Bilcare, KSR, Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law

Joshua D Sarnoff

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Abstract

In *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, the Delhi High Court affirmed a lower court order vacating ex parte injunctions against an alleged infringer of a patent, rejecting arguments that the patent should be presumed valid even though the patent was the subject of opposition proceedings. In *KSR International, Inc. v. Teleflex Co.*, the U.S. Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's long-standing interpretation of Section 103 of the Patent Act, *i.e.*, that a challenger seeking to prove invalidity must demonstrate a teaching, suggestion, or motivation to combine prior art references. These cases reveal important insights (within varying procedural and substantive legal contexts) into statutory and judicial presumptions of validity that result from the grant of patents by administrative agencies.

The article explains how such presumptions relate to evidence and proof rather than to the weight accorded to legal judgments. Using *Bilcare* as a reference, the article suggests that opportunities to present evidence challenging validity should be provided even in preliminary relief contexts, and discusses concerns that arise when validity is challenged in both administrative and judicial systems. The article then describes how the *KSR* decision adopted substantive legal rules for obviousness that supersede the statutory presumption of validity, shift the burdens of production and persuasion, and (for some inventions) limit the scope of relevant evidence that can be used by patent holders to prove non-obviousness. Finally, the article argues that the U.S. statutory presumption should not continue to be construed by the courts to impose heightened burdens of proving invalidity.
# Bilcare, KSR, Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law

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Patent validity is a curious thing. Patents are issued, and by their very existence are assumed to be valid by the granting authority. If a patent were 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.²

Patent statutes often declare the truism that issued patents are assumed to be valid,³ provisionally inferring the “ought” of their validity from the “is” of their existence.⁴ 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.”⁵ 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, and the legal process for invalidating wrongly issued patents either may not occur or (again) may not reach the truth of the matter. Thus, a guarantee of validity 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.”⁶ Not all existing patents are valid, and not all always ought to be treated as if they were.

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

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1 Assistant Director, Glushko-Samuelson Intellectual Property Law Clinic, Program on Information Justice and Intellectual Property, Washington College of Law, American University. Thanks to Elliot Cook for research assistance, to Jeff Lubbers, Arti Rai, Paul Rice, and Shamnad Basheer for clarifications, and to Carlos Correa for translation.

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


4 Cf. 3 DAVID HUME, A TREATISE OF HUMAN NATURE 245-46 (Longman, Green London 1898) (criticizing this mode of reasoning about morality from nature: “For as this ought, or ought not, expresses some new relation or affirmation, 'tis necessary that it shou'd be observ'd and explain'd; and at the same time that a reason should be given; for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it.”).


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. As explained in 1890 by Professor William C. Robinson in his seminal patent treatise:

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

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. Because the presumption of validity – like any other presumption – may reflect both the strength of logical inference and social policies, however, it also may shift the burden of persuasion of the presumed fact. The U.S. 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, the nature of 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

7 BLACK’S LAW DICTIONARY (8th ed. 2004). See also id. (a “natural presumption” is “[a] deduction of one fact from another, based on common experience”); id. (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”).

8 See, e.g., Morgan v. Daniels, 153 U.S. 120, 123-24 (1894) (noting different review standards applied to proof of prior invention and priority of invention, and stating “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”).


11 See id. at 432.

12 See, e.g., id. (noting historic dissatisfaction and consequent disregard by courts of the limited presumption of validity imposed by Fed. R. Evid. 301, which does not shift the burden of persuasion).

provides are vigorously contested, as are the burden of persuasion of invalidity that it may impose and the type of evidence that can be used to rebut the logical inferences from the presumption (and from any additional evidence of validity). The nature and strength of the presumption of validity and its concomitant burdens of production and persuasion, however, 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 Bilcare Ltd. v. M/S The Supreme Industries Ltd.,  

which addressed the presumption of patent validity in regard to preliminary relief. The Bilcare decision upheld the vacatur of ex-parte injunctions, based on traditional preliminary injunction considerations of a prima facie case, balance of convenience, and irreparable loss.  

I then discuss (in Part IV) the recent U.S. Supreme Court decision in KSR International Co. v. Teleflex, Inc. The KSR decision addressed the standards for determining obviousness – or inventive step – under U.S. law, and rejected the excessively narrow test for proving obviousness that had been applied for many years by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) – which possesses nearly exclusive appellate jurisdiction over patent matters – and consequently the U.S. Patent and Trademark Office (Patent Office). I conclude (in Part V) by discussing recent studies of patent granting conditions and validity rates that


16 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 decision is made – on the face of the evidence without considerations of credibility.”).  

17 See id. at ¶ 25.  


19 See id. at 1739-43.  

provide reasons to believe that the logical inference of validity from the grant of a patent is weak, as well as policy considerations that provide additional arguments for placing only a minimal burden of persuasion on parties challenging validity. In doing so, I join the U.S. 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.21

In reviewing and discussing the Bilcare case, I seek to highlight the importance of providing an opportunity for evidentiary rebuttal of the presumption of validity in all procedural contexts, even at preliminary stages of patent litigation. If a presumption of validity supplies only a rebuttable inference based on evidence, challengers should be allowed to present evidence that would disprove the inference. Even for preliminary relief, there should 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.22 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.23

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.24 Establishing the proper rules for determining validity is extremely

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22 See infra notes 108-40 and accompanying text.

23 See, e.g., Abbott Labs., Inc. v. Andrx Pharmas. 452 F.3d 1331, 1334-45 (Fed. Cir. 2006) (discussing the standards for obtaining preliminary injunctive relief, providing an opportunity to challenge validity, in regard to a patent for an extended relief formulation of the antibiotic clarithromycin); Michael W. Carroll, Patent Injunctions and the Problem of Uniformity Cost, 13 MICH. TELECOMM. TECH. L. REV. 421, 433-34 (2007) (noting that if competitors enter the market, “the injury cuts to the quick, for it undermines the very purpose for rewarding inventors with patents in the first instance”).

24 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,
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 sequential innovation and investment.\textsuperscript{25}

Finally, I hope to shed light on and thereby exorcise a persistent specter of confusion that haunts validity analysis when the presumption of validity comes into play. Presumptions of validity, like all presumptions, operate in regard to findings of facts and factual inferences to be drawn. In contrast, validity determinations are legal conclusions, based on the facts that have been found and the factual inferences that they supply.\textsuperscript{26} There is an unfortunate and erroneous tendency to confuse the questions of fact with legal conclusions regarding validity of the patent,\textsuperscript{27} and thus to treat the presumption of validity as if it affected the weight to be accorded to the relevant legal factors or to the competing conclusions drawn from the factual inferences. But the presumption of


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

\textsuperscript{26} \textit{See}, e.g., \textit{KSR Int'l Co. v. Teleflex}, Inc., 127 S. Ct. 1727, 1745 (2007) (“The ultimate judgment of obviousness is a legal determination.”); \textit{Hybritech Inc. v. Monoclonal Antibodies, Inc.}, 802 F.2d 1367, 1375-76 (Fed. Cir. 1986) (“prior invention is a question of law, requiring like other validity issues proof of the facts by clear and convincing evidence in light of the presumption of validity in 35 U.S.C. § 282”); \textit{Liebel-Flarsheim Co. v. Medrad, Inc.}, 481 F.3d 1371, 1377 (Fed. Cir. 2007) (“Whether a claim satisfies the enablement requirement … is a question of law…. Anticipation is a question of fact, but validity is a question of law.”) (citations omitted); \textit{Glaxo Group, Ltd. v. Apotex, Inc.}, 376 F.3d 1339, 1345 (Fed. Cir. 2004) (“A determination of whether a patent satisfies the written description and definiteness requirements … is also a question of law that we review de novo.”) (citations omitted).

validity is not a direction to bias the legal scale’s measurements. Rather, it is at most (where it supplies heightened burdens of proof) an evidentiary thumb on that scale.28

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. The Federal Circuit has previously stated that its “precedent requires that the party urging obviousness demonstrate a teaching, suggestion, or motivation [TSM] to combine references,”29 and has prescribed the TSM test to avoid uncertainties of legal judgment that may be supplied by hindsight analysis.30 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 combination31 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.32 Obviousness decisions therefore may require not only finding facts, but also the exercise of administrative and judicial policymaking discretion.33 It would be better if the actual grounds for such legal conclusions were explicitly articulated,34 although it may be

28 See, e.g., Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004) (“On the legal issue of obviousness (as opposed to the underlying factual issues) the grant of a patent does not create a presumption of validity beyond the requirement that the party seeking to invalidate a patent must prove invalidity by clear and convincing evidence.”) (citing SSIH Equip. S.A. v. USITC, 718 F.2d 365, 375 (Fed. Cir. 1983)); Legille v. Dann, 544 F.2d 1, 6 n.24 (D.C. Cir. 1976) (“We distinguish the presumption ‘of law’ the procedural rule dictating a factual conclusion in the absence of contrary evidence from the presumption ‘of fact,’ which in reality is not a presumption at all … and from the ‘conclusive’ presumption, which is actually a substantive rule of law.”) (citations omitted).
29 Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337, 1343 (Fed. Cir. 2007).
30 See, e.g., In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006) (“By requiring the Board to explain the motivation, suggestion, or teaching as part of its prima facie case, the law guards against hindsight in all cases-whether or not the applicant offers evidence on secondary considerations-which advances Congress’s goal of creating a more practical, uniform, and definite test for patentability.”); Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1290 (Fed. Cir. 2006) (“The Court of Appeals for the Federal Circuit’s and its predecessor’s “motivation to combine” requirement likewise prevents statutorily proscribed hindsight reasoning when determining the obviousness of an invention.”) (citing Kahn, 441 F.3d at 986, and In re Fridolph, 134 F.2d 414 (C.C.P.A. 1943)). See generally Gregory N. Mandel, Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational, 67 OHIO ST. L.J. 1391 (2006) (discussing the pervasive effect of hindsight bias on obviousness determinations and noting that both secondary consideration evidence and the TSM test were developed to prevent such bias).
31 Alza Corp., 464 F.3d at 1289 (citations omitted).
32 Great A. & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 153-54 (1950). See id. at 156 (Douglas, J., concurring) (“it is the ‘standard of invention’ that controls…. No ‘finding of fact’ can be a substitute for it in any case.”).
34 Cf. KSR Int’l, Co., 127 S. Ct. at 1741 (“To facilitate review [of whether there was an apparent reason to combine], this analysis should be made explicit.”) (citing In re Kahn, 441 F.3d at 988).
asking too much to expect either complete legislative or judicial specification of the relevant policies and coherent results from their application.\textsuperscript{35}

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 negative the factual inference that the presumption otherwise would require to be drawn from the evidence that triggers it.\textsuperscript{36} The nature of the presumption and the strength of the evidence required to overcome it therefore require careful specification, so as to best arrive at the truth. Presumptions also may serve goals other than arriving at the truth, and thus may need calibration to achieve these goals.

What kind of presumption and what weight should attach to the presumption of validity that exists by virtue of patent grant and statutory declaration? The answer to the question should have a two-fold character. First, the strength of the presumption should reflect the likelihood that the presumed fact of validity of the granted patent is true given the truth of the proven fact that the patent was issued. After all, if invalid patents are commonly granted, reliance on the presumption may routinely result in errors of holding invalid patents to be valid. Second, the weight of the presumption should reflect public policies regarding the importance of various outcomes (or errors) in different substantive and procedural contexts. For example, a weak presumption may result either in errors of holding valid patents to be invalid or delays in providing appropriate relief. Although it should be clear that one shape and size of presumption is unlikely to fit all procedural and substantive contexts,\textsuperscript{37} non-uniformity also has its costs\textsuperscript{38} and finders of fact may be unable to make the fine distinctions that would be required to apply such presumptions.\textsuperscript{39}

Presumptions of patent validity also express normative beliefs regarding the applicable legal rules.\textsuperscript{40} The normative message of the presumption (and the behaviors

\textsuperscript{35} Cf. Janis, supra note 13, 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.”).

\textsuperscript{36} See, e.g., 2 MCCORMICK ON EVIDENCE, § 337, at 414 (5th ed. 1999); PAUL R. RICE & ROY A. KATRIEL, EVIDENCE: COMMON LAW AND FEDERAL RULES OF EVIDENCE 1309-13 (5th ed. 2005).

\textsuperscript{37} See, e.g., Sag & Rohde, supra note 21, at 7 (proposing, \textit{inter alia}, “a variable presumption of validity depending on the level of review that a patent has been subject to”).


\textsuperscript{39} See, e.g., Janis, supra note 13, at 927-28 (citing Addington v. Texas, 441 U.S. 418, 424-25 (1979)).

\textsuperscript{40} See id. at 925-27.
that it seeks to condition) may be affected (or not) by the choice of the evidentiary standard adopted. 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. Legislation, however, is not always carefully drafted regarding how burdens should be apportioned, at different stages of trials, and thus who bears the burdens of pleading, production, and persuasion (particularly of exceptions to general provisions). 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.”

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

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. 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). 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.

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41 See id. at 927-28.
42 See RICE & KATRIEL, supra note 36, at 1309.
43 See 2 MCCORMICK ON EVIDENCE, supra note 36, § 337, at 414.
44 Id., § 337, at 415. See id., § 340, at 424-27 (discussing reasons for adopting a “clear and convincing” standard of proof rather than the traditional “preponderance of the evidence” standard).
45 RICE & KATRIEL, supra note 36, at 1309.
46 Id. at 1311-14 (citing JAMES B. THAYER, PRELIMINARY TREATISE ON EVIDENCE AT THE COMMON LAW 353-389 (1898); J. WIGMORE, EVIDENCE § 2491 (Chadbourn rev. 1961)).
47 RICE & KATRIEL, supra note 36, at 1313-14, 1317-19. Cf. id. at 1317 (noting the tendency for courts to “confuse[] the presumption with the strength of the logical inference that often forms the basis for it”).
48 See id. at 1312, 1319 (citing Edmund M. Morgan, Instructing the Jury Upon Presumptions and Burdens of Proof, 47 HARV. L. REV. 59 (1933); E. MORGAN, BASIC PROBLEMS OF EVIDENCE 34-44 (1962), and MCCORMICK ON EVIDENCE, § 338 (3d ed. 1984)).
Presumptions also may be in conflict, 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.” For example, in Legille v. Dann, 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, a disputed issue of fact remained (precluding summary judgment) regarding the balance of inferences from the competing evidence, with both presumptions having been dispensed with. 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)

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But cf. Legille v. Dann, 544 F.2d 1, 10 n.58 (D.C. Cir. 1976) (“Presumptions do not conflict. The evidentiary facts, free from any rule of law as to the duty of producing evidence, may tend to opposite inferences, which may be said to conflict. But the rule of law which prescribes this duty of production either is or is not at a given time on a given party. If it is, and he removes it by producing contrary evidence, then that presumption, as a rule of law, is satisfied and disappears; he may then by his evidence succeed in creating another presumption which now puts the same duty upon the other party, who may in turn be able to dispose of it satisfactorily. But the same duty cannot at the same time exist for both parties, and thus in strictness the presumptions raising the duty cannot conflict.”) (citing 9 J. WIGMORE, EVIDENCE § 2493, at 292 (3d ed. 1940)).

29 AM. JUR. 2D Evidence § 201 (2007).

51 544 F.2d 1 (D.C. Cir. 1976).

52 See id. at 5-10.

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

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

55 FED. R. EVID. 301.
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. Although various

57 See 2 McCormick on Evidence, supra note 36, § 338, at 416-21 (discussing the need for more than a “scintilla” and particular difficulties when rebuttal evidence is circumstantial, and the need for judicial judgment regarding the inferences).
58 See Rice & Katriel, supra note 36, at 1346-47; Buchanan, supra note 20, at 15 (quoting published model patent law jury instructions of Northern District of California, which recited inability of drafting committee to agree on whether to instruct the jury about the existence of the presumption, and thus including such a presumption in brackets with an explanatory footnote) (citations omitted).
63 See Janis, supra note 13, at 928-29 (citing, inter alia, Hobbs v. U.S. Atomic Energy Comm’n, 451 F.2d 849, 856 (5th Cir. 1971), and 2 Donald S. Chisum, Patents § 5.06 n.84 (2003)); Morgan v. Daniels, 153
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 [w]ere “highly probable.”’”64 In contrast, under the preponderance of evidence standard, disputed facts only must be proved more likely than not to be true.65

The Federal Circuit has treated the presumption of validity as imposing an unvarying burden of production and of persuasion in all contexts by “clear and convincing evidence.”66 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.67

U.S. 120, 124-25 (1894) (holding that Patent Office decisions regarding priority of invention “are to be taken as presumptively correct … unless some obvious error has intervened in the application of the law, or some serious or important mistake has been made in the consideration of the evidence”); id. at 124 (adopting a higher standard than a preponderance of evidence, because the action was in the nature of “set[ting] aside the conclusions reached by the administrative department,” which would be conclusive but for the statutory right to challenge the decision); Radio Corp. of Am. v. Radio Eng’g Labs., 293 U.S. 1, 5-10 (1934) (noting the presumptions that issues of fact decided in the Patent Office should be decided the same way in subsequent litigation “unless the contrary is established by testimony which in character and amount carries through conviction” and the presumption that concurrent findings of lower courts will be accepted “‘unless clear error is shown,’” and requiring to overcome the presumption of validity that the “countervailing evidence is clear and satisfactory.”) (citations omitted).


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


67 See, e.g., Alco Standard Corp. v. Tennessee Valley Auth., 808 F.2d 1490, 1497-98 (Fed. Cir. 1986) (citing, inter alia, Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452 (Fed. Cir. 1984)); Fleming, supra note 13, at 147. In contrast, neither the presumption of validity nor proof by clear and convincing evidence apply to administrative reexamination and reissue proceedings in the Patent Office when a substantial new question of patentability is raised, even though the patent has already been issued. See id. at 149 (citing In re Etter, 756 F.2d 852 (Fed. Cir. 1985), and In re Sneed, 710 F.2d 1544 (Fed. Cir. 1983)); 37 C.F.R. § 1.555 (2007) (“A prima facie case of unpatentability of a claim pending in a reexamination proceeding is established when the information compels a conclusion that a claim is unpatrientable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion
The placement of the ultimate burden of persuasion of invalidity on the party asserting it is 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 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

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68 See American Hoist & Derrick Co., 725 F.2d at 1358.
69 Cf. FTC Innovation Report 2003, supra note 14, at 10 (“it does not seem sensible to treat an issued patent as though it had met some higher standard of patentability” when evaluated earlier only under a preponderance of evidence standard). In contrast, one could readily impose a low burden of production and a higher burden of proof, considering that the presumption operates solely as an inference in the absence of evidence. Where the presumption runs with the heightened burden of proof, additional evidence may be needed to sustain it. Where the presumption runs the other way, the presumption should suffice, as evidence is required to sustain the burden of proof but not to establish it.

70 Fleming, supra note 13, at 147. See Stefan A. Riesenfeld, The New Patent Act in the Light of Comparative Law II, 102 U. PA. L. REV. 723, 741 (1954) (noting that the Patent Office was not bound by res judicata in reconsidering invalidity in light of new references, once courts had found validity in regard to other references) (citing Hoover v. Coe, 325 U.S. 79, 89 (1945), and Jeffrey Mfg. Co. v. Kingsland, 179 F.2d 35 (D.C. Cir. 1949)); Buchanan, supra note 20, at 13 & n.36 (citing cases prior to creation of the Federal Circuit that had held the presumption of validity to be “weakened or destroyed when a challenger relied on PTO-unconsidered art.”). But cf. American Hoist & Derrick Co., 725 F.2d at 1359-60 (“When an attacker, in sustaining the burden imposed by § 282, produces prior art or other evidence not considered in the PTO, there is, however, no reason to defer to the PTO so far as its effect on validity is concerned. Indeed, new prior art not before the PTO may so clearly invalidate a patent that the burden is fully sustained merely by proving its existence and applying the proper law; but that has no effect on the presumption or on who has the burden of proof.”); Corning v. Burden, 56 U.S. (15 How.) 252, 271 (1853) (“It is evident that a patent, thus issued after an inquisition or examination, made by skilful and sworn public officers, appointed for the purpose of protecting the public against false claims or useless inventions, is entitled to much more respect, as evidence of novelty and utility, than those formerly issued without any such investigation.”); Buchanan, supra note 20, at 4 & n.10, 13 n.37 (citing Federal Circuit and earlier cases treating the presumption as strengthened when the art was considered by the Patent Office).

71 See Benjamin & Rai, supra note 21, at 280-84. See also id. at 284-93 (arguing that the APA’s “arbitrary and capricious” standard, 5 U.S.C. § 706(2)(A) (2007), should govern review of factual determinations by the Patent Office).
record before it) and as new evidence is almost always adduced and new issues regarding validity are sometimes raised.\(^{72}\) Instead, such actions may be better characterized as determinations de novo 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 U.S. Patent and Trademark Office (PTO or Patent Office) may be accorded varying degrees of deference in subsequent judicial actions for infringement or declaratory relief.\(^{73}\)

\(^{72}\) See 35 U.S.C. § 143 (2007) (establishing the administrative record for an appeal under 35 U.S.C. § 141). Cf. American Hoist & Derrick Co., 725 F.2d at 1360 (“When new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to disagree with the PTO or with deferring to its judgment or with taking its expertise into account.”). Similarly, because the issues may be determined de novo with newly adduced evidence, deferential APA review standards should not apply to trials following patent denials, even though the administrative agency is a party. See 35 U.S.C. § 145 (2007) (civil actions to obtain patents); 35 U.S.C. § 146 (2007) (civil actions in case of interferences); Dickinson v. Zurko, 527 U.S. 150, 164 (1999) (rejecting arguments regarding inconsistency of review standards for such district court challenges, based on new factfinding and the possibility of new evidence). Cf. 5 U.S.C. § 706(2)(f) (creating a category of APA “de novo review” for agency action “unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court,” which review standard has not been applied except where expressly provided by another statute). The case for APA review in trials is stronger for those resulting from denials by the Board of Patent Appeals and Interferences than for grants, particularly given that the statute provides for a determination regarding claims “involved in the decision of the Board….” 35 U.S.C. § 145 (2007). In contrast, in infringement and declaratory litigation only the patent need be offered into evidence, and not any of the prosecution history or reasoning of the Patent Office. APA review standards thus should likely apply only on direct review of the record of administrative action in appeals from patent denials and in appeals from grants in interferences and in inter partes reexaminations. See 35 U.S.C. § 141 (appeals from Board of Patent Appeals and Interferences). The Patent Act does not provide jurisdiction for third parties to challenge grants of patents on the record of the Agency’s action, although such actions if allowed would likely be subject to deferential APA review standards. Cf. Benjamin & Rai, supra note 21, at 280-84 (arguing that APA review standards apply to such judicial challenges to granted patents).

\(^{73}\) See American Hoist & Derrick Co., 725 F.2d at 1359 (“When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.”). Cf. id. (noting that new prior art or other new evidence “eliminate[s], or at least reduce[s], the element of deference due” to the Patent Office); Benjamin & Rai, supra note 21, at 294-301 (arguing that agency applications of law to fact are likely subject to the same review standards as interpretations of law, that patent grants should be subject to Skidmore deference – which applies to non-precedential decisions and depends on the thoroughness of the agency’s reasoning – rather than Chevron deference – which applies to agency decisions to which Congress delegated authority to create law and under which reasonable agency interpretations of an unclear provision should be sustained; that patent denials should be accorded greater deference either under Chevron or Skidmore as they are more likely to go through multiple layers of review; and that policy decisions are subject either to the APA “abuse of discretion” and “arbitrary and capricious” standard of 5 U.S.C. § 706(2)(A), which is actualized through evaluating whether the agency took a “hard look” at the competing policies) (citing United States v. Mead Corp., 533 U.S. 218, 226-30 (2001); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944); Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 842-44 (1984); Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Ins. Co., 463 U.S. 29, 43 (1983); Al-Fayed v. CIA, 254 F.3d 300, 309 (D.C. Cir. 2001) (noting that the “application of a legal standard to a set of underlying facts … may best be classified as a mixed question of law and fact” but noting that the proper appellate review standard for such questions “is often difficult to determine”); NLRB v. Hearst, 322 US 111 (1944) (articulating the pre-APA standard for applications of law to fact). Even if
III. Bilcare and Preliminary Relief in India and the United States

In *Bilcare Ltd. v. M/S The Supreme Industries Ltd.*, the appellate court decided two appeals from trial court orders vacating earlier ex parte injunctions, during which appeal one of the respondents had filed administrative opposition proceeding in the Indian Patent Office to invalidate the patent at issue. The patent addressed moisture-resistant, translucent, multi-layer, metal-coated, polyvinylchloride (PVC) films for packaging medicine tablets. The appellate court noted that the “controversy … swirl[ed] around the question, ‘is there any presumption in favour of the validity of the patent for grant of temporary injunction in favour of patentee.’” More precisely, the question is what kind of presumption should apply to 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 lies in its favour, and (iii) it would suffer irreparable injury if injunction is not granted.” 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, and engaged in a detailed evaluation of five APA review standards were to apply to facts found by the Patent Office, however, they should not apply to factual questions where new (perhaps even cumulative) evidence is introduced at trial, which must be determined de novo. See supra note 72; Benjamin & Rai, supra note 21, at 319 (noting that APA deference cannot apply to factfinding where the agency has not passed on the question).

74 See Mrinalini Kochupillai, The Bilcare decisions by the Delhi High Court: Preliminary injunctions and the presumption of validity of a ‘new’ patent (May 12, 2007), available at http://spicyipindia.blogspot.com/search/label/Injunction (last visited July 5, 2007) (noting strategic reasons for filing in different courts; by filing in the District Court, Bilcare sought to avoid transfer to the Delhi High Court and the possibility of a caveat that might delay issuance of an ex parte injunction, based on the prior filing of an opposition by one defendant).


77 *Id.* at ¶ 6. See also id. at ¶¶ 7-12. In other cases, the preliminary injunction test is framed as a four-part inquiry similar to that in the United States, including reasonable likelihood of success and impact on the public interest. See Tarun Mathur, *Patent Litigation Trend in India 30-31 Social Science Research Network, Working Paper No. 995994), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=995994 (last visited July 5, 2007) (citing Godrej Soaps Ltd. & Ors. v. Hindustan Lever Ltd. & Ors PTC (Suppl.) (1) 501 (Cal) (DB)),.


79 See id. ¶ 9 (quoting Giridhari Balaram Radhakrishnani and another v. M/s Mahisa Electronics and others, ILR 1995 Karnataka 2010, ¶ 10-15, which required consideration not only of these issues but also of appropriate security, and rejected the holding in American Cyanamid Co. v. Ethicon Ltd., ILR 1976 Karnataka 426), that it was not necessary to make out a prima facie case of infringement in order to obtain an interlocutory injunction so long as the claim is not frivolous). In a related, case, Judge Sanjay K. Kaul
considerations: “(i) [w]hether the Act in question is really an invention…. (ii) [w]hether it is not of recent origin? (iii) [w]hether it pertains to three-layered product or two-layered product [and thus infringes]? (iv) … whether the damages will provide adequate remedy should the claim succeed? (v) … 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 that

“the 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.”

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 defence 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 given that there were “tangible grounds of the Delhi High Court noted Bilcare had not established a prima facie case for preliminary relief given evidence raising doubts about validity. See M/S Bilcare Ltd. v. M/S Amartara Private Ltd., IA NOS 10848/2006, 13971/2006 and 11160/2006 IN CS(OS)No.1847/2006, ¶¶ 51-59 (Mar. 20, 2007).

80 See id. at ¶ 9 (quoting Giridhari Bali Ram Radhakrishnani, at ¶ 15, that no temporary injunction would issue “when the patent is a recent one and its validity is questioned.”); id. at 21 (quoting M/s National Research Development Corp. of India, New Delhi v. M/s The Delhi Cloth & General Mills Co. Ltd. and others, AIR 1980 Delhi 132, “that 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 worked the court would … presume the patent to be valid one. If the patent is more than 6 years old and there has been actual user it would be safe for the court to proceed upon this presumption.”). In contrast, Bilcare had relied on M/s Metro Plastics Indus. v. Galaxy Footwear, AIR 2000 New Delhi PTC (20) 1 (Del.) (FB), which held that an injunction should not be refused merely because the registration was recent. See Nair, supra note 75.


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

85 Id. at ¶ 24 (quoting Telemechanique v. Controls (I) Ltd. v. M/s Schneider Electric Indus. SA, [2002 I AD (Del.) 451]).
for suspicion of the alleged invention\textsuperscript{86} 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 lean on the side of respondents.\textsuperscript{87}

In summary, the appellate court in Bilcare appears to have: (1) adopted the traditional three-part framework for assessing preliminary relief with a high burden of justification placed on the party seeking it; (2) rejected a presumption of validity based on the existence of the patent or on the time that elapsed since its grant (particularly given 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.\textsuperscript{88} 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.\textsuperscript{89} Irreparable harm and likelihood of success are normally considered the most important of the factors.\textsuperscript{90}

\textsuperscript{86} See id. at ¶ 14 (discussing a prior art publication that referenced multi-layer films of varying finish, placing “a large question mark over the so called invention,” which would require “evidence of experts, investigation and other evidence”).

\textsuperscript{87} Id. at ¶ 25.

\textsuperscript{88} See, e.g., Brian Daley, Rachel Morgan & Kimberly Van Voorhis, Pre-Trial Proceedings in Patent Infringement Actions: A Comparison Among Canada, The United Kingdom, and the United States of America, 35 AIPLA Q.J. 113, 118 (2007) (describing essentially the same three factors under Canadian law for interlocutory injunctions) (citing RJR MacDonald Inc. v. Canada, [1994] 1 S.C.R. 311, 314-15 (Can.)); id. at 134 (describing the requirements to persuade the court “that there is a serious issue to be tried, that damages would not be an adequate remedy, and that the balance of convenience favors the granting of an injunction”) (citing Am. Cyanamid Co. v. Ethicon, [1975] A.C. 396 (H.L.) (U.K.)). But cf. David W. Hill & Shinichi Murata, Patent Litigation in Japan, 1 Akron Intell. Prop. J. 141, 181-82 (2007) (noting that provisional injunctions in Japan are decided in a separate proceeding from the main infringement action, where the issues are scrutinized as closely as in the main suit and which employs a two-part test of proving infringement and the necessity of temporary relief, based on considering relative hardship of denying or granting the provisional injunction without hearing witnesses and without considering the amount of damages).


It would be difficult to make a convincing argument that courts (at least in the United States) should presume irreparable harm and inadequacy of damages from refusing to grant a preliminary injunction. This is particularly true given the U.S. Supreme Court’s recent decision in *eBay, Inc. v. MercExchange L.L.C.*, which held that traditional equitable considerations apply to permanent injunctions in patent law and that there is no general rule that courts should issue such injunctions. If a Court may not do so once it has determined a patent to be valid and infringed, it should have even less reason to do so in a preliminary relief setting. Rather, courts must carefully evaluate the nature of the patent in question, how the patent holder has sought to exploit it, and how the alleged infringement will affect the patent holder’s interests before determining whether irreparable harm will result and a damages remedy will be inadequate. An economic analysis of the incentive effects and need for preliminary or permanent injunctive relief for the wide variety of patentable subject matter, industries, and patent-holder and competitor practices is far beyond the scope of this article.

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

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91 See, e.g., *z4 Techs., Inc. v. Microsoft Corp.,* 434 F.Supp.2d 437, 439-40 (E.D. Tex. 2006) (rejecting arguments for a presumption of irreparable harm for permanent injunctions once validity and infringement have been found, raised by patent holder’s citation to Supreme Court dicta regarding preliminary injunctions and analogy to copyright cases, because the only lost licensing revenues were from the infringer and a reasonable royalty would adequately compensate for them) (citing *Amoco Production Co. v. Village of Gambell, Alaska*, 480 U.S. 531, 542, (1987)).
93 See *id.* at 1841 (requiring courts to consider permanent injunctions under “the traditional four-factor framework that governs the award of injunctive relief” and that courts’ equitable discretion “must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards”). See also *id.* at 1839, 1841 (rejecting the lower court’s articulation of “the general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances”) (quoting *MercExchange L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005));
94 See *Carroll, supra* note 23, at 431-32 (noting that such a presumption is unwarranted in light of the *eBay* decision even after the plaintiff has shown a likelihood of success on the merits).
95 See *id.* at 432-35 (citing, *inter alia*, Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking, 85* TEX. L. REV. (forthcoming 2007)). Cf. *Novozymes A/S v. Genecorp Intern., Inc.*, 474 F.Supp.2d 592, 612-13 (D. Del. 2007) (finding irreparable harm from losses suffered by the patent holder’s subsidiary-licensee and because “the statutory right to exclude represents a benefit that, under these circumstances, cannot be equated by an award of cash” by preventing the patent holder from having “to assist its rival with the use of proprietary technology”).
practices. Uncertainties regarding the scope or validity of a particular patent or class of patents thus should affect the willingness of courts to grant injunctive relief. 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. 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.” As the appellate court in Bilcare noted, however, the need for such tailored determinations regarding the nature of the patent holder’s market and effects on that market have the potential to turn preliminary matters into mini (if not large) trials. Although the presumption of validity may be relevant to such decisions, it cannot by itself supply the requisite policies nor limit the evidence to be considered.

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

In regard to infringement, the appellate court in Bilcare recited a case holding that it was not necessary for the patent holder to present a prima facie case, but only to demonstrate “that the claim is not frivolous or vexatious,” following which the court

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97 See Carroll, supra note 23, at 435-37 (discussing the situation articulated in eBay where disproportionate harms may result by granting an injunction because the patent is a small component of the product sold) (citing 126 S. Ct. at 1842).
98 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).
99 See id. at 439-42 (noting the non-uniformity of public interest considerations, that “the public interest factor [for injunctive relief] is “particularly salient in intellectual property cases because the very point of granting the owner a right to exclude is to encourage investments that will serve the public interest,” and that static versus dynamic efficiencies must be considered – which require considerations beyond the particular case before the court).
100 Commonwealth Scientific and Indus. Res. Org. v. Buffalo Tech., Inc., 2007 WL 1739999, at *7 (W.D. Tex. June 15, 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.”).
101 Cf. supra note 79 and accompanying text.
103 See, e.g., Feldhaus, supra note 90, at 535.
should consider the balance of convenience. In regard to validity, the decision in Bilcare likely imposed either a heightened evidentiary standard (precluding injunctive relief where “the validity of the patent itself has been questioned and a revocation petition has been filed,”) 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. 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 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.”

In sum, in the United States the patent holder seeking preliminary relief bears the burden 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

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106 See id. ¶ 25 (“Secondly, there are tangible grounds for suspicion of the alleged invention.”).
107 Abbott Labs. v. Andrx Pharmas., Inc., 452 F.3d 1331, 1335 (Fed. Cir. 2006) (citing, inter alia, Amazon.com, Inc. v. Barnesandnoble.com, 239 F.3d 1343, 1350-59 (Fed.Cir.2001), and Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1364 (Fed.Cir.1997)). The standard for appellate review of the grant or denial of the preliminary injunction is an abuse of discretion. See id. at 1334-35 (citing Polymer Techs., Inc. v. Bridwell, 103 F .3d 970, 973 (Fed.Cir.1996)).
substantial question regarding validity, in which case the burden or production and persuasion shifts back to the patent holder to prove likelihood of validity by demonstrating that the substantial question “lack[s] substantial merit” without resort to the clear and convincing evidence burden of persuasion imposed by the presumption of validity. Evidence of a substantial question regarding validity also negates any presumption of irreparable harm and, absent any other relevant concerns, inclines the public interest to favor denying a preliminary injunction. If this were not enough, factual determinations made in this context are reviewed on appeal only for clear error.

As noted by the dissenting judge, this approach alters both the burden of persuasion and eliminates the presumption of validity that supposedly attaches at all stages of litigation. Under the dissenting judge’s view, the patent holder would merely need to rely on the presumption in regard to validity, or if the challenger had presented sufficient evidence to demonstrate it was likely to rebut the presumption the patent holder would need only to present sufficient evidence to preserve the likelihood that it would succeed in preventing the challenger from proving invalidity under the applicable burden of persuasion (by clear and convincing evidence). In contrast, to have the likelihood of success factor weigh in its favor, the alleged infringer would need to produce sufficient evidence not only to raise a substantial question of patentability but also to rebut the presumption of validity and to likely overcome under the clear and convincing burden of persuasion any additional evidence to be introduced by the patent holder.

The point I wish to make here is not to resolve which evidentiary approach is correct. Of course, the choice of burdens of production and persuasion for preliminary relief would be much simpler if the presumption of validity either did not arise in such a context or were treated as a bursting bubble and imposed no heightened burden of persuasion. Rather, I wish to emphasize that policy choices are needed in regard to whether and how presumptions of validity should apply in different procedural contexts. Policies must be developed not only regarding the legal weight to be accorded to various

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108 Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1375 (Fed. Cir. 2006) (citing Genentech, Inc. 108 F.3d at 1364). See PHG Tech., LLC v. St. John Co., Inc., 469 F.3d 1361, 1365 (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 Uniao Do Vegetal, 126 S. Ct. 1211, 1219-20 (2006)). Given the burden on the patent holder to demonstrate likely success on the merits, it is unclear whether the patent holder must bear a burden of production regarding the lack of substantial merit of an anticipated (but not yet produced) showing of a substantial question invalidity. But cf. Sanofi-Synthalabo, 470 F.3d at 1378 (noting argument that the District Court erred in concluding that challenger had not raised a substantial question of patentability).

109 See id. at 1347-48.

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

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

112 See Abbott Labs., 452 F.3d at 1350.
equitable balancing factors, but also regarding the evidentiary burdens to be imposed when demonstrating the facts that trigger the conclusions regarding those factors.  

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

Given that the timing of decisions in the 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.  

Given that courts may not be as efficient as administrative agencies in invalidating invalid patents, but that administrative agencies typically are not

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113 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”).

114 See, e.g., J. Steven Baughman, Reexamining Reexaminations: A Fresh Look at the Ex parte and Inter partes Mechanisms for Reviewing Issued Patents, 89 J. PAT. & TRADEMARK OFF. SOC’Y 349, 354-56 (2007) (noting the absence of the “clear and convincing” evidentiary presumption and burden of persuasion in reexamination proceedings, as well as different claim construction rules and the ability to avoid discovery and cross-examination); Hill & Murata, supra note 88, at 177-78 (discussing relatively recent decision permitting “courts presiding over infringement actions [to] decide whether it is clear that a patent is valid,” in which case no injunction will issue, and a new statutory provision preventing the patent holder from enforcing the patent if it has been held invalid in the Japanese Patent Office) (citing Texas Instruments v. Fujitsu, MINSHU, vol. 54, No.4, 1268, and Section 104ter of the Japanese Patent Law, TOKYO HO, Law No. 120 of 2004, art. 104-3, translated at http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf).

115 See e.g., Baughman, supra note 114, at 355 & nn. 27, 28 (noting the potential for stay of litigation when a reexamination is pending, depending on how much litigation activity has occurred, whether the reexamination is posed for proper purposes or delay, whether reexamination is likely to simplify trial issues, and whether a court believes that it would benefit from having the Patent Office make a first assessment of invalidity evidence, and noting statutory provisions for expedited consideration and for stay unless it “would not serve the interests of justice” in case of inter partes reexaminations) (citing 35 U.S.C. §§ 305, 314(c) (2007), and quoting 35 U.S.C. § 318 (2007)); Hill & Murata, supra note 88, at 178 (noting that judgments based on changed administrative actions provide cause for retrial, but that administrative determinations may have one-way effect to permit retrial only when a decision of invalidity follows a judicial finding of validity but not when a determination of validity follows a judicial finding of invalidity, and noting provisions for consultation – but not deferral – between the courts and the Japanese Patent Office) (citations omitted). See also Kenji Shimada, et al., Patents as Property: International Injunctive Relief, 14 CASRIP Newsletter (2007) (noting the German rule that an injunction may be denied if there is any doubt as to the patent’s validity and also strategic filing in Italy, where patents are rarely granted but filing will preclude another signatory country from taking jurisdiction under the Brussels Convention on Jurisdiction and enforcement of Judgments in Civil and Commercial Matters, O.J. L 299/32 (1972), amended by O.J. L 304/77 (1978), amended by O.J. L 258/1 (1989)).

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

It is also 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 so as 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.

117 In the United States, the factual determination of infringement but not construction of the patent claims may raise the constitutional right to a trial by jury. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 384-88 (1996).
119 Id. at ¶ 26. See also Nick Bennett, United Kingdom: Awards of Damages in UK Patent Cases Will Prevail Notwithstanding Findings of EPO, available at http://www.mondaq.com/article.asp?articleid=48492&print=1 (last visited July 5, 2007) (noting that patentees will seek to bring infringement actions as early as possible in jurisdictions where the procedure for doing so is quick and efficient, before an unfavorable EPO ruling could be issued, and that defendants will seek stays of such litigation, with the result being even less uniformity across Europe).
120 See, e.g., Sag & Rohde, supra note 21, at 78-79 (recommending a general preponderence of evidence presumption of validity, which would be raised following post-grant review that sustains validity and would be replaced with a presumption of invalidity following post-grant review, so as to make more fair the comparative lack of procedural safeguards in such review).
121 See Carroll, supra note 23, at 429-30 (noting concerns raised by the Chief Justice in concurrence in eBay regarding predictability of outcomes and “‘the basic principle of justice that like cases should be decided alike.’”) (quoting eBay, Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1841-42 (2006) (Roberts, C.J., concurring) (quoting Martin v. Franklin Capital Corp., 126 S. Ct. 704, 710 (2005)).
122 Cf. eBay, 126 S. Ct. at 1841 (“the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts”).
B. The presumption of validity, patent life, and variable burdens.

The appellate court in *Bilcare* appears to have rejected a presumption of validity in regard to preliminary relief, basing its conclusion both on the statutory declaration that there is no guarantee of validity and on the fact that the patent was recently 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 since the patent was issued is highly suspect. The timing of the lawsuit assessing validity may reflect the degree of opportunity for competitors to have sought earlier invalidation. But it seems an extremely poor proxy for the likelihood that the patent was granted correctly and is valid. As many commentators have noted in regard to United States law, where a determination of invalidity in one action will bar enforcement in another but not vice-versa, the incentives for bringing challenges to validity are substantially inadequate, and thus the timing of making such a challenge (based on the patent holder’s or challenger’s choices to litigate) may have little to do with 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, or at least not in the way the Indian rule of

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124 See *Bilcare*, No. FAO 70/2007, at ¶ 21; id. at ¶ 23 ((quoting Hindustan Lever Ltd. v. Godrej Soaps Ltd. and Others, [1997 PTC (17) 756], at ¶ 29 (“if the patent is a new one, a mere challenge at the Bar would be quite sufficient for the refusal of a temporary injunction, but if the patent is sufficiently old and has been worked, the Court would, for the purpose of a temporary injunction, presume the patent to be a valid one”)); supra note 77 and accompanying text.


126 *Cf. Sag & Rohde*, supra note 21, at 22-23 (noting that litigation costs, rather than validity of claims, may determine whether a prospective licensee will pay the demand or seek to litigate validity).

practice suggests. The length of time since the patent issued may actually decrease the likelihood of irreparable harm or of success on the merits of proving infringement and validity (or of overcoming invalidity challenges). Patents are more likely to be valuable and damages harder to calculate during their early years.\textsuperscript{128} Similarly, the amount of time since the patent has issued may be a weak proxy for assessing the balance of hardships (or the “balance of convenience”).\textsuperscript{129} If significant time has gone by, both the patent holder and the alleged infringer may have made extensive investments and may have significant reliance interests. Nor is it clear how additional time would affect public interests in assuring protection of incentives for valid patents and protection from market harms where invalid patents are asserted.\textsuperscript{130} Substantial additional empirical and policy analysis is required before time should be treated as a relevant variable.

The more difficult presumption of validity questions raised by Bilcare relate to likelihood of success on the merits, particularly given the scant record that was before the appellate court and its citation to “settled law” in India that an injunction should not issue when an administrative revocation proceeding had been filed.\textsuperscript{131} It may have been entirely unnecessary to assess validity to justify upholding the vacatur of the ex parte injunctions, given that the burden of proving infringement was on the patent holder and that a significant question of non-infringement was demonstrated by the respondents.\textsuperscript{132} 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

\textsuperscript{128} See Carroll, supra note 23, at 432-33 (given that litigated patents tend to be recently granted, and that for new inventions market values are much less certain – and 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, 20 BERKELEY TECH. L.J. 435, 460 (2004)). See also John R. Allison & Thomas W. Sager, Valuable Patents Redux: On the Enduring Merit of Using Patent Characteristics to Identify Valuable Patents, 85 TEX. L. REV. 1769 (2007) (updating the Valuable Patents analysis with additional tests and responding to criticisms of that analysis in David E. Adelman & Kathryn L. DeAngelis, Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate, 85 TEX. L. REV. 1677 (2007)).

\textsuperscript{129} See, e.g., id. at 433-37 (discussing how post-grant licensing and working behaviors by the patent holder will affect the harm of infringing conduct and how the nature of the patent relative to the infringer’s activities affects the balance of hardships).

\textsuperscript{130} See, e.g., id. at 440-41 (noting uncertainties in trading off short-term and long-term interests).


\textsuperscript{132} See Comments of Mrinalini Kochupillai and Shamnad Basheer on The Bilcare decisions by the Delhi High Court: Preliminary injunctions and the presumption of validity of a ‘new’ patent, available at https://www.blogger.com/comment.g?blogID=17664472&postID=3538153164842343905&isPopup=true (last visited July 5, 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).
then had no reason to opine that the traditional equitable factors all inclined against the injunctions (and thus in favor of upholding their vacatur).  

In the U.S., the decision to commence an *ex parte* or an *inter partes* reexamination proceeding requires an initial finding by the Patent Office of a “substantial new question of patentability.”  

Such a finding arguably should eliminate the presumption of validity once made, not only for the administrative proceeding but also for judicial actions (unless and until a decision is reached). After all, if the presumption arises from the inference of correct process in the Patent Office (even if it serves additional purposes), the reexamination order reflects a preliminary determination that calls its earlier determination of a correct process into question.  

What court would then believe (much less believe strongly) in the factual inference provided by the initial determination from the grant to the validity? Of course, formally eliminating the presumption of validity and thus changing the standard for proof may not necessarily lead to different outcomes in administrative and judicial decisionmaking, given that deference to the initial administrative judgment may nevertheless be supplied.

In contrast, once a patent issues from an *ex parte* or *inter partes* reexamination, the factual inference from the grant to its validity 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 decisionmakers, 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. Of course, even a successful opposition does not guarantee validity, and the heightened presumption still might not apply to evidence of invalidity not considered in the reexamination or opposition proceedings.

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

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133 *See Bilcare*, No. FAO 70/2007, at ¶ 25.
135 *Cf.* Benjamin & Rai, supra note 21, 297-99 (arguing that Patent Office determinations of validity are likely entitled only to *Skidmore* deference); *id.* at 296 (*Skidmore* deference considers, among other factors, “‘the thoroughness evidence 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)).
137 *See* 35 U.S.C. § 303(a).
138 *See* e.g., Sag & Rohde, supra note 21, at 77-79 (suggesting a higher presumption of validity for patents upheld in post-grant review).
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.\textsuperscript{139} 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 decisionmaking documented in the administrative record.\textsuperscript{140}

IV. \textit{KSR} and Substantive Rules Regarding Invalidity

A. \textit{KSR}, proof of obviousness, and the presumption of validity

In contrast to the complex procedural considerations raised by \textit{Bilcare}, the recent decision in \textit{KSR International Co. v. Teleflex, Inc.}\textsuperscript{141} raises complex substantive considerations regarding when the presumption of validity should be superseded by competing presumptions or by substantive legal rules that may shift the burdens of persuasion and proof, and that may limit the scope of relevant evidence. As discussed below, the \textit{KSR} decision reaffirmed earlier U.S. Supreme Court precedents that imposed such substantive rules regarding the obviousness of particular categories of inventions (combination patents).\textsuperscript{142} That superseding presumptions of invalidity could be adopted should not be a surprise, much less a cause for concern.\textsuperscript{143} For example, legislation was recently introduced in the United States that would have adopted a rebuttable, preponderance-of-the-evidence presumption of obviousness in regard to patents for business method inventions.\textsuperscript{144} Nor should it be a surprise that legal rules may shift burdens of production and persuasion or may limit the evidence. For example, in the employment discrimination context, courts have adopted rules that shift the burden of persuasion to the defendant to produce evidence of a non-discriminatory motive, once the plaintiff presents a prima facie case of disparate treatment.\textsuperscript{145} The Federal Rules of

\textsuperscript{139} Cf., e.g., Ravicher, supra note 20, at 14 (recommending that examiners document in the record of the patent grant their claim constructions, which should not impose additional burdens as they are already required to adopt such constructions in order to perform examinations); Joseph S. Miller & James A. Hilsenteger, \textit{The Proven Key: Roles and Rules for Dictionaries At the Patent Office and the Courts}, 54 AM. U. L. REV. 829, 896-901 (2005) (recommending that the Patent Office require applicants to specify during examination the choice of dictionaries to be used when construing their claims, and noting the relatively low additional costs of doing so and substantial systemic cost savings that would result).

\textsuperscript{140} See supra notes 30, 34, 71-73 and accompanying text.

\textsuperscript{141} 127 S. Ct. 1727 (2007).

\textsuperscript{142} See id. at 1837-41.

\textsuperscript{143} See, e.g., Philippe Signore, \textit{There is Something Fishy About a Presumption of Obviousness}, 84 J. PAT. & TRADEMARK OFF. SOC’Y 148 (2002).

\textsuperscript{144} See John H. Barton, \textit{Non-Obviousness}, 43 IDEA 475, 501 & n.19 (2003) (citing H.R. 1332, 107th Cong. (Apr. 3, 2001), which would have created a rebuttable presumption of obviousness, using a preponderance of evidence standard, for “a business method invention … if the only significant difference between the combined teachings of the prior art and the claimed invention is that the claimed invention is appropriate for use with a computer technology,” with two specified exceptions).

Evidence expressly permit exclusion of certain types of evidence having some logically
probative force on substantive policy grounds (including that it would lead to “confusion
of the issues” or “waste of time”),146 and numerous substantive legal rules (or conclusive
presumptions) may prevent consideration of evidence regarding what would otherwise be
highly relevant facts.147

Whether and when such substantive rules should supersede the presumption of
validity from the grant of the patent, however, will require further legislative or judicial
elaboration and resolution. If the 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.148 Even if the burden of
producing a prima facie case is placed initially on the Patent Office,149 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
again returns us to the question of the deference to be accorded to administrative
decisions in regard to evaluation of similar and of new evidence.

What then did KSR establish in regard to the legal rules for proving obviousness?
The patented invention at issue addressed an adjustable-position pedal assembly with an
electronic sensor for controlling a vehicle engine’s throttle. The trial court granted
summary judgment of obviousness of the invention (considering the presumption of
validity), based on the defendant’s evidence that all of the elements of the claim were
make out a disparate impact claim is an evidentiary standard that does not apply to pleading and motions to
dismiss).

146 FED. R. EVID. 403. See, e.g., Old Chief v. United States, 519 U.S. 172, 180-84 (discussing the factors to
consider when balancing the probative value of evidence with unfair prejudice it may cause). See generally
Edward J. Imwinkelried, The Meaning of Probative Value and Prejudice in Federal Rule of Evidence 403:

conclusive presumption – that declared evidence of actual paternity irrelevant except in limited
circumstances and thus precluded putative natural father from presenting evidence of paternity). Cf. RICE &
KATRIEL, supra note 36, at 1311 (“so-called ‘conclusive presumptions’ … are not presumptions at all.
They are simply rules of law that conclusively establish certain facts in a cause of action.”); Daniel A.
Richman, Applying the Constitutional Doctrine of Irrebuttable Presumption to the Handicapped –
Gurmankin v. Costanzo, 27 DEPAUL L. REV. 1199, 1199 & n.4 (1978) (noting Due Process concerns with
irrebuttable presumptions and citing 2 MCCORMICK ON EVIDENCE, § 342, at 802-04 (2d ed. E. Cleary

148 See Barton, supra note 144, 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, which burden of production for practical reasons should be placed on the applicant given the
frequency of rejections under the proper standard and given that the “kind of evidence needed, a
comparison with industry practice, is probably better known to the applicant-indeed many patents already
include information on the reasons why the proffered invention is much better than what was happening in
Oetiker, 977 F.2d 1443 (Fed. Cir. 1992)).

149 See Signore, supra note 143, 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); id. at 153-56 (discussing support for the prima facie case approach under the
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 the combination of elements found in the prior art” 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.

*Graham* itself 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* implicitly 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.

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150 *See* 127 S. Ct. at 1734, 1737-38.
151 *See id.* at 1738-39.
153 127 S. Ct. at 1739.
154 383 U.S. at 17-18.
155 *Id.* at 18.
156 52 U.S. (11 How.) 248 (1851).
157 127 S. Ct. at 1734.
158 *Id.* at 1735.
But *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 non-obvious 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 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 possess a new (and not just an improved) function, the legal question of obviousness is fully determined.

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160 127 S. Ct. at 1740 (quoting 425 U.S. at 282) (emphasis added).
161 Evidence also might rebut the showing that all the elements of the combination were in the prior art, which triggers the legal rule. It is unclear whether the legal rule is triggered merely by a prima facie showing that all of the elements were in the prior art, or whether the challenger must introduce some evidence of the lack of novel functions or unexpected results.
163 See id. at 50-52.
164 See id. at 50-52. However, the Court also described the holding in *Adams* as based on “the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious,” suggesting a competing (but not clearly superseding) presumption. Id.
165 Id.
166 See *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976) (“Though doubtless a matter of great convenience, producing a desired result in a cheaper and faster way, and enjoying commercial success, *Dairy Establishment* ‘did not produce a “new or different function” . . . within the test of validity of
At other points, however, 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.,\textsuperscript{167} 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.”\textsuperscript{168} 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.”\textsuperscript{169} 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 because a person skilled in the art would not have had an apparent reason to make the combination.\textsuperscript{170}

The Court further suggested that different substantive legal rules for obviousness may apply depending on the nature of the combination invention. “Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement.”\textsuperscript{171} The Court thus implied that the substantive rules limiting evidence of non-obviousness should be reserved for these special cases (simple substitution and mere application of a known technique), with the remaining categories of combination inventions subject to less stringent evidentiary requirements. In these other cases, “often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”\textsuperscript{172} But for all cases, the Supreme Court expressly directed lower courts to evaluate obviousness by determining if

\textsuperscript{167} 340 U.S. 147, 152 (1950).
\textsuperscript{168} 127 S. Ct. at 1739 (emphasis added).
\textsuperscript{169} Id. at 1740 (emphasis added).
\textsuperscript{170} One of the amicus briefs in KSR proposed a similar, burden-shifting approach based on whether the elements of the invention were in the analogous art, creating a rebuttable presumption of a motivation to combine them. See Brief for International Business Machines Corp. as Amicus Curiae in Support of Neither Party, KSR International Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007) (No. 04-1350), at 18-26 (also noting that the presumption gives meaning to the level of ordinary skill in the art and thus is consistent with both the statutory language and the Graham test).
\textsuperscript{171} 127 S. Ct. at 1740.
\textsuperscript{172} Id. at 1740-41. See id. at 1741 (“Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”) (emphasis added).
the invention triggers the legal rules applicable to combination inventions. In some cases, the combination invention rules will not apply, because the evidence will not be sufficient to prove that all of the elements of the invention were in the prior art.

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

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173 *See id.* (“a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.”) (emphasis added).
174 *Id.* at 1741.
175 *Id.* (citing *Application of Bergel*, 292 F.2d 955, 956-57 (C.C.P.A. 1961)).
176 *Id.* at 1742-43.
177 *Id.* at 1743-46.
178 *See id.* at 1743 (“When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court's recitation of the relevant prior art and its determination of the level of ordinary skill in the field.”); *id.* at 1745-56 (noting that the ultimate judgment of obviousness is a legal question and “the obviousness of the claims is apparent” in light of the undisputed facts regarding the prior art, the scope of the claim, and the level of ordinary skill).
179 *See id.* at 1745 (“Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious.”).
180 The patent holder had offered evidence regarding commercial success, but had not provided sufficient evidence to demonstrate the amount of success or the required nexus of such success to the patented invention, and had not introduced any other secondary consideration evidence (such as a long-felt but unsatisfied need for the invention). *See* Teleflex, Inc. v. KSR Int’l, Co., 298 F.Supp.2d 581, 596 (E.D. Mich. 2003).
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, it 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 clearly 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 U.S. 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 response, various businesses and law professors argued that obviousness is a legal issue which the TSM test improperly treats as a question of fact, thereby eliminating the “analytic step” of determining obviousness and “effectively replac[ing] the broad legal and policy considerations properly embodied in the obviousness determination with a factual inquiry into what is already available in the prior art.”

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181 127 S. Ct. at 1745.
Unfortunately, the Supreme Court declined the opportunity to clarify the law of obviousness and the presumption of validity further, particularly regarding the nature of the ultimate legal conclusion of obviousness. The Court only hinted at the character of the legal question. The Court quoted with approval both the “functional approach” of the Hotchkiss decision (and its requirement for an invention of more than mechanical skill186) and the language of Great Atlantic (that patents on obvious inventions withdraw prior knowledge from the public domain187) as the “principal reason” for the obviousness standard, 188 and stated that “as progress beginning from higher levels of achievement is expected in the normal course, the results of 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.”189 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). 190 As the U.S. Government put it in its KSR brief: the Supreme Court “has applied the Graham framework in a variety of context to resolve the core issue: Whether the claimed invention manifests the extraordinary level of innovation that justifies the award of congressionally prescribed rights to exclude others from practicing the invention.”191 There are sound historical reasons to believe that this legal question of the obviousness threshold reflects discretionary policy judgments made by the judiciary.192 The brief thus suggested that the Court clarify the legal standard to appropriate. See, e.g., Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337, 1345 (Fed. Cir. 2007) (discussing “factual underpinnings implicit in the jury’s verdict” as sufficient to support the jury’s verdict of obviousness). As one of the amici argued, however, courts, not juries, determined obviousness prior to the Federal Circuit. See Brief of Cisco Systems, Inc. et al., KSR Int’l Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007) No. 04-1350, at 9 (citing cases).

186 See Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 265 (1851); supra note 33 and accompanying text.
188 127 S. Ct. at 1739.
189 Id. at 1746.
192 The 1790 Patent Act originally vested discretionary authority in the Patent Board to grant patents when it deemed them to be “sufficiently useful and important.” Patent Act of April 10, 1790, ch. 7, § 1, 1 Stat. 109, 110 (repealed 1793) (1790). The 1793 Patent Act eliminated this authority when changing to a registration system. In Grant v. Raymond, 31 U.S. 218 (1832), the Supreme Court held that the Secretary of
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”193), 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.”194

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.*195 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 U.S. by the patent holder under the trade name Norvasc®), because the infringer had proved obviousness below by clear and convincing evidence.196 The trial court had rejected the showing of obviousness, based on another patent and other prior art (that the Patent Office most likely considered.)197 that arguably taught away from the besylate salt and failed to

State had the power to grant a patent for the unexpired term of a surrendered patent, in the process stating that he acts as “a ministerial officer [and i]f the prerequisites of the law be complied with, he can exercise no judgment on the question whether the patent shall be issued.” Id. at 241. Nevertheless, Congress in the 1836 Act restored the discretionary authority to the Commissioner to “deem” inventions “sufficiently useful and important” to issue the patent, when reinstating an examination system. Patent Act of July 4, 1836, ch. 357, § 7, 5 Stat. 117, 121 (repealed 1870) (1836). In doing so, Congress noted the failure of the Secretary to refuse patents for inventions that lacked novelty or utility but met formal application requirements. See S. Rep. No. 24-338, at 2 (1st Sess. 1836). Following the 1836 Act, Congress failed to appropriate sufficient funds to hire examiners resulting in backlogs, and following a political campaign against rigid examination standards that were being applied scientists were replaced with political appointees who applied more lowered examination standards, fueling an explosion of patenting beginning in 1850. See Robert C. Post, “Liberalizers” versus “Scientific Men” in the Antebellum Patent Office, 17 Tech. and Culture 24, 33-52 (1976); Steven Lubar, The Transformation of Antebellum Patent Law, 32 Tech. and Culture 932, 941-45 (1991). In this context, the Court decided *Hotchkiss* and adopted the requirement for inventions to reflect more than mechanical skill. Nothing in *Hotchkiss* suggests that the Court relied on Section 7 of the 1836 Act to adopt the obviousness standard, and thus that the judiciary substituted its policy judgments for those of the administration. However, Congress ultimately eliminated the “sufficiently useful and important” discretionary authority only in 1952, because it was “unnecessary” in light of the simultaneous codification of the obviousness standard. Giles S. Rich, The Principles of Patentability, 42 J. Pat. Off. Soc’y 75, 80-81 (1960) (quoting 35 U.S.C.A. § 131 revision note (1954)). 195 *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 11 (1966).

194 Brief of Economists and Legal Historians as Amici Curiae in Support of Petitioner, KSR Int’l, Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007) (No. 04-1350), at 17. If obviousness is a discretionary policy decision, moreover, concerns over hindsight bias may be overstated because such decisions may properly be retrospective in outlook. Cf. Mandel, supra note 30, at 1411 (“Ex post knowledge of invention deeply affected [study] participants’ conclusions regarding whether an invention was non-obvious ex ante.”).

195 480 F.3d 1348 (Fed. Cir. 2007).

196 See id. at 1352-53.

197 See id. at 1356 & n.4 (interpreting the District Court’s oral findings that the reference was cited in the patent and must have been considered).
suggest the unexpectedly superior function of that salt, and 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 motive 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 an expert evidence suggesting such motivation, because: (1) maleate, an acyclic anion with a double bond, did not work, 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, 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 fact that formation of a salt and determination of its properties were unpredictable precluded a sufficient expectation of success that combination would work for its intended purpose, in light of expert testimony that various salts including besylate would form improved compounds over maleate, suggestions in the prior art patent, and prior statements of the patent holder regarding interchangeability of salts. 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. 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

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198 See id. at 1356-58.
199 See id. at 1359.
200 See id. at 1360-61.
201 See id. at 1361-63.
202 See id. at 1363.
203 See id. at 1364.
204 See id. at 1365-66.
205 Id. at 1366.
Upon what is already generally known.” In regard to secondary considerations, the Federal Circuit first found the trial court’s findings of fact clearly erroneous, because there was no evidence that the patent holder would have abandoned a search for useful amlodipine salts or stood to lose time and money by switching research strategies. It then rejected arguments regarding unexpected success in regard to 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. 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.

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 because skill in the art and prior art references would have directed the search to besylate salts, and that the panel erred by failing to give weight to the secondary evidence of improved manufacturing (rather than therapeutic) properties. Another dissent focused on confusion the panel decision would cause regarding rebuttal of a prima facie case of chemical obviousness, by failing to defer to non-clearly-erroneous trial court 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. A third dissent made similar points, also noting that most pharmaceutical invention involves routine screening of both active compounds and new formulations and salts. All emphasized the “exceptional importance” of the legal issues to the pharmaceutical and chemical industries and their investments and thus to society.

How does KSR affect these arguments (and thus arguments that will be made in the wide range of similar cases that will arise in the U.S. – and if followed, worldwide)? The dissenting concerns in Pfizer regarding the “obvious to try” analysis

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206 Id. at 1368 (citing cases).
207 See id. at 1369.
208 See id. at 1369-71.
209 Id. at 1372.
210 See Pfizer, Inc. v. Apotex, Inc. 488 F.3d 1377, 1379-81 (Fed. Cir. 2007) (Newman, J., dissenting from denial of rehearing en banc).
211 See id. at 1381-82 (Lourie, J., dissenting) (citing In re Papesch, 315 F.2d 381, 391 (CCPA 1963)). See generally Harold C. Wegner, Chemical Obviousness in a State of Flux (unpublished draft June 22, 2007).
212 See Pfizer, 488 F.3d at 1383-84 (Rader, J., dissenting).
213 Id. at 1381-82 (Lourie, J., dissenting). See id. at 1379-80 (Newman, J., dissenting); id. at 1384 (Rader, J., dissenting).
214 See, e.g., Angiotech Pharms. & ANR. v. Conor Medsystems, Inc., [2007] EWCA (Civ) 5, [31] leave to appeal to the House of Lords granted, Minutes of June 7, 2007 (rejecting appeal from conclusion of obviousness because “[j]ust to name one ‘other’ [specific compound having the identified property but not expressly enumerated] which, on the information given in the patent, is no more and no less likely to be found to work in practice is not to make an invention.”).
are unlikely to find favor, given that 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.215 Similarly, the dissenting concerns that secondary considerations were unfairly discounted by the panel also are undermined by KSR’s similar dismissal of the argument that secondary consideration evidence dictated a legal conclusion of obviousness or at least precluded summary judgment, and given KSR’s reiteration that obviousness is a legal conclusion and not a factual question.216

Perhaps the greatest effect of KSR will be to shift the burdens of production and persuasion on the patent holder (and possibly limit the relevant evidence for rebuttal) once a prima facie case is made that the invention is merely a combination of prior art elements performing their expected (even if significantly improved) functions.217 The panel decision took pains to reiterate the high burden of persuasion throughout its decision,218 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 but were not wholly new functions but those typical of and desirable for pharmaceutical products.219 The dissenting concerns that the panel had improperly emphasized certain properties would have become moot. But even if they were not, KSR suggests that the policy discretion remaining in the legal conclusion of obviousness would permit the judiciary to privilege therapeutic properties over other properties when determining whether the inventive contribution warrants the grant of a patent.220

Similarly, as the Pfizer panel concluded, the demonstration through scientific research of hoped-for properties (where there is a reasonable expectation of success) will not be enough to make an invention patentable. Relying on both KSR and Pfizer as authority, the Federal Circuit in a more recent, split opinion reversed a jury verdict of non-obviousness in a case addressing a transplantation invention that used hematopoietic

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215 See KSR Int’l, Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1742 (2007); Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976) (“The ultimate test of patent validity is one of law … but resolution of the obviousness issue necessarily entails several basic factual inquiries.”). For another example of this change in approach, compare Cross Medical Prods., Inc., 424 F.3d at 1321 (“In determining whether a combination of old elements is non-obvious, the court must assess whether, in fact, an artisan of ordinary skill in the art at the time of invention, with no knowledge of the claimed invention, would have some motivation to combine the teachings of one reference with the teachings of another reference.”) (emphasis added and citing In re Fulton, 391 F.3d 1195, 1200-02 (Fed.Cir.2004)) with KSR Int’l, Inc., 127 S. Ct. at 1744 (“The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.”) (emphasis added).

216 See id. at 1745; supra notes 29, 181-84 and accompanying text.

217 See id. at 1739-41; supra notes 152-72 and accompanying text.

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

219 See supra note 166 and accompanying text.

220 See supra notes 184-91 and accompanying text.
stem cells, concluding 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.”\textsuperscript{221} \textit{KSR} truly will have important implications not just for pharmaceutical patents but also for information technologies, business methods, and other patents.\textsuperscript{222} These implications will emanate far beyond U.S. borders, including but not limited to India and other countries seeking to limit follow-on pharmaceutical patents and focusing on their therapeutic (as opposed to other) improvements.\textsuperscript{223} Of course, other countries

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\item[\textsuperscript{221}] Pharmastem Therapeutics, Inc. v. Viacell, 2007 WL 1964863, at *19 (Fed. Cir. July 9, 2007) (citing \textit{KSR Int'l Co.}, 127 S. Ct. at 1732 (“advances that would occur in the ordinary course without real innovation retards progress”)), and \textit{Pfizer, Inc.}, 480 F.3d at 1367-69 (verification of new properties through testing does not satisfy the test for patentability, as “the expectation of success need only be reasonable, not absolute”). \textit{Cf. McNeil-PPC, Inc. v. Perrigo Co.}, 2007 WL 1624764, at *8-*9 (S.D.N.Y. June 5, 2007), (rejecting arguments that costs of coating processes would have dissuaded skilled practitioners from combining references and noting that “\textit{KSR} casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness”). \textit{But cf. Takeda Chemical Indus. Ltd. v. Alphapharm Pty. Ltd.}, 2007 WL 1839698, at *4 (Fed. Cir. June 28, 2007) (affirming district court holding of nonobviousness and the absence of a prima facie case of a reason to combine structurally similar compounds in the absence of evidence showing that the “prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention”) (quoting \textit{In re Deuel}, 51 F.3d 1552, 1558 (Fed.Cir.1995), and citing, \textit{inter alia}, \textit{In re Jones}, 958 F.2d 347 (Fed.Cir.1992)); \textit{id. at *5} (holding that this standard is consistent with \textit{KSR}); \textit{id. at *12} (Dyk, J., concurring) (concurring as to a species claim, based on clearly demonstrated unexpected results, suggesting that two broader claims were obvious given that they covered a compound within the scope of a prior art patent genus claim that was acknowledged to have no unexpected results, but noting that the overbreadth argument had been waived).

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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.224

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

The Patent Office in some cases may be able to perform the complete analysis contemplated by the Supreme Court in KSR, considering and evaluating the full range of evidence that may create a prima facie case and thus may weigh against 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 arise only after the grant of the patent.225 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.226

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.227 Where the

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224 See, e.g., Indra Bhattacharya & Robert Cooper, *Australia High Court Locks in the Law on Obviousness*, 21 WORLD INTELL. PROP. REP. NO. 7 (July 2007) (noting that the Australian High Court recently “reinforced the long-standing principle that even a small advance may be inventive so long as it offers some material benefit to the existing state of the art.”) (citing Lockwood Security Prods. Pty. Ltd., [2007] HCA 21 (Austl.).

225 See, e.g., Barton, *supra* note 144, at 484.

226 NARAYANAN, *supra* note 6, ¶ 1-19.

227 Cf. Charles E. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 FED. CIR. B.J. 143, 143-44 (2000) (arguing that only the presumption of administrative correctness, and not 35 U.S.C. § 282, provides a basis for a heightened evidentiary standard and only for validity issues that are within examiners’ area of expertise, excluding issues that examiners are not tasked to consider).
Patent Office has not evaluated or weighed all of the relevant evidence, moreover, significant questions remain as to whether a presumption of validity should apply at all.

V. Patent Law Policies, Examination, and a Weak Presumption of Validity

When Congress codified the statutory presumption of validity in 1952, it did so in response to calls from the business community concerned with uncertainty regarding the validity of patents resulting from the “‘ever-widening gulf” between the grant of patents in the Patent Office and their later invalidation (principally on obviousness grounds) in the courts. 228 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 interpretations of the invention as claimed229 – 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.

228 Riesenfeld, supra note 3, 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. NATIONAL PATENT PLANNING COMM’N, THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 239, 78th CONG., 1st Sess. 5, 6 (1945), and quoting U.S. NATIONAL PATENT PLANNING COMM’N, THIRD REPORT ON THE AMERICAN PATENT SYSTEM, H.R. Doc. No. 283, 79th CONG., 1st Sess. 4 (1945)).

229 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) (this approach permits applicants to clarify their claims so as to avoid invalidity). Cf. id. at 1375 (claims may be invalidated for indefinite if they are “insolubly ambiguous, and no narrowing construction can properly be adopted”). In theory, this approach to claim construction should best preclude claims from issuing when they are invalid. In contrast, courts determine the meaning of claims following the methodology articulated by the Federal Circuit in Phillips v. AWH Corp., under which courts may, if they find that interpretive uncertainties with granted patents remain after reviewing all the evidence, adopt narrowing constructions so as to preserve claim validity. 415 F.3d 1303,1312-24, 1327-28 (Fed. Cir. 2005) (en banc) (adopting an approach starting with ordinary meaning of claim terms as understood by a person having ordinary skill in the art, and then looking to other claims, the specification, the prosecution history, and – if ambiguities remain – to extrinsic evidence – including dictionaries – of claim term meaning).
A. Policies favoring challenges to validity and invalidation of invalid patents.

Since at least Lear v. Atkins,230 patent law has affirmatively encouraged litigation challenges to the validity of granted patents. The U.S. Supreme Court’s rationale is worth quoting at length:

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

It seems to us that such a [contractual] requirement [to continue paying royalties until a validity challenge is concluded] would be inconsistent with the aims of federal patent policy. Enforcing this contractual provision would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning. If a licensee has reason to believe that he will replace a patented idea with a new one in the near future, he will have little incentive to initiate lengthy court proceedings, unless he is freed from liability at least from the time he refuses to pay the contractual royalties. Lastly, enforcing this contractual provision would undermine the strong federal policy favoring the full and free use of ideas in the public domain.231

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.232 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.233 The policy favoring

231 Id. at 670-71.
232 Lear extended its holding to contracts negotiated before the patent issues, based on concerns that patent applicants would negotiate licenses precluding validity challenges by those having the strongest incentives “to show that a patent is worthless.” Id. at 672. See id. at 672-73 (“While the equities supporting Adkins’ position are somewhat more appealing than those supporting the typical licensor, we cannot say that there is enough of a difference to justify such a substantial impairment of overriding federal policy.”).
233 See id. at 673-74 (overriding the contractual obligation “at least from the time [the licensee] refuses to pay the contractual royalties”).
challenges to validity would seem to be even stronger where such contractual fairness concerns were not applicable. 234

More recently, the Supreme Court held in Medimmune, Inc. v. Genetech, Inc.235 that licensees need not materially breach their contracts in order to have constitutional standing to sue236 (and thus Declaratory Judgment Act jurisdiction237) to raise contractual or patent validity challenges.238 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,239 the Court nevertheless called into question a long line of lower court cases limiting the application of Lear based on the idea that an assignor240 or licensee241 who reaps contractual benefits from a patent should be required to sow contractual compliance therewith.242 The Supreme Court in Medimmune focused on the actual language of the contract and the nature of the contractual licensing bargain (which may not in fact provide the patent holder with an insurance policy against validity challenges).

To begin with, it is not clear where the prohibition against challenging the validity of the patents is to be found. It can hardly be implied from the mere promise to pay royalties on patents “which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken,”…. Promising to pay royalties on patents that have not been held invalid does not amount to a promise not to seek a holding of their invalidity…. Petitioner is not repudiating or

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234 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.”).
236 See U.S. CONST., art. III (authorizing judicial power over “cases” and “controversies”).
238 See Medimmune, 127 S. Ct. at 770-77.
239 See id. at 769-70, 776.
240 See, e.g., Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1224-25 (Fed. Cir. 1988) (“To allow the assignor to make that representation [of the worth of the patent] at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee.... [D]espite the public policy encouraging people to challenge potentially invalid patents, there are still circumstances in which the equities of the contractual relationships between the parties should deprive one party ... of the right to bring that challenge.”).
241 See, e.g., Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co., 112 F.3d 1561, 1568 (Fed. Cir. 1997) (“as in Diamond Scientific, Shell executed a contractual agreement which produced significant benefits for the corporation and attested to the worth of the patent. Under the agreement ... Shell had the benefits of producing polypropylene insulated from unlicensed competition, insulated from investigations of infringement, and even insulated from royalties .... To these benefits, Shell now seeks to add the benefit of abrogating its agreement and avoiding its breach of the contract.... [T]his court must prevent the injustice of allowing Shell to exploit the protection of the contract and patent rights and then later to abandon conveniently its obligations under those same rights.”).
242 See, e.g., Eric Belt & Kieth Toms, The Price of Admission: Licensee Challenges After Medimmune v. Genentech, BOSTON BAR J. 10, 10 (May/June 2007) (“The opinion upset a balance that had existed between patent owners and their licensees and .... will not return until key issues of patent policy are resolved.”).
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. 243

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 “given the extent to which the estoppel principle had been eroded by
[its] prior decisions.”244

The lower court cases limiting Lear also established that the payment of patent
licensing royalties was required at least until notice was provided of the licensee’s belief
in invalidity of the patent.245 These cases therefore precluded the recoupment of royalties
that had been paid under the license once the patent was held invalid, even though the
contractual licensing language may have contemplated royalty payments only for
infringement of valid claims.246 Although the language from Medimmune quoted above
might suggest the enforceability of express license terms that prohibit recoupment of
royalties paid prior to finding a patent invalid, it does not actually determine that such
contractual provisions are permissible in light of Lear.247 Express contractual provisions
prohibiting validity challenges are more strongly suspect. Both kinds of contractual
provisions would reduce incentives for licensees to challenge validity, and thus would
conflict with the public policy of encouraging challenges by the parties having the
greatest interest in doing so. Lear expressly refused to enforce contractual obligations to

243 Medimmune, 127 S. Ct. at 776. The Court also noted that any such contractual provision or common-law
rule that might expressly preclude validity challenges would not raise a jurisdictional but only a merits
question. See id.
244 Lear, 395 U.S. at 674 n.19. See id. at 664-68 (discussing historic judicial treatment of the estoppel rule,
in particular an early assignor-estoppel case holding “that it was improper both to ‘sell and keep the same
thing’”)(quoting Faulks v. Kamp, 3 F. 898, 902 (2d Cir. 1880)).
245 See, e.g., Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1381-82 (Fed. Cir. 2004) (licensee is liable for
unpaid royalties accrued under a license before invalidation of the patent, payment of royalties under
protest precludes a declaratory judgment action to contest validity, and allowing such actions would defeat
contractual covenants and discourage patent licensing) (citing Studiengesellschaft Kohle, M.B.H., 112 F.3d
at 1568); id. at 1568 (because failing to notify of contractual breach also may delay validity challenges,
licensee is not relieved of its obligation to pay contractual royalties for infringing conduct until it actually
ceases payment of royalties and notifies the licensor that the reason for doing so is a belief of invalidity of
the patent)
(construing a license imposing royalties on products “‘covered by …valid claims’” as requiring payment
until a patent is determined invalid, or at least until challenged as invalid) (citing Studiengesellschaft Kohle,
M.B.H., 112 F.3d at 1568, and Gen-Probe, Inc., 359 F.3d at 1378). Cf. Studiengesellschaft Kohle, M.B.H.,
112 F.3d at 1567 (“Nothing in this license made payment of royalties contingent upon the validity” of the
patent); Gen-Probe, Inc., 359 F.3d at 1378 (discuss licensing terms imposing royalties for licensed methods
and products, defined by reference to granted claims that have not been ruled invalid and all appeals have
run).
247 Of course, where the license is not as explicit, Medimmune may suggest the alternate result as the
contractual bargain may not itself contemplate payment if the patent is later held invalid. An agreement to
pay royalties on claims that are valid and infringed does not necessarily entail an agreement to pay royalties
on claims subsequently determined to be invalid or not-infringed, or to preclude recoupment of royalties
erroneously paid once they have been determined to be invalid or not infringed.
pay before invalidity had been determined (at least from the time that validity was challenged), without regard to whether the contractual terms required payment only in regard to infringement of valid claims. 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 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 *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 moot, and thus courts must adjudicate and resolve validity questions. Nor is an invalidity defense waived by failing to advance it in the context of preliminary litigation matters addressing infringement questions.

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248 See supra note 231.
249 See Medimmune, Inc. v. Genetech, Inc., 127 S. Ct. 764 772-75 (2007) (noting that constitutional standing and declaratory judgment jurisdiction are present even when private conduct eliminates the risk of a lawsuit, so long as that conduct was coerced by threatened enforcement action of a government or of a private party). See also *Seymour v. McCormick*, 57 U.S. 480, 488-89 (1853) (holding that enhanced patent damages are punitive in nature and should be imposed only on proof that the defendant “deliberately and wantonly infringed what it knew to be a valid patent”).
250 See, e.g., *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476-77 (Fed. Cir. 1991) (finding a strong public interest in favor of early resolution of litigation by consent judgments, and suggesting that such judgments have *res judicata* effect as to the litigated matter and are enforceable when they contain express provisions precluding further validity litigation); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1367-70 (Fed. Cir. 2001) (finding that settlement agreement containing express preclusion of subsequent validity challenges, followed by dismissal with prejudice, was enforceable as a contractual estoppel even though it did not create a collateral estoppel, distinguishing *Lear* as it did not involve a settlement and as the contract in *Lear* did not contain an express provision precluding challenges to validity, and noting that “settlement of litigation is more strongly favored by the law”) (citing *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 349-51 (Fed.Cir.1988)).
252 See id. at 100. See id. at 96.
253 See id. at 102-03; *Altavater v. Freeman*, 319 U.S. 359, 365-66 (1943). However, declaratory jurisdiction may be rendered moot by dismissing infringement claims and convenanting not to sue before an infringement determination. See *Benetec Australia, Ltd. v. Nucleonics, Inc.*, _ F.3d __, 2007 WL 2069646, at *4-*8 (Fed. Cir. July 20, 2007). Cf. id. at *9-*11 (Dyk, J., dissenting) (arguing that *Cardinal Chemical* shifts the burden of esbalishing moothness to the party challenging validity, to prove “there is no reasonable likelihood that the controversy over the patent’s validity and enforceability will recur”).
254 See, e.g., *Pandrol USA, LP v. Airboss Prods. Ry., Inc.*, 320 F.3d 1354, 1364-66 (Fed. Cir. 2003) (party does not waive invalidity defense and counterclaim by failing to raise it in opposition to cross motions for summary judgment of infringement); *Scosee Indus. v. Visor Gear, Inc.*, 121 F.3d 675, 679 (Fed. Cir.
This returns us to the earlier theme, discussed in regard to preliminary relief, that challenges to validity should not be precluded absent very strong policy grounds. Even if public policies of minimizing litigation and assuring finality are considered 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 res judicata.

Finally, some lower courts in declining to extend Lear have looked to the presumption of patent validity to construe ambiguous licensing language to avoid having royalty payments conditioned on litigation to prove validity, But relying on the presumption of validity in this context puts the cart before the horse. The Lear and Cardinal Chemical policies favoring challenges to validity cannot be overcome by the presumption of validity or by the strength of the inference regarding whether the granted patent is valid. Rather, these policies are premised on the presumption of validity resulting from the grant of patents, which creates the need to assess the truth of validity to protect the public domain. After all, it was precisely such policies regarding res judicata and stability of prior litigated determinations of priority in creating patented inventions that led courts to adopt a presumption of validity in the first place.
The presumption of validity thus can only affect how the burdens of production and persuasion should apply in challenges to patent validity, not whether they 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 that we currently “have only the first sort of error in the patent system.” Although the statement may be hyperbolic, given the existence of appeals of a small percentage of rejected applications to the Board of Patent Appeals and 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 U.S. applications) or the Japanese Patent Office (44.5% of same). As discussed below,

presumption not to be overthrown except by clear and cogent evidence. The question is whether the respondent has sustained that heavy burden.


262 See, e.g., Ravicher, supra note 20, at 8 (citing Cecil D. Quillen, Ogden D. Webster, & Richard Eichman, Continuing Patent Applications and Performance at the U.S. Patent and Trademark Office-Extended, 12 FED. CIR. B.J. 35 (2002), and Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, Disharmony in International Patent Office Decisions, 16 FED. CIR. B.J. 679 (2006)). See also Buchanan, supra note 20, at 37-38 (additional studies provide similar results, ranging from 75% to 97% of applications are ultimately
there is little reason to think that the American patent examiners are doing a better job than their international colleagues, 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.

There is no necessary reason to think that the two kinds of errors of administrative evaluation should have the same social consequences and thus should be treated equally. In fact, they are not, although the applicable legal doctrines may impose the


Cf. Kesal & Ball, supra note 116, at 242 (noting data suggesting a relative paucity of challenges in U.S. reexaminations compared to foreign oppositions regarding similar patents, so that unless U.S. examiners do a better job of examination – which is a questionable assumption – courts in the United States are more likely to confront invalid patents than courts in other countries).

See supra note 20 and accompanying text. These litigated patents, moreover, reflect patents whose value warrants the expense of litigation (after considering the likelihood of success in challenging validity). See supra note 28; Buchanan, supra note 20, at 39 (noting differing views of the high rate for a “small but economically important subset of patents”). Cf. Allison et al., supra note 128, at 437 (stating their assumption for analysis that there is “no reason to believe that valuable patents that are not litigated differ in any systematic ways from valuable litigated patents”); Allison & Sager, supra note 128, at 1787-88 (discussing factors that will be practically considered to assess whether patents are “substantially more valuable than the average and are substantially more likely to be enforced through litigation” and noting that the average age of litigated patents is significantly lower than the average patent). Separate efforts have been made to link various metrics to patent validity, including prior art citations (and whether they were reviewed by the Patent Office), elapsed time from patent grant, and whether patents that have survived administrative validity challenges, but these metrics may not relate directly to patent value. See Allison & Lemley, supra note 20, at 228-40; Allison et al., supra note 128, at 441 n.28, 443 n.32, 449-54 (citing, inter alia, Dietmar Harhoff et al., Citations, Family Size, Opposition and the Value of Patent Rights (Working Paper, 1999); GLORIA K. KOENIG, PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS (rev. ed. 1980); and Kimberly A. Moore, Xenophobia in American Courts, 97 Nw. U. L. Rev. 1497, 1538 (2003)). Cf. James Bessen & Michael J. Meurer, Lessons for Patent Policy from Empirical Research on Patent Litigation, 9 LEWIS & CLARK L. REV. 1, 20-22 (2005) (discussing endogeneity of validity of patents); Mathur, supra note 77, at 41-42 (noting that patents in India with increased citation to prior art and numbers of claims were more likely to result in litigation, and concluding that the high levels of settlements of the relatively few cases suggests “a lack of faith in the Judiciary”). Other studies suggest significant differences in litigation outcomes based on the nature of the parties involved and other factors, but which may not necessarily provide predictive value in regard to assessing validity of particular patents. See generally Moore, supra; Paul M. Janicke & LiLan Ren, Who Wins Patent Infringement Cases?, 34 AIPLA Q. J. 1 (2006).

Cf. Alden F. Abbott & Suzanne T. Michel, The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation, 46 IDEA 1, 7, 8 & n.27, 19-20 (2005) (noting cases rejecting antitrust claims based on anticompetitive pharmaceutical patent litigation settlements based on findings that such social harms do not extend beyond the exclusive rights that valid patents entail, and criticizing arguments that the presumption of validity should apply to such settlements in the absence of sham or baseless litigation, because the presumption itself has no evidentiary value and because it does not affect the character of the patent that results in such anticompetitive power).
wrong burdens of production and persuasion given the policies articulated above that challenges to invalid patents reflect the paramount social policy (except for stability of litigation). In regard to proving the same factual validity issue – e.g., whether a reference is sufficient to qualify as prior art – burdens of production and persuasion for rejections are initially placed on the Patent Office but then are shifted to applicants (under deferential administrative review standards) in direct appeals from the Patent Office, whereas the clear and convincing evidentiary burdens placed on challengers apply after the grant.266

As Professor Mark Lemley has cogently argued, moreover, it may be excessively costly to prevent high rates of granting errors,267 even if it might make sense to spend significantly more than we do at present to prevent the chilling social effects that wrongly granted patents produce.268 The growing number of patent applications in the United States and around the world269 and the increasing disparity between such applications and examination resources,270 however, makes the ever-widening gap between the grant of a

(citing, inter alia, In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 536 & n.1 (E.D.N.Y. 2005), and In re Tamoxifen Citrate Antitrust Litig, No. 03-7641.2005 WL 2864654, at *17 (2d Cir. Nov. 2, 2005))

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


270 See, e.g., Thomas, supra note 268 at 1-2 (discussing even larger per-examiner application burdens and delays for Japanese and European examiners than for U.S. examiners).
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.

Many commentators and the U.S. 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, and adequate training and supervision will invariably be an issue in any large institution. Of greater relevance, the Patent Office itself has recently suggested that applicants may need to assume a greater role in demonstrating patentability, which is not too far from suggesting a shift in the burden of production regarding validity during initial examination.

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271 See, e.g., 2007-2012 STRATEGIC PLAN, supra note 269, at 13 (projecting an eight percent annual increase in patent filings through 2012).
273 See, e.g., 2007-2012 STRATEGIC PLAN, supra note 269, at 13 (noting the increased numbers and complexity of applications and questioning whether increased hiring will adequate address them); id. at 16-17 (noting measures to be taken to assure high examination quality, including enhanced recruiting, recruiting and retention incentives for employees, and an enhanced training through a “Patent Training Academy” and other initiatives). See also FTC Innovation Report 2003, supra note 14, at 9-10 (estimating application increases at ten percent per year and discussing the constraints of evaluating applications with only “8 to 25 hours” to perform all required functions).
275 Cf. Menell, supra note 38, at 16 (hypothetically and humorously claiming a new method of patent legislative reform which would avoid adopting biased burdens of proving that patent protection should be available for all innovations in all fields without empirical rebuttal evidence to show that such protection would be harmful, and noting that “those possessing the best information” regarding public and private costs “may enjoy private benefits (such as exclusion of competition) that make them unwilling to reveal
In addition, existing incentives for examiners “provide a bias towards allowing claims rather than continuing to reject them…. Patent Office productivity metrics and examination procedures thus favor allowance over continued rejection.” These incentives, as well as the burdens of production and persuasion placed on examiners to search for evidence and provide reasoned explanations, further call into question that the presumption of correctness that forms the basis for the presumption of validity. Because of these practical realities, moreover, the Patent Office may not properly apply its prophylactic measure of adopting the broadest reasonable construction of claims so as to better assure that issued patents are valid. Recent analyses suggest that uncertainty regarding patent scope and claim boundaries is the principle driver of increased patent litigation, leading to the patent system exerting a net tax on innovation (particularly for the information technology industry), which calls into question applying any presumption of validity (particularly when a claim construction is applied to validity questions that differs significantly from the understanding of the invention applied in the Patent Office).

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276 Buchanan, supra note 20, at 36. See id. (discussing “disposal counts” and how they are accrued, and the need for time-consuming explanation when making rejections); Ravicher, supra note 20, at 7-9 (noting financial incentives for the Patent Office to generate fees by granting patents, leading to a culture of treating applicants as “customers,” and incentives for examiners who “should be rewarded, not penalized, for improving patent quality”). Cf. supra note 139 (recommending documentation of reasons for grants).

277 See supra notes 14, 148 and accompanying text.

278 See supra notes 67, 114, 139 and accompanying text.


281 This problem may be even more significant than has been previously realized, given that patent claim terms may expand their application – if not also their meaning – over time, not just for infringement analysis but also for validity analysis. See, e.g., In re Hogan, 559 F.2d 595, 604-06 (C.C.P.A. 1977) (enablement is determined solely by reference to the meaning of claim terms as of their filing date, but that meaning may encompass later-arising equivalents not known on the filing date); Superguide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 878 (Fed. Cir. 2004) (method and apparatus claims can include later-arising technology within their literal scope, because (unlike means-plus-function claims), they “are defined by the language of the claims themselves”). But cf. Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254-55 (Fed. Cir. 2004) (noting that claim meaning that includes later-arising technology must be held invalid for lack of written description, but not necessarily for lack of enablement, because applicants would not be able to “possess and disclose” that scope); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (noting that the written description is focused on preventing applicants from later “asserting that he invented that which he did not”). See generally Mark A. Lemley, The Changing Meaning of Patent Claim Terms, 104 MICH. L. REV. 101 (2005); Christopher A. Cotropia, "After-Arising" Technologies and Tailoring Patent Scope, 61 N.Y.U. Am. Surv. Am. L. 151 (2005).

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In summary, even if we were to increase the number, amount of time spent by, incentives for and training and expertise of examiners, to alter the legal standards to better assure that proper examination occurs under the same legal standards that apply after grant, and to increase incentives for administrative challenges to invalidate patents before litigation, Patent Office determinations to grant patents will remain suspect. Nor are patent holders likely to be deterred from asserting their patents, even when they know that they are invalid but the costs of proving invalidity make such challenges unlikely. For these reasons, public policy favors challenges to validity, and should not suggest imposing any (much less heightened) burdens of production and persuasion based on the mere fact that the patent was granted. As the U.S. 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.

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282 See, e.g., Sag & Rohde, supra note 21, at 43 (“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 47-48 (“The [assertion-focused] model predicts that where targeting costs are low and the expected cost of retaliation is small, a rational patent holder will broadly assert her patent, even where the probability that a target will accept a license is low. The model also indicates that a patent holder's incentive to assert her patent increases as the target's probability of accepting a license increases.”); Bessen & Meurer, supra note 264, at 16 (discussing anti-competitive and opportunistic lawsuits that rely on weak patents to exclude competitors and to induce licensing).


286 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.

287 See supra note 73 and accompanying text.
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 inference or factors when making such legal conclusions, or to import from the presumption of validity public policies that do not exist that granted patents should be preserved from invalidation in the face of such competing factual inferences.