by O.J. L 70/7 (1978), amended by O.J. L 128/1 (1980)).


17 See 2008] PATENTS AND PRESUMPTIONS OF VALIDITY 1025 geographical jurisdictional concerns involved. "In truth asking which tribunal is 'top' is simply not helpful - there is just the unduly compromise inherent in the EPC and one which cannot properly be resolved unless and until a rational patent litigation system for Europe is created."

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. Rather, it appears more important to tailor the presumption as so to obtain more accurate and predictable results. 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.

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

The appellate court in Bilkem 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 validity and on the fact that the patent was recently

114 Id. ¶ 26. See also Nick Becket, United Kingdom: Awards of Damages in UK Patent Cases Will Prior Notwithstanding the Findings of EPO, MONDAY, May 14, 2007, available at http://www.mondaq.com/article.asp?article=104622&print=1 (noting that patentees will seek to bring infringement actions as soon 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 stay of such litigation, and that the lack of provisions for the latter will create a "system with little or no consistency or uniformity across Europe.")

115 See, e.g., Sag & Kohle, supra note 20, at 79-80 ("recommending a general peremptory rule 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 reviews.")


117 Cf. ibid., 125 S. Ct. at 1861 ("[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts.").

granted (compared to a substantive rule favoring a presumption in regard to a worked patent of long standing). The premise of conditioning the existence of a presumption of validity on the length of time the patent was issued is highly questionable. 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. 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. 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. Similarly, the fact that time has gone by should not directly affect the three-factor (or four-factor) test for preliminary relief, if the patent is a new one, a mere challenge at the Bar would be quite sufficient for the renewal 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 supra note 76 and accompanying text; Lichtman & Lemley, supra note 30, at 51 (recalling a heightened presumption of validity based on passage of time between issuance and evaluation, because "delay means that there was more opportunity for reliable outside evaluations to come to light").


125 See The India Patent Act, No. 39 of 1970 § 151, as amended by The Patents Amendment Act of 2005, No. 5, Act of Parliament (2005, No. 5, Act of Parliament (2005, noting that section 151 of the India Patent Act provides that a patent is deemed to be invalid if the Controller of Patents is satisfied (a) that it is not his duty to grant the patent or (b) that it is not his duty to register the patent. See also supra note 20, at 222-23 (noting that litigation costs, rather than validity of claims, may determine whether a prospective licensee will pay the demand or seek to litigate validity).


127 See Carroll, supra note 22, at 452-53 (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 patents") (citing John R. Allison et al., Valuable Patents, 92 GEO. L.J. 435, 460 (2004) and Kimberly A. Moore, Worthless Patents, 94 BERKELEY TECH. L.J. 1291 (2009)). See also John R. Allison & Thomas W. Sager, Valuable Patents Redux: On the Enduring Merits of Using Patent Characteristics to Identify Valuable Patents, 85 TEX. L. REV. 1769 (2007) (upgrading the Valuable Patents analysis with additional tests and responding to criticisms of that analysis in David E. Adelman & Kathryn L. DeAngelo, Patent Metrics: The Mismeasurement of Innovation in the Biotech Patent Debate, 85 TEX. L. REV. 1677 (2007)).

128 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. 945, 946 (2004))) (footnote omitted) (explaining why private parties lack incentives to challenge valid patents in courts); Jay P. Kesan & Andreas A. Gallo, Why "Bad" Patents Survive in the Market and How Should We Change? - The Private and Social Costs of Patents, 85 EMORY L.J. 61, 85 (2006) (same); Joseph Scott Miller, Building a Better Bount: 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 exonerated 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 contest the validity. See Blonder-Tongue Labs., Inc. v. United States, 402 U.S. 315, 317-19 (1971). Q. The India Patent Act, No. 39 of 1970 § 151, as amended by The Patents Amendment Act of 2005, No. 5, Act of Parliament (2005, No. 5, Act of Parliament (2005, noting that section 151 of the India Patent Act provides that a patent is deemed to be invalid if the Controller of Patents is satisfied (a) that it is not his duty to grant the patent or (b) that it is not his duty to register the patent. See also supra note 20, at 222-23 (noting that litigation costs, rather than validity of claims, may determine whether a prospective licensee will pay the demand or seek to litigate validity).

justify upholding the vacatio 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. 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 vacatio). 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
pateibitability.” Such a finding should arguably 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. 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
decision to the initial administrative judgment may nevertheless
be supposed.

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

183 See Povings of Minhaln Kochuphllia and Shunmad Basheer to SPICY IP,
https://www.blogger.com/comment.g?blogID=17664472&postId=5580146849343895
&Popupservice (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).
185 See U.S.C., §§ 305(a), 304, 312(a), 313 (2007).
186 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))).
187 Id., e.g., Benjamin & Rai, supra note 20, at 300-31 (discussing changes in appellate
and administrative review deference standards and their effects on judicial
decision-making) (citing, inter alia, Peter H. Schuck & E. Donald Elliott, To the Chevron
St. U. L. REV. 745, 755 (2000)).

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 reexaminations) 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. 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. 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.)
substantive legal rules (or conclusive presumptions) may prevent consideration of evidence regarding what would otherwise be highly relevant facts.16

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.17 Even if the burden of producing a prima facie case is placed initially on the Patent Office,18 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.


17 See Barton, supra note 145, 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/whether 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) §§ 214-43 and 11 n. Oetiker, 977 F.2d 1443 (Fed. Cir. 1992))).

18 See Siglos, 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. 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.

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. The Supreme Court thus reiterated “the need for caution [by the Patent Office] in granting a patent based on [such a] combination,” 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. 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.” KSR affirmed the Graham 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... and its progeny” as an “objective” analysis. KSR noted, however, that “[w]hile the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry.” 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., 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.” 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 nonobvious only by evidence that the elements perform different functions in the combination or that the combination yields more than one would expect. 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. 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 obvious.

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110 Id. at 1738-39.
112 KSR Int’l Co., 127 S. Ct. at 1739.
113 Id. at 1738-39.
115 Evidence also might rebut the showing that all 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.
non-obvious. 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." 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." Absent proof by the patent holder that the improved function was beyond the skill of the ordinary artisan, or that the invention possesses a new (and not just an improved) function, 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." 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." 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.

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162 See id. at 50-52.
163 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" . . . unless the extraordinary skill of ordinary patenters." (quoting Anderson's Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 60 (1969))).
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" . . . unless the extraordinary skill of ordinary patenters." (quoting Anderson's Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 60 (1969))).
167 KSR Int'l Co., 127 S. Ct. at 1790 (emphasis added).
168 Id. at 1790 (emphasis added).
169 See id. at 1740-41 (emphasis added). See *id.* at 1741
170 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 prevented a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.
171 See *KSR Int'l Co.*, 127 S. Ct. at 1790 (emphasis added).
obviousness inquiry reflected in its application of the TSM test[.]" which had created "a rigid rule that limits the obviousness inquiry."

In contrast, the original TSM test had been introduced by the Federal Circuit’s predecessor and "captured a helpful insight." 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." 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.

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.

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. It appears that the Court considered such evidence to be legally relevant but legally insufficient to rebut the inferences of obviousness otherwise established.

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

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. 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. In contrast, various businesses and
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.\textsuperscript{16} 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).\textsuperscript{16} As the United States Government put it in its KSR brief, the Supreme Court "has applied the Graham framework in a variety of contexts 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."\textsuperscript{15} There are sound historical reasons to believe that this legal question of the obviousness threshold reflects discretionary policy judgments made by the judiciary.\textsuperscript{15}
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") 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.")

**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.* 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.

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) 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 besylate salt. 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).

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.

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. 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).

Given the evidence, the Federal Circuit held that a reasonable factfinder could only conclude that clear and convincing evidence demonstrated a motivation to combine.

Similarly, the Federal Circuit found error in the trial court's holding that the facts of 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...
that various salts, including besylate, would form improved compounds over maleate, and suggestions in the prior art and prior statements of the patent holder suggested the interchangeability of salts. 209 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. 210 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." 211 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 amlopidine salts or stood to lose time and money by switching research strategies. 212 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. 213 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. 214

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. 215 Another dissent focused on confusion the panel decision would cause rebuttal of a prima facie
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. 216 A third dissent made similar points, also noting that most pharmaceutical invention involves routine screening of both active compounds and new formulations and salts. 217 All emphasized the "exceptional importance" of the legal issues to the pharmaceutical and chemical industries and to their investments, and to society. 218

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)? 219 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. 220 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. 221

209 See id. at 1366-67.
210 Id. at 1365.
211 Id. at 1369-70 (quoting In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003)).
212 See id. at 1367.
213 See id. at 1369-71.
214 See id. at 1370.
216 See id. at 1381-82 (Lourie, J., dissenting) (citing In re Papesch, 315 F.3d 381, 391 (CCPA 1999)); See generally Harold C. Wegner, Chemical Obviousness In a State of Flux (June 22, 2007) (unpublished draft, on file with author).
217 See Pfizer, Inc. v. Aventis, Inc., 488 F.3d at 1383-84 (Rader, J., dissenting).
218 Id. at 1381-82 (Lourie, J., dissenting). See id. at 1379-80 (Newman, J., dissenting); id. at 1384 (Rader, J., dissenting).
219 See, e.g., Angiotech Pharm. & ANR. v. Conor MedSystems, Inc., (2007) 698 F.3d 5, 21 (Fed. Cir. 2007) (EVCA vs. [31] leave to appeal to the House of Lords granted, Minutes of June 7, 2007 (rejecting appeal from conclusion of obviousness because "[i]nto 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)").
221 See id. at 1746; supra notes 28, 180-83 and accompanying text. See also Sokolowski v. Ag Pro, Inc., 425 U.S. 278 (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 Gross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1295, 1317 (Fed. Cir. 2005). 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. The panel decision in *Pfizer* took pains to reiterate the high burden of persuasion throughout its decision, 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. 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. Similary, 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."
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.\textsuperscript{225}

In summary, the Supreme Court in \textit{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 \textit{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.\textsuperscript{226} As noted by an Indian commentator:

[The 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 decided only by the High Court in infringement or revocation proceedings.\textsuperscript{227}

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.\textsuperscript{228} 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 PRESCRIPTION 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.\textsuperscript{229} 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

\textsuperscript{225} NARAYANAN, supra note 5, ¶ 1-19.

\textsuperscript{226} See, e.g., Indra Bhattacharya & Robert Cooper, \textit{Australia High Court Locks in the Law on Obviousness, 21 WORLD INTEL. PROP. REG. NO. 7} (July 2007) (noting that the Australian High Court recently "reinforced the longstanding principle that even a small advance may be inventive so long as it offers some material benefit to the existing state of the art" following Lockheed Security Prods. Pty. Ltd. v. Doric Prods. Pty. Ltd., (2007) 235 A.L.R. 502 (Austl.)).

\textsuperscript{227} Rinehardt, 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. NATL. PATENT PLANNING COM'NS, THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 629, 74th Cong., 1st Sess. 5, 6 (1945), and citing U.S. NATL. PATENT PLANNING COM'NS THIRD REPORT ON THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 283, 74TH CONG., 1ST Sess. 4 (1945)).

\textsuperscript{228} Narayanan, supra note 1, ¶ 1-19.

\textsuperscript{229} Cf. Charles E. Phillips, The Presumption of Administrative Correctness: The Proper Basis for the Grant and Controlling 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. § 292, 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).
interceptions of the invention as claimed[259] — 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, 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 uses 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 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 patent 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.260

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.261 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.262 The policy favoring challenges to validity would seem to be even stronger where such contractual fairness concerns were not applicable.263

More recently, the Supreme Court held in Medimmune, Inc. v. Genetech, Inc.264 that licensees need not materially breach their contracts in order to have constitutional standing to sue265 (and thus Declaratory Judgment Act jurisdiction266) to raise contractual or patent validity challenges.267 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,268 the Court nevertheless called into question a long line of lower court cases limiting the

259 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 interpretations uncertainties with granted patents remain after reviewing all the evidence, adopt narrowing constructions so as to preserve claim validity. 415 F.3d 1390, 1396-97 (Fed. Cir. 2008) (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). 260 Lear v. Atkins, 395 U.S. 533 (1969).

261 Id. at 675-76.

262 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 Atkins’ 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 exercising federal policy.”).

263 See id. at 675-74 (overruling the contractual obligation “at least from the time the [licensee] refuses to pay the contractual royalties”).

264 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”).


266 See U.S. CONST. art. III (authorizing judicial power over "cases" and "controversies").


268 See Medimmune, 127 S. Ct. at 770-77.

269 See id. at 769-70, 776.
application of Lear based on the idea that an assignor or license who reaps contractual benefits from a patent should be required to seek contractual compliance therewith. 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 at best 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.

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


241 Medimmune, 127 S. Ct. at 776. The Court also noted that any such contractual proviso or comity-like rule that might expressly preclude validity challenges would not raise a jurisdictional but only a merits question.

242 Lear, 595 U.S. at 674 n.19. See id. at 654-58 (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 Faulk v. Kump, 3 F. 988, 992 (3d Cir. 1880))).

243 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 Studengeellschaft Kohle, M.B.H., 112 F.3d at 1586); see also id. at 1586 (refusal to notify of contractual breach also may delay validity challenges, license is not relieved of its obligation to pay contractual royalties for infringing conduct unless it actually ceases payment of royalties and notifies the licensor that the reason for doing so is a belief of invalidity of the patent).

244 See, e.g., Potts, P. v. Claire's Boutiques, Inc., 2006 WL 4863554, at *2 (S.D.N.Y. Mar. 31, 2006) (constructing 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 Studengeellschaft Kohle, M.B.H., 112 F.3d at 1586, and Gen-Probe, Inc., 359 F.3d at 1578))).

245 See, e.g., Eric Bitt & Keith Toms, The Price of Admission: License Challenges To Patents upset a balance that had existed between patent owners' and their licensees' interests and will not return until key issues of patent policy are resolved.

246 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' interests and will not return until key issues of patent policy are resolved.

247 Medimmune, 127 S. Ct. at 776. The Court also noted that any such contractual proviso or comity-like rule that might expressly preclude validity challenges would not raise a jurisdictional but only a merits question.

248 The lower courts also limited Lear to protect the rights of the assignee or licensor. The patent holder was not bound to pay royalties on invalid patents and was not bound to seek a holding of invalidity. The lower courts also limited Lear to protect the rights of the assignee or licensor.
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 damages), 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 \textit{Lear}, however, lower courts have prioritized public policies of minimizing litigation and assuring the finality of judicial processes and of settlements. 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 \textit{Cardinal Chemical Co. v. Morton Int'l, Inc.}, 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." For this reason, a finding of non-infringement does not render a claim of invalidity invalid, and thus courts must adjudicate and resolve validity claims when properly filed. Nor is an invalidity defense waived by failing to advance it in the context of preliminary litigation matters addressing infringement questions.

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. 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 \textit{res judicata}.

Finally, some lower courts in declining to extend \textit{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, but relying on the presumption of validity in this context puts the cart before the horse. The \textit{Lear} and \textit{Cardinal Chemical} policies favoring challenges.

\footnote{See Medianune, Inc. v. Genetech, Inc., 127 S. Ct. 764, 775-76 (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 Seymore 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").}

\footnote{See, e.g., Foster v. Hallow 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., 258 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 contract integument even though it did not create a collateral estoppel, distinguishing \textit{Lear} as it did not involve a settlement agreement and as it not contain any 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)).}

\footnote{Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993).}

\footnote{Id. at 19. See id. at 96.}

\footnote{See id. at 102-03; Alvarez 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 Benveniste, Australia Ltd. v. Nutronics, Inc., 495 F.3d 1340, 1344-49 (Fed. Cir. 2007). Cf. id. at 1350-04 (Dyk, J., dissenting) (arguing that Cardinal Chemical shifts the burden of establishing mootness to the parties raising invalidity, to prove "there is no reasonable likelihood that the controversy over the patent's validity and enforceability will recur").}

\footnote{See, e.g., Pandoor USA, LP v. Airboss Prod. Rs. Inc., 520 F.3d 1354, 1564-66 (Fed. Cir. 2008) (a party does not waive invalidity defense and counterclaim by failing to raise it in opposition to cross motions for summary judgment of infringement); Escosio Indus. v. Vicker, Inc., 191 F.3d 675, 679 (Fed. Cir. 1999) (a party does not waive the invalidity defense by making an offer of judgment under Fed. R. Civ. P. 68, whereby it admits infringement).}

\footnote{See, e.g., Foster v. Hallow Mfg. Co., 947 F.2d 469, 472, 481-82 (Fed. Cir. 1991) (holding that strict construction fosters the policies of both finality and of \textit{Lear}, and that a consent judgment that merely stated the asserted patents were "valid and enforceable in all respects" did not surrender invalidity defense to future accused products that were not essentially the same); Ecobal, Inc. v. Paradise, Inc., 285 F.3d 1302, 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 accused products were not essentially the same). Cf. Diversity Res., Inc. v. Ecobal, 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").}

\footnote{See Foster, 947 F.3d at 475-76 (discussing \textit{res judicata} principles and noting earlier cases distinguishing consent judgments from imposed judgments, based "on the theory that \textit{Lear} precludes parties from removing possible challenges to validity merely by their agreement in the consent judgment contract in \textit{Lear} 258 F.3d at 1369 (noting that the presumption of validity was not a condition to the settlement agreement)."

\footnote{Mark Lemeley for having suggested this point.}


\[1\] A federal patent law, against which background the parties entered into the Agreement, provides a presumption of patent validity . . . it seems counterintuitive and needlessly h razor to construe the Agreement to require Plaintif 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 inference of patent, 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.279

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."

Although the statement is apt, it is hyperbolic, given the existence of appeals of a small percentage of rejected applications to the Board of Patent Appeals and Interferences and from there to the Federal Circuit, it may be 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).280 As discussed below, there is little reason to think that the American patent examiners are doing a better job than their international colleagues,281 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.282

279 Radio Corp. of America v. Radio Eng’g Labs., 293 U.S. 1, 3 (1944).

280 Symposium, Panel 1: KSR v. Teleflex: The Nonobviousness Requirement of Patentability, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 875, 880 (2007). Cf. Ambroziet A. Barabas and Peter Nijkamp, Is There a Tradeoff between Average Patent Pendency and Examination Errors-5 (Social Science Research Network, Working Paper No. 908579), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=908579 (last visited Dec. 23, 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 to so as to determine—assuming fixed resources—whether to have smaller numbers of examiners 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, 57 ST. L. J. 419, 420 (2004)).

281 See supra note 19 and accompanying text. These ligated patents, moreover, reflect patents whose value is diminished and the expense of litigation (after consider.com the likelihood of success in challenging validity). See supra note 27; Buchanan, supra note 19, at 59 (noting differing views of the high rate for a "small but economically important subset of patents"). Cf. Allison et al., supra note 127, at 427 (stating their assumptions for analysis that there is "no reason to believe that valuable patents that are not ligated differ in any systematic ways from valuable ligated patents"); Allison & Sager, supra note 127, at 1787-88 (noting that 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 ligated patents is significantly longer than the average patent). Separate analysis for all the 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 such different social consequences and thus should be treated equally. 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 rejection 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.


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. As the Patent Office itself has acknowledged, it cannot hire its way out of the current problem.

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wrongly granted patents produce. The growing number of patent applications in the United States and around the world and the increasing disparity between such applications and examination resources, however, makes the ever-widening gap between the grant of a patent and the presumption of validity unlikely to close soon. 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

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and adequate training and supervision will invariably be an issue in any large institution. 277 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), 278 which may shift the burden of production and persuasion regarding validity during initial examination. 279

277 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 achieve innovation in them); see also id. at 10-17 (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 5-10 (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).


Whether the Patent Office can shift such burdens of production and persuasion by rule is questionable, particularly as it currently lacks authority to require their application. See Director, Office of Workers’ Comp. Programs, Dept of Labor v. Greenholtz Collectives, 512 U.S. 267, 271 (1994) (assigning burdens of proof is substantive lawmaking); Merck & Co. v. Kessler, 11 F.3d 1543, 1550 (Fed. Cir. 1993) (the Patent Office lacks substantive rulemaking authority).

Cf. Menell, supra note 57, at 16 (hypothetically and humorously claiming a new method of patent legislative reform, which would avoid adopting biased burdens of proving that would be made for all 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 be able to use this leverage as a tool to dissuade of competition") that make them unwilling to reveal such information."

278 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).

279 Buchanan, supra note 19, at 78 (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).

280 See supra note 13, 148 and accompanying text.

281 See supra notes 85, 114, 159 and accompanying text.


284 This problem may be even more significant than has been previously realized, given that patent claims do not expunged their applications — if not also there meaning — over time, not just for infringement analysis but also for validity analysis. See, e.g., In re Hogan, 559 F.2d 595, 694-96 (C.C.P.A. 1977) (enablement is determined solely by reference to the claims at issue at the time of filing, but not at the time of issuance of the patent); Superguide Corp. v. DirectTV Enters., Inc., 538 F.3d 870, 876 (Fed. Cir. 2008) (method and apparatus claims can include later-developed technology only if it is described in the claims at the time of filing); see also discussion supra notes 85, 114, 159 (noting that claiming means that include later-developed technology must be held invalid for the same reason (such as being necessitated by later-developed technology not necessarily for lack of enablement, because applicants would not be able to "point and disclose" that scope); Angen Inc. v. Hochst Marion Roussel, Inc., 314 F.3d 1313, 1319 (Fed. Cir. 2002) (asserting that validly claims are invalid (at least as a matter of law) (C.C.P.A. 1977).
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. 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. 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."

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. 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 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 Office), 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.

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 in violation of the fact of factual inferences of invalidity.

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280 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.

289 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 irrefutable presumptions of validity even after more extensive review. See, e.g., Lichtenman & Lemley, supra note 20, at 418 (suggesting conclusive presumptions for otherwise 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 assure validity is not lessened after such review, even if the likelihood of discovering errors is decreased. Cf. supra notes 229-27 and accompanying text.


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

282 (the 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.

283 [Cf. id. at 45-48

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.

284 See, e.g., id. at 8

285 FTC INNOVATION REPORT 2003, supra note 13, at 15 (discussing anti-competitive and opportunistc lawsuits that rely on weak patents to exclude competitors and to induce licensing).