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## CASENOTE

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### **KNOCKING THE EAGLE OFF THE PATENT OWNER'S SHOULDER: *CHIRON* HOLDS THAT JURORS DON'T HAVE TO BE TOLD THAT A PATENT IS PRESUMED VALID**

David C. Bohrer†

#### I. INTRODUCTION

The development of patent law in the United States has been marked by a high level of confidence that the Patent Office “gets it right” when it issues a patent. This confidence sprang up from the belief that a patent application is subjected to a thorough investigation by well-trained examiners who regularly analyze the technical issues presented by the patent application, and whose job it is, day in and day out, to make sure that patents are awarded to only those applications that comply with the patent rules.

Based upon the high level of confidence in the decisions made by Patent Office examiners, courts derived the presumption that a patent is valid. Congress ultimately codified both this presumption, and that the burden of proving invalidity, falls upon the person challenging the patent, in amendments to the patent statute. Courts, in turn, have interpreted the amended statute as requiring that the challenger meet a higher standard of proof, clear and convincing evidence, in order to overcome the presumption.

The overall effect of the presumptions, burdens and standards originating from the core confidence in the patent examiner's decision is to make it harder to invalidate an issued patent. *Patent owners therefore wear the American eagle on their shoulders*: those who

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attack the validity of a patent must overcome the significant obstacles that spring from the belief that *the government "gets it right."*

There is a perception among an increasing number of legislators, judges, and practitioners, however, that patent examiners are making mistakes and issuing an unduly large number of invalid patents. This perception has caused the Federal Trade Commission (FTC) and, most recently, the National Academy of Sciences (NAS) to propose changes to the patent laws that make it easier to challenge the validity of issued patents.<sup>1</sup> *The proposed reforms therefore seek to knock the eagle off of patent owners' shoulders: the growing suspicion that the government "gets it wrong" has created the impetus for reforms directed at lowering, if not eliminating, the significant obstacles to proving invalidity.*

The recent decision in *Chiron Corp. v. Genentech, Inc.* demonstrates that the Federal Circuit is already moving in the same direction as the proposed reforms.<sup>2</sup> In *Chiron*, the Federal Circuit held that the district court was not required to instruct the jury that a patent is presumed valid.<sup>3</sup> The decision of the Federal Circuit thus set the stage to approve of a situation where the presumed correctness of the government's actions and the presumed validity of the patent are not readily transparent to the jury in the trial of a patent infringement case.<sup>4</sup> Although not so far reaching as the FTC's proposal to lower the burden of proving invalidity, *Chiron* knocks the eagle off of the patent owner's shoulder by denying the jury the compelling explanation for why the heavy burden of proving invalidity is imposed upon the party challenging the validity of the patent. *Chiron* is likely a harbinger of further judicial implementation of the proposed reforms. Its unspoken, but nonetheless obvious rationale, is

1. See FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, A REPORT BY THE FEDERAL TRADE COMMISSION (2003), available at <http://www.ftc.gov/reports/index.htm> [hereinafter FTC RPT.]. The FTC RPT. is the end product of 24 days of hearings on the "proper balance of competition and patent law and policy" and includes an eighteen page executive summary. *Id.* at Executive Summary, at 3. See also NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY (Stephen A. Merrill et al. eds., 2004), available at <http://books.nap.edu/catalog/10976.html> (last visited October 30, 2004) [hereinafter NAS RPT.]. The NAS RPT. by the National Research Council, operating arm of the National Academy of Sciences was the result of a series of public meetings involving economists, scholars, practitioners, judges, legislators and business people regarding the operation of the patent system and whether changes should be made in the administration of the patent system. *Id.* at ix, 2.

2. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004).

3. *Id.* at 1258-1259.

4. *Id.*

that the challenger should not bear the traditional heavy burdens associated with proving invalidity if the patent examiner cannot be relied upon to “get it right.”

## II. PATENT OWNERS WEAR THE EAGLE ON THEIR SHOULDERS

A recurrent theme throughout what are literally decades of developing patent law is the confidence expressed by judges, practicing attorneys, and academics in the job done by the Patent Office. Patent examiners have long been viewed as correctly examining patents to make sure the claimed invention meets the statutory tests of patentable subject matter,<sup>5</sup> novelty,<sup>6</sup> nonobviousness,<sup>7</sup> utility,<sup>8</sup> and disclosure<sup>9</sup> such that, at least historically, there has been a high level of confidence that bad patents are *not* being allowed to slip through the system.

The confidence that patent examiners make the right decisions is based first on the belief that patent examiners are both highly trained and well-experienced in investigating patent applications.<sup>10</sup> Model

5. See 35 U.S.C. § 101 (2000). Patentable subject matter encompasses products, processes, machines or compositions of matter. *Id.*

6. See *id.* § 102. The patent laws protect only “new” inventions that are not already known to persons skilled in the same field or are not already described in the prior art. The phrase “prior art” refers to any information (including technical articles, existing patents or other materials) which describe public technical knowledge that was effectively known before the invention. See MARTIN FLIESLER ET AL., MODEL PATENT JURY INSTRUCTIONS FOR THE NORTHERN DISTRICT OF CALIFORNIA 47 (2002), available at [www.cand.uscourts.gov/cand/ForAttys.nsf/0/4ed41e5a5972b27a88256d6e005cee5d/\\$FILE/ModelPat.PDF](http://www.cand.uscourts.gov/cand/ForAttys.nsf/0/4ed41e5a5972b27a88256d6e005cee5d/$FILE/ModelPat.PDF) (last visited October 30, 2004) [hereinafter 2002 N.D. CAL. PATENT INSTR.].

7. See 35 U.S.C. § 103 (2000). Section 103 effectively requires that the subject matter of the invention is beyond the ordinary abilities and knowledge of persons skilled in the same field (art) as the invention. *Id.* (“A patent may *not* be obtained . . . if the *differences* between the subject matter sought to be patented and the prior art are such that the subject matter as a whole *would have been obvious* . . . to a person having ordinary skill in the art . . .”) (emphasis added).

8. See *id.* § 101. The utility test requires that the invention have a practical purpose.

9. See *id.* § 112. Among other things, the *quid pro quo* for obtaining a patent is that the inventor provides a written description of the invention sufficient to ensure that the inventor was at the time of invention in possession of what he may later claim is covered by his patent, describe in the patent, or “enable” persons skilled in the art to make the invention without undue experimentation, and describe what the inventor deemed was the best way (“best mode”) of carrying out his invention. *Id.*

10. See, e.g., *Parker v. Motorola, Inc.*, 524 F.2d 518, 521 (5th Cir. 1975) (recognizing “the acknowledged experience and expertise of the Patent Office personnel”); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)

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

jury instructions have incorporated this sentiment in instructions, providing that “[a] patent results from the action of a patent examiner technically trained in the field to which the patent relates and also trained in the legal requirements and regulations of the Patent and Trademark Office for the issuance of valid patents,”<sup>11</sup> and that:

[The Patent Office] has more than a thousand technically educated examiners who examine applications for patents . . . . [T]he examiner reviews . . . the patent application[,] . . . . makes a search of the [Patent Office] records for prior art[,] . . . . considers . . . whether each claim that defines an invention is new, useful, and not obvious[,] . . . . then advises the applicant in writing what the examiner has found . . . . [T]his process may go back and forth between the patent examiner . . . and the applicant for several months or even for years until the examiner is satisfied that the application and claims meet the conditions for patentability.<sup>12</sup>

Further motivation for deferring to examiners’ decisions comes from the principle that government agencies are presumed to have done their job correctly.<sup>13</sup> The Patent Office, as an “executive department[ ] of the government . . . . charged with the administration of the patent system,” determines among other things whether the validity of claimed inventions is supported by the evidence.<sup>14</sup> The patent examiner’s approval of a patent application, therefore, is entitled to the presumption that he did his job correctly.<sup>15</sup>

Having concluded that the Patent Office “gets it right” when it issues a patent, courts derived the presumption that an issued patent is

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

*Id.*

11. 3 BARRY KRAMER & ALLEN D. BRUFISKY, PATENT LAW PRACTICE FORMS § 80:76 (2004).

12. AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, AIPLA’S GUIDE TO MODEL PATENT JURY INSTRUCTIONS 2–3 (1998), *available at* [http://www.aipla.org/Content/ContentGroups/Publications1/Publications\\_available\\_for\\_viewing/1/juryinst.pdf](http://www.aipla.org/Content/ContentGroups/Publications1/Publications_available_for_viewing/1/juryinst.pdf) (last visited October 30, 2004) (hereinafter AIPLA PATENT INSTR.).

13. The rationale of assumed correctness of administrative agencies such as the Patent Office has its genesis in *Morgan v. Daniels*, 153 U.S. 120, 125 (1894). *See also* *Solder Removal Co. v. United States Int’l Trade Comm’n*, 582 F.2d 628, 633 n.10 (C.C.P.A. 1978) (citations omitted).

14. *See Morgan*, 153 U.S. at 124; 35 U.S.C. §§ 1(a) (“[The Patent Office] is an agency of the United States, within the Department of Commerce.”) and 2(a) (“[The Patent Office] shall be responsible for the granting and issuing of patents . . .”).

15. *See Am. Hoist*, 725 F.2d at 1359; *Solder*, 582 F.2d at 633; *see also* *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1992).

*valid*,<sup>16</sup> which in turn provided the basis for imposing several significant obligations upon accused infringers whose defense is that the patent is *invalid*.

First, the presumption places the burden of going forward on the challenger, such that the challenger has the burden of proceeding first and establishing a *prima facie* case.<sup>17</sup> Second, the presumption places the burden of proving invalidity, also known as the burden of persuasion, on the challenger.<sup>18</sup> This burden remains in existence throughout the litigation and cannot be shifted back to the patent owner.<sup>19</sup> Even if the challenger presents evidence of prior art at trial that was not considered by the patent examiner, this does not effect the presumption of validity, *i.e.*, the presumption is not “weakened” or “undercut,” nor does it change who has the burden of proof.<sup>20</sup>

Third, in order to overcome the presumption of validity and show that the challenged patent is invalid, the challenger’s evidence must meet the standard of proof of “clear and convincing evidence.”<sup>21</sup> This is a higher standard of proof than the “preponderance of the evidence” standard that a patent owner must meet in order to prove infringement of its patent. To prevail under the “preponderance of the evidence” standard, the patent owner need only persuade the jurors that what the patent owner seeks to prove is more probably true than

16. See *Am. Hoist*, 725 F.2d at 1359 (“Behind [the presumption of validity] was the basic proposition that a governmental agency such as the then Patent Office was presumed to do its job.”); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985) (“Th[e] statutory presumption [of validity] derives in part from recognition of the technological expertise of the patent examiners . . . [T]he examination procedure and result should be given appropriate consideration and due weight by the court.”).

17. See *Am. Hoist*, 725 F.2d at 1360; *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *Avia Group Int’l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988).

18. *Am. Hoist*, 725 F.2d at 1360.

19. *Id.*

20. *Id.*; see also *Applied Materials, Inc. v. Advanced Semiconductor Materials Am. Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996); *Solder*, 582 F.2d at 633. While new prior art not before the Patent Office does not affect the presumption of validity, it *does* eliminate or reduce the deference due the Patent Office and thereby may discharge the attacker’s burden, but neither shifts nor lightens the challenger’s burden of proof or standard of proof. *Am. Hoist*, 725 F.2d at 1360; *Solder*, 582 F.2d at 633. Thus, the Federal Circuit distinguishes the burden and standard of proof, on the one hand, from the deference due the Patent Office based upon the rationale of assumed administrative correctness, on the other, insofar as the consideration of new prior art is concerned.

21. *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002). *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 736 (Fed. Cir. 2002); *Monsanto Co. v. Mycogen Plant Science, Inc.*, 261 F.3d 1356, 1362 (Fed. Cir. 2001).

not true.<sup>22</sup> Trial counsel will often explain this standard to the jury by asking them to think of the patent owner's and challenger's evidence as having been placed on opposite sides of a scale.<sup>23</sup> The patent owner meets the burden of proving infringement by a preponderance of the evidence so long as the evidence supporting the patent owner's claims would make the scales "tip even the slightest" in the patent owner's favor.<sup>24</sup>

In comparison, "clear and convincing evidence" must not just "tip the scales" in one direction, but must go further and produce in the minds of the jurors an abiding conviction that the truth of what the challenger seeks to prove, namely, the invalidity of the patent, is "highly probable."<sup>25</sup> Some model patent jury instructions go so far as to expressly advise the jury that the burden imposed upon the challenger of proving invalidity by "clear and convincing" evidence is a higher standard than "preponderance of the evidence."<sup>26</sup>

In *Radio Corp. of America v. Radio Laboratories, Inc.*, the Supreme Court recognized a high standard of proof in the face of presumed patent validity long before the statutory codification of the presumption.<sup>27</sup> Speaking for the Court, Justice Cardozo concluded that "[t]hrough all the verbal variances, however, there runs this common core of thought and truth, that one otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy

22. See UNIFORM JURY INSTRUCTIONS FOR PATENT CASES IN THE UNITED STATES COURT FOR THE DISTRICT OF DELAWARE, Preliminary Jury Instructions, Burden of Proof at 7, and General Jury Instructions, § 1.3, Burdens of Proof, at 3 (2003) (on file with author) [hereinafter 2003 DEL. PATENT INSTR.]. These proposed jury instructions are promulgated by the Jury Instruction Subcommittee of the Intellectual Property Section of the Delaware State Bar Association in June 2003. Notwithstanding their status as drafts that have not yet formally been adopted by the Federal Court in Delaware, the federal court judges are already requiring that counsel use them. Cf. 2002 N.D. CAL. PATENT INSTR., *supra* note 6, at 9 ("To prove infringement of any claim, [patent holder] must persuade you that it is more likely than not that [alleged infringer] has infringed that claim.").

23. See *e.g.*, 2003 DEL. PATENT INSTR., Preliminary Jury Instructions, Burdens of Proof, at 7, and General Jury Instructions § 1.3, Burdens of Proof, at 3.

24. *Id.*

25. *Id.*

26. See *id.*, General Jury Instructions, § 4.1 Presumption of Validity, at 33 ("Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence."); THE FEDERAL CIRCUIT BAR ASSOCIATION MODEL PATENT JURY INSTRUCTIONS, § 1.1, Burdens of Proof, at 2 [hereinafter FCBA PATENT INSTR.] ("The first burden of proof standard requires that, in order for a party to prevail, you must be persuaded that what the party seeks to prove is more probably true than not true. The second burden of proof standard is a *higher one*. It requires that you must be persuaded that it is highly probable that what the party seeks to prove is true.") (emphasis added).

27. *Radio Corp. of Am. v. Radio Lab., Inc.*, 293 U.S. 1, 8 (1934).

burden of persuasion, and fails unless his evidence has more than a dubious preponderance.”<sup>28</sup>

The trend over time has been to further strengthen the presumption of validity. Historically, the presumption was part of a judge-made body of patent law that came into existence over 100 years ago.<sup>29</sup> Nevertheless, courts were far from consistent, even contradictory, in their application of the presumption.<sup>30</sup> The legislature therefore sought to impose statutory restraint in the form of the Patent Act of 1952, which added to the patent statute the simple statement that “a patent shall be presumed valid” and that “the burden of establishing invalidity of a patent shall rest upon a party asserting it.”<sup>31</sup> The drafters of the amendments sought to give the presumption “greater dignity and effectiveness.”<sup>32</sup>

Notwithstanding the codification of the presumption in the patent statute, the presumption still “carried no weight in some circuits and little weight in most.”<sup>33</sup> One of the primary motivations behind the creation in 1982 of the Federal Circuit—a national court that hears all patent appeals—was the widely perceived need to recognize and consistently apply the presumption of validity.<sup>34</sup> By any measure chosen, the creation of the Federal Circuit has done just that. The Federal Circuit has emphasized that the presumption of validity is permanent, clarified that the challenger’s burden of proving invalidity is the high standard of clear and convincing evidence, and held that the presumption controls even where the prior art introduced at trial as proof of invalidity was not considered by the examiner, and that “where supposedly invalidating prior art was considered by the

28. *Id.*

29. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

30. *Id.*

31. *Id.*

32. P.J. Federico, *Commentary on the New Patent Act*, 35 *U.S.C.A. 1*, 54–55 (1954), reprinted in 75 *J. PAT. & TRADEMARK OFF. SOC’Y* 161, 215 (1993).

33. Robert P. Taylor, *Twenty Years of the Federal Circuit: An Overview*, 716 *PLI/PAT* 9, 15 (2002).

34. *See id.* at 11 n.3 (citing Federal Courts Improvement Act. Pub. L. No. 97–164, 96 Stat. 25 (1982). Among other things, this legislation created the U.S. Court of Appeals for the Federal Circuit. *See also* Brenda Sandburg, *A Slow Road to Patent Reform: Congress Unlikely to Move Quickly on FTC’s Controversial Proposals*, *THE RECORDER*, Oct. 30, 2003, at 3 (citing Prof. Mark Janis, University of Iowa Law School, “The subtext of the past debate was that people wanted a strong application of the presumption of validity, . . . [t]hat was a problem in the 1960s, 1970s and early 1980s.”)



Examiner, the Federal Circuit usually sides with the . . . Patent Office, which was not true in many of the regional circuit[ ] [courts.]”<sup>35</sup>

So strong did the presumption of validity become under the Federal Circuit’s tutelage that, in its present form, it not only shifts to the challenger the burden of going forward with evidence to rebut the presumption, but also shifts to the challenger the ultimate burden of persuading the decision-maker that the patent is invalid.<sup>36</sup> In comparison, under the Federal Rules of Evidence, a presumption imposes on the party against whom it is directed only the burden of going forward, but not the burden of persuasion.<sup>37</sup>

The strong belief that the Patent Office is correct when it issues a patent spawned the presumption of validity and related burden of going forward, burden of persuasion, and higher standard of proof, which, collectively, make it much more difficult to invalidate a patent. As the challenger is responsible for proving that the government was wrong when it issued the patent, the challenger must take on not just the patent owner but also the United States Government. The practical significance of these legal developments is that *the patent owner wears the American eagle on his shoulder*. Those who attack the patent must overcome the significant obstacles that have sprung from the belief that *the government “gets it right.”*

### III. PROPOSED REFORMS WANT TO KNOCK THE EAGLE OFF

#### A. *Loss of Confidence in Patent Office*

More recently, the Patent Office has been sharply criticized for issuing too many patents that should have been rejected due to the invalidity or overly broad scope of their claims.<sup>38</sup> These substandard patents are often characterized as “bad,”<sup>39</sup> “questionable”<sup>40</sup> or “low quality.”<sup>41</sup>

There is certainly no lack of examples of apparently bad results. Typical of such lists are a patent on a computer algorithm for

35. Taylor, *supra* note 33, at 15.

36. See *Solder Removal Co. v. United States Int’l Trade Comm’n*, 582 F.2d 628, 633 n.8 (Fed. Cir. 1978).

37. See FED. R. EVID. 301.

38. FTC RPT., *supra* note 1, Executive Summary, at 5; NAS RPT., *supra* note 1, at 47.

39. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1496 (Summer 2001).

40. FTC RPT., *supra* note 1, Executive Summary, at 5.

41. NAS RPT., *supra* note 1, at 48.

searching a mathematical textbook table to determine the sine or cosine of an angle, a patent for cutting or styling hair using scissors or combs in both hands, a patent on storing music on a server and letting users access it by clicking on a list of the music available, and a patent on initiating forward motion on a child's swing by pulling on the ropes and swinging it sideways (the last was subsequently ordered to be re-examined by the director of the USPTO).<sup>42</sup> The criticism is particularly strong as to patents issued on inventions in technology areas that are newly patentable, notably (1) patents allowed on human genetic sequences, (2) business method applications filed in the wake of the *State Street Bank & Trust Co. v. Signature Financial Group*<sup>43</sup> decision and many of the well-known Internet patents, including Amazon's "one-click" shopping method and Open Market's "on-line shopping cart," and (3) computer software patents and related inventions, where the already high rate of filings was further encouraged by *AT&T v. Excel Communications, Inc.*,<sup>44</sup> which "removed the requirement that software could be patented only as embodied in a computer program and therefore effectively permitted patents on algorithms themselves."<sup>45</sup>

Not surprisingly, Patent Office administrators have challenged the criticism as based upon a relatively few hand-picked examples of bad results and as erroneously relying upon anecdotal evidence as opposed to empirical data. As to these points, the patent administrators have allies in the FTC and the NAS. The FTC offers no opinion on whether there are in fact too many bad patents slipping through the system and, with the exception of software patents, avoids characterizing the evidence as reflecting a clear consensus that patent quality has declined.<sup>46</sup> The NAS is more emphatic in calling for greater verification of the criticism of the Patent Office, stating: "[a]berrant or typical or, for that matter, increasing or declining in frequency[, the alleged increased incidence of low quality patents] is impossible to determine on the basis of a few hand-picked examples of apparently bad results."<sup>47</sup> The NAS similarly questioned the reliance of some observers on anecdotal evidence, stating: "[t]he

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42. *Id.* at 47 (citing U.S. Patent Nos. 5,937,468; 6,257,248; 5,963,916; 6,368,227).

43. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998).

44. *AT&T v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999).

45. See NAS RPT., *supra* note 1, at 43–45, 55–56.

46. See FTC RPT., *supra* note 1, ch. 3 at 44.

47. NAS RPT., *supra* note 1, at 48.

claim that quality has deteriorated in a broad and systemic way . . . has not been empirically tested.”<sup>48</sup>

But even absent harder empirical data, there is at the very least a growing suspicion that bad patents are slipping through the system.<sup>49</sup> This cloud over the Patent Office’s capabilities is based upon several related circumstances, including workload pressures on the Patent Office, workplace rules biased in favor of issuing a patent, high patent approval rates, and high number of litigated patents deemed invalid.

### 1. Workload pressures on the Patent Office

The number of patent applications filed on an annual basis is approximately 350,000,<sup>50</sup> and they arrive at a rate of over 1,000 each working day.<sup>51</sup> This is well over double the number of applications filed ten years ago.<sup>52</sup> Moreover, the typical application has grown in complexity, as represented by the growth in the number of claims and prior art citations per application.<sup>53</sup> The number of patent examiners (3,000) has not kept pace with this increase in workload.<sup>54</sup> Although there are different estimates of the total time available for an examiner to take the application from start to finish (*i.e.*, read the application, read the submitted prior art, search for and read the prior art in databases accessible to the Patent Office, compare that prior art to the inventions claimed in the application, write an office action, read and respond to the response to the office action, most likely repeat the steps related to generating an office action at least once, conduct an interview with the applicant, and ensure that the figures and claims are properly formatted), none of these estimates exceed 30 hours,

48. *Id.* at 3.

49. *See id.* at 51 (“There are several reasons to suspect that more issued patents are deviating from previous or at least desirable standards of utility, novelty, and especially non-obviousness and that this problem is more pronounced in fast-moving areas of technology newly subject to patenting than in established, less rapidly changing fields.”); FTC RPT., *supra* note 1, ch. 3, at 44 (“Panelists generally agreed that too many questionable patents [relating to the software and internet industries] are issued . . . .”); Lemley, *supra* note 39, at 1528 (“The presumption of validity has little if any basis in fact . . . . [Examiners] regularly miss the most relevant prior art.”).

50. Steve Kunin, Opposition and Post-Grant Review Panel, Remarks at the Ideas Into Action: Implementing Reform Of The Patent System Conference sponsored by Berkeley Center for Law and Technology, FTC and NAS (Apr. 16, 2004), *available at* [http://www.law.berkeley.edu/institutes/bclt/patentreform/transcripts/BCLT\\_Patent\\_Opposition.pdf](http://www.law.berkeley.edu/institutes/bclt/patentreform/transcripts/BCLT_Patent_Opposition.pdf).

51. FTC RPT., *supra* note 1, ch. 5, at 4.

52. NAS RPT., *supra* note 1, at 51.

53. *Id.*

54. *Id.*

which is far less than the time spent by either the lawyers or the triers of fact in patent infringement cases.<sup>55</sup> Examiners simply do not spend large amounts of time poring over a patent application or prior art. These circumstances, accordingly, do not permit examiners to make accurate judgments on the validity of the patents under consideration.<sup>56</sup>

## 2. Workplace rules biased in favor of issuing patent

The combination of the examiner's compensation structure and patent application procedures place tremendous pressure on the examiner to issue a patent rather than reject an application, no matter how weak the alleged invention seems. First, the examiner has the burden of proving that an application does not meet the requirements for patentability.<sup>57</sup> Second, examiners are only required to write up reasons for rejection but not reasons for allowance.<sup>58</sup> Third, in the words of one observer, "it is [almost] impossible to reject a patent once and for all" due to the regulations providing that after "final rejection" an applicant can re-file the same application (e.g., "a continuation") an unlimited number of times.<sup>59</sup> "The only way for an examiner to guarantee that an application is finally disposed of is to issue the patent."<sup>60</sup> Fourth, the examiner compensation system functions through a combination of salary and bonus points accumulated for "dispositions," i.e., final allowances or rejections of patents.<sup>61</sup> "[G]iven [the] opportunities to continue prosecutions even after rejections, 'the only way to earn bonus points with confidence is

55. See FTC RPT., *supra* note 1, ch. 5, at 5 (estimating the time spent on the application process to be 8–25 hours); NAS RPT., *supra* note 1, at 51 n.31 (estimating the time spent on the application process to be 15–30 hours); Lemley, *supra* note 39, at 1496 n.3, 1500 n.19 ("Examiners have astonishingly little time to spend on each application—on average, a total of eighteen hours . . .").

56. See Brenda Sandburg, *Reinventing the Patent System: National Academy of Sciences Adds Voice to Chorus on Fixing Patent Litigation*, THE RECORDER, Apr. 20, 2004, at 10 citing Prof. Lemley as saying "The PTO is not set up to make strong determinations on the validity of a patent . . . [It's] a light screen of the patent."

57. Lemley, *supra* note 39, at 1496 n.3 (citing John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 325 (2001) ("Long-established practice places the burden of persuasion and initial burden of production upon examiners to generate rejections. Otherwise the application must be allowed.")).

58. *Id.*

59. *Id.*

60. *Id.*

61. FTC RPT., *supra* note 1, ch. 5, at 5 n.34 (citing Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 607 (1999)).

to allow a patent application.”<sup>62</sup> The cumulative effect of these factors is to create “a strong incentive to issue patents to persistent applicants, rather than to continue rejecting the applications.”<sup>63</sup>

### 3. High patent approval rates

The percentage of patents applied for that end up being issued is extremely high. Depending upon how continuation, continuation-in-part and divisional applications are accounted for, the approval rate ranges from seventy-four to as high as ninety-seven percent.<sup>64</sup> These rates are in fact higher than officially reported by the United States Patent Office and higher than patent approval rates in Europe and Japan.<sup>65</sup> The concern is that the U.S. patent system yields an unduly high “success” rate.<sup>66</sup>

### 4. High number of litigated patents deemed invalid

Only a relatively small number of patents, no more than two percent, are the subject of litigation.<sup>67</sup> It can reasonably be inferred that the patents that are litigated must have some competitive significance or high economic value; otherwise, there is not sufficient incentive to take on the very high cost of litigation. One observer characterized litigated patent cases as “the cases that matter,” suggesting that the additional time and money required to improve the examination of the ninety-five percent of patents “that will either never be used, or will be used in circumstances that don’t crucially rely on the determination of validity,” is “largely [ ] wasted.”<sup>68</sup> Thus, data regarding the quality of litigated patents is significant, and what this data shows is that in litigated cases that actually result in a final

62. *Id.*

63. *Id.* (citing Lemley, *supra* note 39, at 1496 n.3.)

64. NAS RPT., *supra* note 1, at 53–54; FTC RPT., *supra* note 1, ch. 5, at 6; *see also* Judge Ronald Whyte, Remarks on Patent Reform at the Ideas Into Action: Implementing Reform Of The Patent System Conference sponsored by Berkeley Center for Law and Technology, FTC and NAS (Apr. 16, 2004), *available at*

[http://www.law.berkeley.edu/institutes/bclt/patentreform/transcripts/BCLT\\_Patent\\_Remarks.pdf](http://www.law.berkeley.edu/institutes/bclt/patentreform/transcripts/BCLT_Patent_Remarks.pdf) (stating that the most shocking thing he learned after being on the bench is the percentage of patents applied for that end up being issued, figures ranging from 74 percent to 90 percent); Sandburg, *supra* note 52, (“Whyte said he hears students say all the time that they think only a small percentage of patents are approved. Students will tell him that ‘inventions don’t come along every day,’ he said. ‘I agree with that.’”).

65. NAS RPT., *supra* note 1, at 62.

66. *Id.* at 54.

67. Lemley, *supra* note 39, at 1501.

68. *Id.* at 1510–1511.

judgment on validity, issued patents are held invalid forty-six percent of the time.<sup>69</sup> These are not the results one would expect to see if the patent examiner was doing his job correctly.

Thus, while the debate over whether examiners issue questionable patents rages on, the seeds of doubt regarding patent examiners' capabilities have not just been planted but have flowered to a full bloom. The confidence that the government "gets it right" no longer exists, thus undercutting the core justification for both the presumption that a patent is presumed valid and the obstacles to invalidating patents that are based upon the presumption.

### *B. Proposed Reforms Reflect Loss of Confidence*

The loss in confidence has fueled several of the major proposed reforms to the patent system. The common thread running through these proposals is that the stacked deck of presumptions and burdens of proof favoring the patent applicant no longer comports with the real-world shortcomings of patent examination such that it should not be so hard for a challenger to prove that a patent is invalid.

The FTC has proposed lowering the burden imposed upon the challenger of providing invalidity from the heightened standard of "clear and convincing evidence" to only a "preponderance of the evidence."<sup>70</sup> The FTC expressly disagreed with the rationale that the heightened standard was justified because the issued patent embodies the finding of patent validity by a "neutral government agency using a knowledgeable examiner."<sup>71</sup> The FTC said the realities of patent examination dictated the application of a less stringent standard:

Presumptions and procedures that favor the grant of a patent application, combined with the limited resources available to the PTO, counsel against requiring "clear and convincing evidence" to overturn that presumption. We believe the "clear and convincing evidence" burden can undermine the ability of the court system to weed out questionable patents . . . .<sup>72</sup>

In addition, both the FTC and NAS have proposed changes that will make it easier for the challenger to prove that an issued patent is invalid because it is obvious from the perspective of what is already in the scientific or technological literature or known to persons who

69. *Id.* at 1500 (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 *AIPLA Q.J.* 185, 205-06 (1998)).

70. *FTC RPT.*, *supra* note 1, ch. 5, at 28.

71. *Id.*, Executive Summary, at 10; *see also id.*, ch. 5, at 27-28.

72. *Id.*, Executive Summary, at 10.

research, work, or publish in these areas.<sup>73</sup> The obviousness inquiry seeks to confirm that the claimed invention is “a significant enough technical advance to merit the award of a patent.”<sup>74</sup> It requires “a level of development” that is a step “beyond not only the documented prior art but also the practice of people of ordinary skill in th[e] art . . . before a patent can issue.”<sup>75</sup> Both the FTC and NAS view the proper application of the standard as crucial to preventing the issuance of questionable patents.<sup>76</sup>

The FTC specifically recommended that the courts tighten the standards for the “commercial success” and “suggestion” tests that are presently used to evaluate the obviousness of the claimed invention.<sup>77</sup> Courts may consider the commercial success of a claimed invention as evidence that it was not obvious. The problem, according to the FTC, is that courts and juries are willing to find commercial success whenever the claimed features of the patent are co-extensive with those of a successful product.<sup>78</sup> This approach ignores the very real possibility that factors other than the use of the inventive features may have caused commercial success.<sup>79</sup> The bar for satisfying the commercial success test is set too low, which contributes to patents issuing on obvious inventions. The FTC therefore recommended that courts evaluate on a case-by-case basis whether commercial success is a valid indicator of nonobviousness, and, further, that patentees, not the challengers, bear the burden of proving that, in fact, the claimed invention caused the commercial success.<sup>80</sup>

As for the “suggestion” test, the underlying rationale is that if prior art would have suggested the claimed invention, then the claimed invention is obvious. If not, then the claimed invention is not obvious. The suggestion test thus asks to what extent the prior art would have suggested to a skilled artisan that the subject invention should be carried out and would have a reasonable likelihood of success.

The FTC’s recommended improvement of the suggestion test is best explained with reference to some of the basic principles guiding

73. See 35 U.S.C. § 103(a); FTC RPT., *supra* note 1, Executive Summary, at 10; NAS RPT., *supra* note 1, at 81–82.

74. FTC RPT., *supra* note 1, Executive Summary, at 10; *see also id.*, ch. 4, at 4.

75. *Id.*, ch. 4, at 4; NAS RPT., *supra* note 1, at 59.

76. FTC RPT., *supra* note 1, ch. 4, at 4–6; NAS RPT., *supra* note 1, at 61.

77. FTC RPT., *supra* note 1, ch. 4, at 9–19.

78. *Id.* at 17.

79. *Id.*; *see also id.*, Executive Summary, at 11.

80. *Id.*, ch. 4, at 19.

the use of prior art to prove that an invention is obvious and therefore invalid. A claimed invention will usually consist of several key features or elements. For example, a system for inspecting a silicon wafer on which chips are fabricated could include, as separate elements, a laser beam projected onto the surface of the wafer, an acousto-optic deflector that uses sound waves to deflect the beam in very rapid and precise movements across the wafer surface, and a collector or collectors that “see” and analyze light scattered by the laser beam as it strikes the wafer surface in order to determine whether the wafer is defective.

The invention in the example is entitled to patent protection whether its individual elements are all new, *i.e.*, they are not disclosed in the prior art, all old, *i.e.*, they can be found in the prior art, or are partly new or partly old.<sup>81</sup> As explained by the Federal Circuit, “[v]irtually all inventions are combinations and virtually all are combinations of old elements.”<sup>82</sup>

What is directly relevant to patentability is whether resources such as the scientific literature (prior art) teach or “suggest” the same combination of elements as is claimed in the patent.<sup>83</sup> If so, the patent is obvious and therefore invalid in the eyes of the patent law.<sup>84</sup> Recalling the example of the wafer inspection system, it is irrelevant whether all three of its key elements, the laser, the acousto-optic deflector and the collectors, are old. This invention is patentable so long as the *combination* of these elements, as they are described in the hypothetical patent, is *not* suggested by one or more prior art references.<sup>85</sup>

The problem, according to the FTC, is that courts have conditioned satisfaction of the suggestion test upon the introduction by the challenger of evidence that the prior art *expressly* teaches the same *combination* of elements as is described in the patent, something that the FTC says is often not actually needed by persons skilled in

81. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546 (Fed. Cir. 1984).

82. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983); *see also* *GNB Battery Tech., Inc. v. Exide Corp.*, 876 F. Supp. 582, 603 (D. Del. 1995) (Holding that it was not error to instruct the jury that “[i]t is irrelevant that some or all of the elements of the claims of . . . [the] patents may have been old. Virtually all inventions are combinations and virtually all are combinations of old elements.”).

83. *Envtl. Designs, Ltd.*, 713 F.2d at 698 (“A court must consider what the prior art as a whole would have suggested to one skilled in the art.”).

84. *Id.*

85. *Id.*



the art.<sup>86</sup> Moreover, the FTC observed that insufficient weight was being given to suggestions implicit in prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one skilled in the art.<sup>87</sup> Thus, the FTC feels the bar for satisfying the suggestion test is set too high, which again results in patents issuing on obvious inventions. The solution recommended by the FTC was that the courts, in applying the suggestion test, assume an ability to combine or modify prior art references that is commensurate with the knowledge of those skilled in the relevant art.<sup>88</sup>

Although it does not offer specific recommendations regarding obviousness, as does the FTC report, the NAS report similarly documents what it describes as “the evolution of the law over the last generation as reducing the size of the step required for patentability under the non-obviousness standard and as allowing the issuance of patents on obvious inventions.”<sup>89</sup> Translation: the courts, in their application of the obviousness standard, are making it too hard for the challenger to prove invalidity on the basis of obviousness.

### C. “Rational Ignorance” of the Patent Office

That both the FTC and NAS propose significant reforms directed to the courts as opposed to the Patent Office, is itself a manifestation of the loss of confidence in the ability of patent examiners to correctly apply the patentability requirements. The FTC actually takes this insight a step further and embraces the “rational ignorance” theory of Stanford Law School Professor, Mark Lemley.<sup>90</sup> The theory is premised in the first instance on empirical data showing that the majority of issued patents, as many as ninety-five percent, are never litigated or even licensed.<sup>91</sup> What logically follows from this data is

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86. FTC RPT., *supra* note 1, ch. 4, at 11–13. The Federal Circuit has on different occasions said that the suggestion need not be express, but can be “implicit from the prior art as a whole.” See *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000); *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997) (stating there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention.”). However, the testimony taken by the FTC was that the Federal Circuit generally fails to interpret the suggestion test consistent with these quotes. FTC RPT., *supra* note 1, ch. 4, at 11–12.

87. FTC RPT., *supra* note 1, ch. 4, at 14.

88. *Id.* at 15.

89. NAS RPT., *supra* note 1, at 61.

90. FTC RPT., *supra* note 1, Executive Summary, at 7 n.24 (citing Lemley, *supra* note 39, at 1497).

91. Lemley, *supra* note 39, at 1501.

that many of the questionable patents that slip through the system are never litigated nor licensed. As explained by Professor Lemley, it is therefore more efficient and cheaper for society to conduct a detailed and thorough investigation of validity in those relatively few instances where somebody cares enough to litigate the patent.<sup>92</sup> He concludes that “[i]n short, the PTO doesn’t do a very detailed job of examining patents, but we probably don’t want it to. It is ‘rationally ignorant’ of the objective validity of patents, in economics lingo, because it is too costly for the PTO to discover those facts.”<sup>93</sup>

The FTC’s reliance upon Professor Lemley’s analysis is a stinging indictment of the Patent Office. The FTC in effect agrees that the amount of time and money required for the Patent Office to get it right exceeds what anyone would reasonably want to pay. According to the FTC, we should therefore acknowledge and accept the “ignorance” of the Patent Office and direct available resources towards making sure the courts get it right when the patents “that matter” are litigated.

This perception, that patent examiners make mistakes, undercuts the rationale favoring a strong presumption of validity and has resulted in proposed reforms such as lowering the burden of proving invalidity, as well as making it easier to prove invalidity based upon the obviousness of the invention. A central reform strategy is that we should accept that all we are going to get from the Patent Office in its review of patent applications is a “quick once over.” That the challenger has the burden of going forward with proof that the government acted incorrectly when it issued the patent is a far less daunting task if the review by the patent examiner is considered more of a preliminary screen, such that the government action receives far less deference than if the examiner is believed to have conducted a thorough investigation of the application. *The proposed reforms therefore knock the eagle off of the patent owner’s shoulder: the loss of confidence in the correctness of the government’s action, i.e., the belief that the government “got it wrong,”* has resulted in proposals to lower, if not eliminate, significant obstacles to proving invalidity.

#### IV. THE FEDERAL CIRCUIT IS HAPPY TO OBLIGE

The Federal Circuit’s recent decision in *Chiron Corp. v. Genentech, Inc.*<sup>94</sup> advances the reform agenda by refusing to require

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92. *Id.* at 1510–11; *see also id.*, at 1497 n.6.

93. *Id.* at 1497.

94. *Chiron*, 363 F.3d at 1258–59.

that the trial court instruct the jury that a patent is presumed valid. The decision effectively bars the patentee from giving the jury the compelling explanation as to *why* a heightened burden of proof is imposed upon the challenger. The jury does not hear about hard-working and well-trained government examiners who are presumed to have done their job correctly, nor do they hear that the patent, the fruit of the government's thorough investigation, is presumed valid. The decision in *Chiron*, therefore, makes it easier for the challenger to meet its burden of proving to the jury that the patent is invalid.

The impetus for the *Chiron* decision and the practical consequences that flow from the decision is the same as that which motivates the recent proposals for reforming the patent system: the government too often issues bad patents. *Chiron* is likely a harbinger of future Federal Circuit decisions reducing the obstacles to proving invalidity.

#### A. Jury Instructions

The importance of jury instructions to the outcome of a case tried to a jury cannot be overestimated. Jury instructions provide the law that governs the rights and obligations of the parties, or, to put it in words closer to how a juror thinks about the instructions, they are "rules" which people are supposed to follow.<sup>95</sup> The importance of jury instructions in the eyes of the jury is underscored by the fact that they come not from any of the parties to the litigation (whom jurors rightfully suspect of biased presentation), but rather from the trial judge.<sup>96</sup> Indeed, one of the instructions given to the jury is that it is the trial judge's job to tell them the rules.<sup>97</sup>

The jury instructions define the scope of argument and evidence that may be given by the parties to the jury. In their closing statements, lawyers may discuss the law (the rules) that are included in the jury instructions. Counsel's discussion of the law is considered so important to the jury's understanding of the significance of the evidence that Rule 51 of the Federal Rules of Civil Procedure requires trial judges to advise counsel of the instructions that the court

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95. ROBERT E. JONES ET AL., RUTTER GROUP PRACTICE GUIDE: FEDERAL CIVIL TRIALS AND EVIDENCE § 15:1 (2004).

96. See *id.*, §§ 14:65, 15:40; *Bellotte v. Zayre Corp.*, 531 F.2d 1100, 1102 n.1 (1st Cir. 1976).

97. See, e.g., 2003 DEL. PATENT INSTR., *supra* note 22, Preliminary Instructions, Course of the Trial, at 13 ("After you have heard all of the evidence, I will instruct you on the law that you must apply in this case."); see also *id.*, General Jury Instructions, § 1.1, Introduction, at 1 ("I will now instruct you about the law that you must follow in deciding this case.").

proposes to give the jury before counsel's final arguments. This rule ensures that counsel know the precise words that will be used before final argument as opposed to speculating as to what the court will say, "giv[ing] counsel the opportunity to explain the instructions, argue their application to the facts and thereby give the jury the maximum assistance in determining the issues and arriving at a good verdict on the law and the evidence," and "supplying a natural outline so that arguments may be directed to essential fact issues which the jury must decide."<sup>98</sup>

The corollary is that in discussing the law in their closing statements, counsel must accurately state the content of the jury instructions and are not allowed to make an argument based on law that the jury will not be given or that is otherwise misleading or irrelevant in view of the jury instructions.<sup>99</sup> Counsel are prohibited from making arguments based on proposed instructions that the court has excluded.<sup>100</sup>

Because jury instructions are blueprints for the legal theories advanced in a case, the instructions are also used by the court as a template to screen for and exclude evidence that is immaterial, irrelevant or unduly prejudicial. The typical practice in federal trials is for the trial judge to solicit proposed instructions, motions *in limine* and dispositive motions prior to, or as part of, the preparation of the final pre-trial order. A practical consequence of this process is that in most instances the trial judge will have made before trial at least a preliminary determination of what instructions will be given. Documents and testimony that do not tend to prove or disprove an issue framed by the instructions under consideration, or that are directed to instructions already rejected by the court, most likely will be excluded from evidence.

Jury instructions are a major consideration in litigated patent cases because a significant number of these cases are tried to a jury. In the late 1960s, just over three percent of patent cases were tried to a jury.<sup>101</sup> This practice shifted dramatically after the Federal Circuit came into being, such that, in 1994, seventy percent of patent trials were to juries.<sup>102</sup>

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98. FED. R. CIV. P. 51(b)(1); *see also id.*, Advisory Committee Notes, 1987 Amendment.

99. JONES ET AL., *supra* note 95, § 14:66.

100. *See id.*

101. Taylor, *supra* note 33, at 29–30.

102. *Id.*

### B. *A Case of First Impression*

In *Chiron*, the Federal Circuit tackled for the first time the question of whether the district court is required to instruct the jury on the presumption of validity. District courts and professional associations have taken very different positions on the question.

District courts in at least the Third, Fifth and Eighth Circuits give instructions that tell the jury that a patent enjoys a presumption of validity.<sup>103</sup> For example, in the Third Circuit, the United States Court for the District of Delaware says the following in its model patent instructions:

#### Presumption of Validity

The granting of a patent by the Patent Office carries with it the presumption that the patent is valid. From issuance of the patent, it is presumed that its subject matter is new, useful and constitutes an advance that was not, at the time the invention was made, obvious to one of ordinary skill in the art. The law presumes, in the absence of clear and convincing evidence to the contrary, that the Patent Office acted correctly in issuing the patent. Nevertheless, once the validity of a patent has been put in issue, it is the responsibility of the jury to review what the Patent Office has done consistent with these instructions on the law.

This presumption of validity puts the burden of proving invalidity on Defendant. While this presumption can be rebutted, the burden is on Defendant to do so. This burden requires that Defendant prove by clear and convincing evidence that in this case each of the asserted claims is invalid.<sup>104</sup>

Similarly, the Federal Judicial Center, an agency that Congress created in 1967 to promote improvements in judicial administration in federal courts, has produced a videotape tutorial on patents. The videotape is now shown to juries on a regular basis as part of the trial judge's preliminary instructions in a patent case. The narration to the videotape tells jurors that "[t]o prove that a patent is invalid, the law

103. See, e.g., Trial Transcript at 1549, *ADE Corp. v. KLA-Tencor Corp.* (No. 00-892 KAJ) (reciting the jury instructions given February 4, 2004); *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 378 (D. Del. 2000); *Standard Havens Prods., Inc. v. Gencor Indus. Inc.*, 1989 U.S. Dist. LEXIS 10333, at \*21-23 (W.D. Mo. Aug. 30, 1989); Trial Transcript at 1648-49, *Itron, Inc. v. Benghiat* (No. 99-501 JRT/FLN) ("The law presumes that the . . . patent is valid and enforceable, and presumes further that the Patent Office acted correctly in issuing the patents.") (reciting the jury instructions given December 20, 2002).

104. 2003 DEL. PATENT INSTR., *supra* note 21, General Jury Instructions, § 4.1 Presumption of Validity, at 33.

requires a higher standard of proof since the PTO is presumed to have done its job correctly.”<sup>105</sup>

The rationale for instructing on the presumption is that jurors are entitled to know what the law is, namely, that “[a] patent shall be presumed valid.”<sup>106</sup> Moreover, this instruction “introduce[s] the jurors to the fundamentals of validity” by explaining *why* the burden of proving invalidity is on the challenger and *why* there is a heightened standard of proof of clear and convincing evidence.<sup>107</sup> An instruction advising the jury on the clear and convincing evidence standard, the presumption of validity and the relationship between the two concepts “[is] at the core of the statutory scheme of patent litigation.”<sup>108</sup>

Another reason for instructing on the presumption of validity is that Federal Circuit decisions have discussed the effect of proposed jury instructions on the presumption of a patent’s invalidity, yet in none of these decisions did the Federal Circuit hold that it is improper to instruct on the presumption itself.<sup>109</sup>

In comparison, the Federal Circuit Bar Association’s model patent jury instructions tell the jury that the challenger has the burden of proving invalidity by a heightened standard of evidence, but omit any reference to the presumption of validity. The core language of this instruction is as follows:

[Defendant] has challenged the validity of the . . . patent claims on a number of grounds. [Defendant] must prove that a patent claim is invalid by the highly probable standard.<sup>110</sup>

Likewise, the model patent instructions of the American Intellectual Property Law Association (AIPLA) advise the jury that

105. Videotape: An Introduction to the Patent System (Federal Judicial Center Oct. 2002), available at <http://www.fjc.gov/newweb/jnetweb.nsf/pages/557>. The seventeen minute video is, in the words of the Federal Judicial Center, “designed to be shown to jurors in patent jury trials. It contains important background information intended to help jurors understand what patents are, why they are needed, how inventors get them, the role of the [PTO], and why disputes over patents arise.” *Id.*

106. See 35 U.S.C. § 282 (2000).

107. See 2003 DEL. PATENT INSTR., *supra* note 21, at General Jury Instructions, § 4.1, Presumption of Validity, Comments, at 33; 2002 N.D. CAL. PATENT INSTR., *supra* note 6, § A.1., Preliminary Instructions, at 2 n.1.

108. *Lifescan, Inc.*, 103 F. Supp. 2d at 377–378 (citing *Standard Havens*, 1989 U.S. Dist. LEXIS, at \*21–23).

109. See, e.g., *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358 (Fed. Cir. 1984); *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1564 (Fed. Cir. 1993).

110. FCBA PATENT INSTR., *supra* note 26, § 10.1 Validity In General, at 54.

the challenger has the burden of proof without commenting on the presumption of validity.<sup>111</sup>

The professional associations' rationale for excluding the presumption is that it is a "procedural device" that imposes certain burdens on the accused infringer, but is not "evidence" to be weighed against the accused infringer's evidence.<sup>112</sup> There is also the concern that "instructing the jury on the presumption in addition to informing it of the clear and convincing burden of proof may cause jury confusion as to its role in deciding invalidity."<sup>113</sup>

Adding to the unsettled nature of this mix, the model patent rules for the Northern District of California incorporate language on the presumption as an *optional* element of the instruction on the burden of proving invalidity.<sup>114</sup> The drafters explain that they simply could not agree on whether to put the presumption into the instruction, and instead chose to offer optional language on the presumption along with a discussion in the drafting notes of the "pro" and "con" arguments regarding its use.<sup>115</sup>

Arguably, there are four major sources of model patent instructions: District of Delaware, Northern District of California, Federal Circuit Bar Association, and AIPLA. The divergent positions taken in these model sets of instructions regarding the presumption of validity show that there was no consensus on this matter as of the time the Federal Circuit decided *Chiron*.

The different positions taken in the model instructions are summarized as follows:

<u>Source</u>	<u>Instruction on Presumption?</u>
Delaware	Yes.
Fed. Cir. Bar Assoc.	Omitted without explanation.
AIPLA	Omitted with explanation.
N.D. California	Optional.

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111. AIPLA PATENT INSTR., *supra* note 12, at 6.

112. FCBA PATENT INSTR., *supra* note 26, § 10.1, Validity In General, at 54 (citing *Avia Group Int'l, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1562 (Fed Cir. 1988)).

113. *Id.*

114. 2002 N.D. CAL. PATENT INSTR., *supra* note 6, § A.1, Preliminary Instructions, at 2 (providing that the optional language is as follows: "[The patent, when granted by the PTO, is presumed to be valid but its validity can be challenged by others.]").

115. *Id.* at 2 n.1.

### C. *Chiron Rationale*

In *Chiron*, the parties were competitors in the engineering of “monoclonal antibodies” used in the diagnosis and treatment of breast cancer. Plaintiff Chiron’s patent was broadly construed before trial to cover defendant Genentech’s product, and partial summary judgment of infringement was entered in favor of Chiron. The parties also stipulated before trial that Chiron’s patent was invalid unless it was entitled to the earlier filing date of applications from which it continued. The ensuing trial therefore focused on whether the claims sued upon were adequately described and enabled in the earlier applications (the precondition to priority under section 120 of the patent statute).

The jury determined that the priority applications did not satisfy the written description and enablement requirements. When the district court denied Chiron’s motion for judgment as a matter of law and a new trial, Chiron appealed to the Federal Circuit, which ultimately affirmed the denial of the post-trial motions.

The bulk of the Federal Circuit’s analysis in *Chiron* is devoted to the issues of written description and enablement, with relatively little attention given to alleged errors in the jury instructions and even less space, a paragraph in fact, devoted to Chiron’s argument that the district court erred by instructing the jury on Genentech’s burden of proof without also adding an instruction on the presumption of the asserted patent’s validity.<sup>116</sup>

The brevity of the Federal Circuit’s discussion of the presumption question is matched by the court’s relatively shallow substantive analysis. The Federal Circuit cited its previous decision in *Avia Group International, Inc.* for the proposition that the presumption is a procedural device as opposed to evidence to be weighed against the challenger’s evidence.<sup>117</sup> It also cited its decisions in *American Hoist* and *Moba* for the proposition that the presumption of validity and the heightened burden of proof are interchangeable expressions of “a single hurdle to be cleared,” such that reference to the latter is sufficient.<sup>118</sup>

The problem with the Federal Circuit relying upon these cases is that none of them dealt with the specific issue of whether it is error

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116. *Chiron*, 363 F.3d at 1258–1259.

117. *Id.* at 1259 (citing *Avia*, 853 F.2d at 1562).

118. *Id.* at 1258 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984), and *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003)).



for the district court to refuse to instruct on the presumption. Moreover, the Federal Circuit did not address the arguments that favored an instruction on the presumption, including the juror's right to hear the law as it is set out in the patent statute, and the explanation of why the burden of going forward, burden of persuasion, and heightened standard of proof imposed upon the challenger assist the jury in applying the "rules" to the evidence.

Whether one agrees or not with *Chiron*, the case is now binding precedent as to whether a patent jury must be instructed on the presumption of validity. Although *Chiron* has petitioned for *certiorari* to the Supreme Court, the Federal Circuit's holding that an instruction on the presumption is not required was not raised in the petition.<sup>119</sup>

#### D. Dramatic Consequences

Notwithstanding *Chiron's* perfunctory analysis of the presumption instruction, the ruling has dramatic consequences. It is far easier to convince the jury that a patent is invalid if they are never told that the government is presumed to have "gotten it right" when its examiners issued the patent in the first place.

The gospel among patent trial attorneys is that jurors are extremely reluctant to second-guess the examiner. This perception is based upon the courtroom experience of many trial lawyers over time, and is strongly reinforced by the "jury psychology" preached by the specialized group of jury consultants that mock-try and consult on the selection of jurors in patent cases,<sup>120</sup> as well as empirical data showing the lower percentage of jury verdicts finding a patent invalid.<sup>121</sup>

*Why* should jurors feel they cannot second-guess the examiner? The answer is clear: this is what they are *told* to feel by the instruction

119. Interview with Robert P. Blackburn, Chief Intellectual Property Counsel, *Chiron Corporation*, in Berkeley, Cal. (Apr. 16, 2004).

120. Two well-known jury consulting services are Trial Behavior Consulting ([at http://www.trialbehavior.com](http://www.trialbehavior.com)) and Bowne DecisionQuest ([at http://www.decisionquest.com](http://www.decisionquest.com)). Dr. Michael Tikitsky, principal at Trial Behavior Consulting is a particularly strong proponent of juror's reluctance to second-guess examiner's decisions. Interview with Michael Tikitsky, Principal, Trial Behavior Consulting, in Wilmington, Del. (Jan. 8, 2004).

121. Allison & Lemley, *supra* note 69, at 212–213 (providing statistical support for proposition that juries tend to favor patentees on validity questions and that juries are unlikely to second-guess an examiner who has already considered and rejected a prior art reference). At trial, only 33% of patents are held invalid. Lemley, *supra* note 39, at 1529 n.129 (citing Kimberly Moore, *Judges, Juries and Patent Cases—Empirical Evidence to Peek Inside the Black Box*, 99 MICH. L. REV. 365, 390 tbl.4 (2000)).

on the presumption and related arguments by counsel. The neutral and all-knowing trial judge, the credible source of “the rules,” tells jurors that patent examiners are trained government experts who are presumed to have done their job correctly when they examined the patent, and, therefore, that the patent issued by the examiner is presumed valid.

The pro-examiner mindset is further strengthened by trial counsel’s entirely legitimate expansion upon the judge’s “rules” that the examiner acted correctly in issuing the patent and that the patent is therefore presumed valid. Counsel, in their argument to the jury, can encourage jurors to read the “rules” as describing examiners as highly trained specialists who not only know more than lawyers or jurors do about the technology in the patent, but who also have spent very long periods of time poring over the patent application. The collective effect of the trial judge’s instructions and related counsel argument is the creation of a very strong juror bias in favor of patent validity; and the challenger has the heavy burden of overcoming this bias.

However, omitting the instruction on a patent’s presumed validity, thereby preventing counsel from extolling the examiner’s virtues, causes the pro-examiner bias to crumble. The *Chiron* ruling, which does just this, therefore topples a major obstacle to proving invalidity. Fully in step with proposed patent reforms, *Chiron* knocks the eagle off the patent owner’s shoulder: it lowers the obstacle to proving invalidity that would otherwise exist if the jury were allowed to hear how the government got it right.

That *Chiron* makes it easier to convince a jury that a patent is invalid assumes even greater significance given recent statistics that demonstrate the high percentage of patent cases that are now tried before a jury.<sup>122</sup> Moreover, the patent jury trials affected by *Chiron* are high stakes, high risk litigation in which the litigants incur large fees and costs.

For example, the Law Practice Management Committee of the AIPLA conducts an annual survey of intellectual property law attorneys in the United States (AIPLA Survey) on subjects such as the typical charges for patent litigation.<sup>123</sup> The 2003 AIPLA Survey obtained information from attorney respondents for any given patent litigation of which they had personal knowledge on the estimated attorney fees and costs of three value-at-risk categories: less than \$1

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122. See Taylor, *supra* note 33, at 29–30.

123. AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, AIPLA REPORT OF THE ECONOMIC SURVEY 2003 1, 19 (2003).

million at risk, \$1–25 million at risk, and more than \$25 million at risk.<sup>124</sup> Over half of the respondents who said their primary practice was devoted to dispute resolution (as opposed to non-litigation activities such as patent prosecution or licensing) reported knowledge of patent litigation where there was more than \$25 million at risk.<sup>125</sup> The median costs and fees of taking such a case to beyond pre-trial discovery up through and including a final resolution (whether trial or settlement), for all jurisdictions, was \$3.9 million, and these figures were even higher in specific jurisdictions that see more patent litigation, including California at \$4.9 million, Texas at \$5 million, Delaware at \$4.9 million, and Washington, D.C. at \$5 million.<sup>126</sup> Thus, the specific milieu affected by the *Chiron* rulings, patent jury trials, is itself grounds for recognizing the important impact of the *Chiron* decision.

A likely objection to these arguments is that *Chiron's* importance is over-estimated because *Chiron* did not lower the heightened standard for proving invalidity. This presumption, after all, is merely a procedural device that imposes upon the challenger the burden of proving invalidity by the higher standard. The presumption and the heightened burden of proof are “in reality different expressions of the same thing—a single hurdle to be cleared.”<sup>127</sup> Thus, *Chiron* does not make it easier to prove invalidity—or so the argument goes.

The problem with this objection is that it fails to take into account what happens when the reasons for imposing a higher burden of proof, namely the presumption and all that it encompasses, are not transparent to the jury. Omit the instruction and related argument on the presumption, and what the jury is told is limited to the court's advice that the challenger has the burden of proving invalidity by clear and convincing evidence and that this is a higher standard of proof than a preponderance of the evidence. There is no context

124. *Id.* at 21.

125. *Id.* at 64 tbl.10 (Table 10, Percent of Time in Primary Practice Devoted to Various Types of Work, Dispute Resolution) and 94 tbl.22 (Table 22, Estimated Costs of Litigation, by Location of Primary Place of Work, Estimate of Total Cost, Through End of Discovery and Inclusive, in a Patent Infringement Suit, More Than \$25 Million at Risk).

126. *Id.* at 94 tbl.22 (Table 22, Estimated Costs of Litigation, by Location of Primary Place of Work, Estimate of Total Cost, Through End of Discovery and Inclusive, in a Patent Infringement Suit, More Than \$25 Million at Risk). Moreover, the average cost of patent litigation is likely even higher given reported fees and costs in the 75th percentile of \$5.9 million for all jurisdictions and \$6 million in California and \$7.9 million in Texas. *Id.*

127. *Chiron*, 363 F.3d at 1258 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

given, no explanation that the presumed correction of the government's action is so strong that the law not only shifts to the challenger the job (i.e., the burden) of proving invalidity, but also requires that the challenger come forward with an especially high level of proof sufficient to overcome the presumption.

The practical consequence is that the jury has little or no understanding of how much evidence is required to satisfy the supposedly higher standard and no motivation for imposing the supposedly heavier burden on the challenger. Under these circumstances, the challenger finds it much easier to convince the jury to invalidate the patent. Common sense dictates that the presumption and the heightened burden of proof are *not* interchangeable expressions of "the same thing—a single hurdle to be cleared." If the jury does not understand the reasons for shifting burdens and higher standards, the likelihood is that the jury would set the hurdle much lower than they would if they knew the full story.

Another objection could be that *Chiron* did not hold that it was improper to give an instruction on the presumption of validity, but only that it was not improper for the district court to refuse to give the instruction. According to this argument, *Chiron* has not really made it easier to invalidate the patent, because the district court still has discretion under *Chiron* to decide that it will go ahead and instruct the jury on the presumption.

The flaw in this argument is that it is based upon the erroneous assumption that when the next case comes up, it is equally as likely that the district court will allow the presumption instruction as it is that it will not allow the instruction, or we at least do not know enough to say which is the greater likelihood because *Chiron* did not hold that the instruction should not be given.

More likely, when next this issue comes before a court, the patent holder will offer the instruction that the patent is presumed valid and the challenger will object, citing *Chiron* for the proposition that the presumption is merely a procedural device and not evidence to be weighed against the challenger's evidence, and that the presumption is merely a different expression of the "same thing" embodied in the higher burden of proof instruction. Not only is this an accurate citation to *Chiron*, but there is also little or no countervailing authority upon which the patent owner could rely that directly requires giving the jury the explanation for imposing on the challenger a higher burden of proving invalidity.

True enough, the patent owner could generally argue the importance of the presumption, but the trial judge will have already figured out that the Federal Circuit does not believe that any additional instruction on the presumption is required. In addition, the trial judge will also want to avoid, at all costs, expanding the instructions beyond the potentially confusing, wordy, and time-consuming set that the trial judge already knows have to be given or else commit reversible error.<sup>128</sup> In the words of one judge, “[p]revailing practices of instructing juries are often so archaic and unrealistic that even in relatively simple cases what jurors hear is little more than legal mumbo jumbo to them,” but that trial judges nonetheless “adher[e] to archaic practices out of fear of being reversed.”<sup>129</sup> In the end, the likelihood that the presumption instruction is accepted over the challenger’s objection is slim to none.

So why would the Federal Circuit devote relatively little attention in *Chiron* to a ruling having such dramatic consequences? The unstated, but highly probable explanation is that the Federal Circuit, just like the proponents of patent reform, has lost confidence in the ability of patent examiners to issue valid patents. Just like the reformers, the Federal Circuit now has serious concerns that too many bad patents are slipping through the system. Having lost confidence in the Patent Office, the Federal Circuit does not find it unduly prejudicial to the patent owner to deny the patent owner the benefit of judge-made rules or practices making it hard for the challenger to prove invalidity. The previous pro-patent owner presumptions and burdens were derived from the now discredited belief that the Patent Office gets it right.

Sure, the practical effect of *Chiron’s* ruling is to remove significant obstacles to proving invalidity, but it is unlikely that the Federal Circuit believes that this is a dramatic upheaval in the law that would require lengthy discussion. Rather, the logical and necessary consequence of recognizing and responding to the real-world issues

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128. It is not unusual in patent infringement cases for the judge to give the jury well over 100 separate instructions and special interrogatories, requiring the jury to listen to formal legal statements for anywhere between 45–60 minutes—and this after sitting through a trial that typically lasts two or more weeks. *See, e.g.*, Trial Transcript at 1546–88, ADE Corp. v. KLA-Tencor Corp. (No. 00–892 KAJ); Trial Transcript at 1608–74, Itron, Inc. v. Benghiat (No. 99–501 JRT/FLN).

129. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 713 (Fed. Cir. 1984) (citing William W. Schwarzer, *Communicating With Juries: Problems and Remedies*, 69 CAL. L. REV. 731, 732 (1981)).

with the Patent Office is that it simply should not be as hard as it has been to prove invalidity.

If it is true that *Chiron* was motivated by the loss of confidence in the capabilities of patent examiners, then *Chiron* is likely a harbinger of future Federal Circuit decisions that will remove additional obstacles to proving invalidity. In particular, the heightened standard of proof for invalidity was a judge-made rule derived from judges' interpretation of the statutory presumption of validity. Section 282 of the patent statute, although expressly recognizing the presumption of validity and imposing upon the challenger the burden of going forward, does not specify the standard of proof that must be met by the challenger.<sup>130</sup> Instead, judges developed the present standard of proof, clear and convincing evidence, through a series of cases dating at least as far back as the Supreme Court's 1934 decision in *Radio Corp. of America v. Radio Engineering Laboratories, Inc.*<sup>131</sup> Thus, no legislative action is required to lower this judge-made standard of proof.

Given the serious concerns that too many bad patents are slipping through the system, and relying upon the relatively few patent litigations as the mechanism for achieving a truly efficient and accurate determination of a patent's validity, the reform position is that there is no reasonable explanation for imposing a higher burden of proof on the challenger. In *Chiron*, the Federal Circuit signals that it is already moving in this direction.

## V. CONCLUSION

The long-standing belief that the government "gets it right" has been the genesis for stacking presumptions and burdens of proof in the patent owner's favor. Patent owners have long worn the eagle on their shoulders. They have for a long time reaped the benefit of the court's confidence in the correctness of the government's action. However, the Patent Office has come under sharp attack of late, including numerous proposals that directly or indirectly reduce or remove the obstacles to proving invalidity, thus knocking the eagle off of the patent owner's shoulder.

*Chiron* effectively denies the jury the explanation for the heavier burden of proving invalidity that is imposed upon the challenger, and thereby makes it easier for the challenger to prove invalidity. *Chiron*

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130. See 35 U.S.C. § 282 (2000).

131. *Radio Corp. of Am. v. Radio Lab., Inc.*, 293 U.S. 1, 8 (1934); see also *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359–1360 (Fed. Cir. 1984).

manifests the same loss of confidence in the Patent Office that gave rise to the proposed patent reforms. It is likely the harbinger of future decisions by the Federal Circuit that will make it even easier to prove invalidity.