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### Cover Page Footnote

J.D. Candidate, May 2018, The Catholic University of America, Columbus School of Law; B.A. 2012, The University of Connecticut. The author wishes to thank the professors and alumni of the Catholic University who provided their support and guidance. The author also wishes to thank *the Catholic University Law Review* staff members and editors for their hard work during the editing of this Comment.

# THE PROPER APPELLATE STANDARD OF REVIEW FOR PTAB FACTUAL FINDINGS MADE INCIDENTAL TO CLAIM CONSTRUCTION

*A. David Brzozowski II*<sup>+</sup>

In 2011, President Obama signed the America Invents Act (AIA), enacting the most significant changes to U.S. patent law since the 1952 Patent Act.<sup>1</sup> The AIA revolutionized both the prosecution and litigation of patents primarily by creating post-grant patent opposition proceedings at the U.S. Patent and Trademark Office (PTO), such as inter partes review (IPR), post-grant review (PGR), and covered-business-method review (CBM).<sup>2</sup> These opposition proceedings are intended to provide cost-effective alternatives to district court litigation.<sup>3</sup> IPRs and PGRs are trial-like proceedings conducted before a panel of three administrative patent judges at the Patent Trial and Appeal Board (“PTAB” or “Board”).<sup>4</sup> Since September 16, 2012, when the PTAB began accepting petitions for AIA proceedings, there have been nearly 6,000 petitions for IPR alone.<sup>5</sup>

Despite the AIA’s support from the intellectual property community at its enactment and the wide popularity of the proceedings created by the AIA, certain aspects of the new system have been controversial.<sup>6</sup> Specifically, federal judges and patent practitioners are debating which standard of review courts

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1. Press Release, Office of the Press Sec’y, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011), <https://obamawhitehouse.archives.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>.

2. H.R. REP. NO. 112-98, pt. 1, at 80–81, 145–47, 150–51 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 105–06, 109.

3. *See* 157 CONG. REC. S5,326, 5,327 (daily ed. Sept. 6, 2011) (statement of Sen. Leahy).

4. H.R. REP. NO. 112-98, pt. 1, at 91.

5. *See* U.S. PATENT & TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD STATISTICS 2 (Nov. 30, 2016), [https://www.uspto.gov/sites/default/files/documents/aia\\_statistics\\_november2016.pdf](https://www.uspto.gov/sites/default/files/documents/aia_statistics_november2016.pdf) (outlining the combined number of IPR, CBM, and PGR petitions received).

6. Matt Cutler, *3 Years of IPR: A Look at the Stats*, LAW360 (Oct. 9, 2015, 3:59 PM), <http://www.law360.com/articles/699867/3-years-of-ipr-a-look-at-the-stats> (outlining the popularity of IPR proceedings with petitioners but suggesting that Congress, the courts, and the PTO may all have modifications to IPR proceedings in the near future).

should apply to the factual findings made by the PTAB during AIA opposition proceedings.<sup>7</sup>

For over seventeen years, the Federal Circuit, in interpreting the Supreme Court's holding in *Dickinson v. Zurko*,<sup>8</sup> has reviewed all factual findings made at the Patent Office under the substantial evidence standard of the Administrative Procedure Act (APA).<sup>9</sup> However, citing the adjudicatory nature of PTAB proceedings and the purpose and intent of the AIA, certain Federal Circuit judges, as well as others in the intellectual property community, have argued that substantial evidence is the incorrect standard.<sup>10</sup>

Federal Circuit judges recently debated this issue in *Merck & Cie v. Gnosis S.P.A.*<sup>11</sup> in which the Federal Circuit reviewed a PTAB decision that invalidated a patent for obviousness.<sup>12</sup> The panel majority applied the standard in *In re Gartside*,<sup>13</sup> holding that the appellate court must review factual findings made by the PTAB relating to a determination of obviousness under the substantial evidence standard.<sup>14</sup> Judge Newman sharply dissented.<sup>15</sup> She argued that substantial evidence is too deferential to affect the AIA's purpose of having courts spot and correct the PTAB's errors and, thus, argued that the court should review PTAB's factual findings for clear error.<sup>16</sup>

Judge Newman's opinion coincided with the Supreme Court's decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*<sup>17</sup> several months earlier. In *Teva*, the Court held that the Federal Circuit should review a district court's factual findings during claim construction for clear error per the express wording of Rule 52(a)(6) of the Federal Rules of Civil Procedure.<sup>18</sup> Although differences

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7. Alana Canfield Mannigé, Note, *The Standard of Review for Claim Construction in Inter Partes Review*, 8 HASTINGS SCI. & TECH. L.J. 157, 169–71 (2016).

8. 527 U.S. 150 (1999).

9. See, e.g., *GraftTech Int'l Holdings, Inc. v. Laird Techs., Inc.*, 652 Fed. App'x 973, 975 (Fed. Cir. 2016) (“We review the PTAB’s . . . factual findings for substantial evidence.”); *Brand v. Miller*, 487 F.3d 862, 868 (Fed. Cir. 2007) (“[F]indings of fact by the [PTAB] must in all cases be supported by substantial evidence in the record.”); see also *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000).

10. See, e.g., *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 840 (Fed. Cir. 2015) (Newman, J., dissenting).

11. 808 F.3d 829 (Fed. Cir. 2015), *reh'g denied*, 820 F.3d 432 (Fed. Cir. 2016).

12. *Id.* at 831.

13. *Gartside*, 203 F.3d at 1315.

14. *Merck*, 808 F.3d at 832.

15. *Id.* at 839 (Newman, J., dissenting).

16. See *id.* at 840–41, 845.

17. 135 S. Ct. 831 (2015).

18. *Id.* at 836. The Supreme Court held in relevant part that:

[FRCP] 52(a)(6) states that a court of appeals “must not . . . set aside” a district court’s “[f]indings of fact” unless they are “clearly erroneous.” In our view, this rule and the standard it sets forth must apply when a court of appeals reviews a district court’s resolution of subsidiary factual matters made in the course of its construction of a patent claim.

exist between the appellate review of district court decisions and the review of administrative agency decisions, certain members of the public have argued that the clear error standard of review for district court factual findings related to claim construction should also be the standard of review for the PTAB's factual findings relating to claim construction.<sup>19</sup>

This Comment seeks to examine the arguments for and against whether courts should review factual findings made incidental to claim construction under the substantial evidence standard (as provided by the APA) or the clearly erroneous standard (as provided in *Teva*). This Comment begins with a discussion of the relevant history and application of claim construction in patent litigation cases, and how the PTAB has evolved under the AIA. This Comment will then explore relevant Supreme Court cases and discuss the views of certain critics and supporters of the substantial evidence and clear error standards of review applied to PTAB factual findings made in AIA proceedings. Ultimately, this Comment concludes that courts should review factual findings made during claim construction for clear error.

## I. HISTORY AND DEVELOPMENT OF CLAIM CONSTRUCTION AND THE EMERGENCE OF THE VARIOUS STANDARDS OF REVIEW

### A. *Claim Construction in District Court Litigation*

Claim construction determines what the terms in a patent claim mean to a person having ordinary skill in the relevant art.<sup>20</sup> Often the meaning of a term affects the scope of the claim and consequently affects the determination of infringement and validity.<sup>21</sup> Therefore, the determination of a claim term's meaning will impact the "metes and bounds" of a patent.<sup>22</sup> During claim construction, "[I]nguistically minor variations in phraseology and meaning can be the difference between a finding of infringement . . . and non-infringement."<sup>23</sup> As the late Federal Circuit Judge Giles Rich observed, in patent litigation, "the name of the game is the claim."<sup>24</sup>

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*Id.* (alteration in original).

19. Thomas L. Irving et al., *Teva's Effect on Review of PTAB Claim Construction Rulings*, LAW360 (May 11, 2015, 10:04 AM), <https://www.law360.com/articles/650953/teva-s-effect-on-review-of-ptab-claim-construction-rulings>.

20. 1 MARK A. LEMLEY ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE*: 2016 III-182 (Clause 8 2016).

21. *Id.* at III-170.

22. *Id.* at III-166.

23. *Id.*

24. See Giles S. Rich, *Extent of Protection and Interpretation of Claims – American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990).

Claim construction is a matter of law.<sup>25</sup> In *Markman v. Westview Instruments*,<sup>26</sup> the Supreme Court posited that judges—rather than juries—were better equipped to construe the meaning of complex patent claim terms because of their training and experience interpreting written instruments, like statutes or contracts.<sup>27</sup> A term’s meaning, however, will often involve a factual dispute.<sup>28</sup> After limited discovery and briefing, district courts normally hold a pre-trial hearing where the parties and their experts explain why the court should adopt their definition of a term or terms.<sup>29</sup> These hearings, known as claim construction, or *Markman*, hearings<sup>30</sup> are critical in many cases because the court’s rulings may provide the basis for a summary judgment determination on issues of validity and infringement.<sup>31</sup>

### B. Post-Grant Patent Reexamination and Relevant Changes to the Patent Act

Prior to the AIA, there were several related and important developments in the field of U.S. patent law.<sup>32</sup> The first major development was the patent

25. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

26. *Id.*

27. See LEMLEY ET AL., *supra* note 20, at III-170 (interpreting *Markman*, 517 U.S. at 372). The Supreme Court explained:

The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis. Patent construction in particular “is a special occupation, requiring, like all others, special training and practice. The judge, from his training and discipline, is more likely to give a proper interpretation to such instruments than a jury; and he is, therefore, more likely to be right, in performing such a duty, than a jury can be expected to be.”

*Markman*, 517 U.S. at 388–89 (quoting *Parker v. Hulme*, 18 F. Cas. 1138, 1140 (1849)).

28. See, e.g., *id.* at 374–75.

29. See generally J. Michael Jakes, *Using an Expert at a Markman Hearing: Practical and Tactical Considerations*, FINNEGAN (Aug. 2002), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=e3962a13-b898-4102-8fca-171c656a6ed2>.

30. See LEMLEY ET AL., *supra* note 20, at III-171. See generally James Ware & Brian Davy, *The History, Content, Application and Influence of the Northern District of California’s Patent Local Rules*, 25 SANTA CLARA COMPUT. & HIGH TECH. L.J. 965 (2012) (discussing the role the Northern District of California played in developing the first set of patent local rules).

31. See LEMLEY ET AL., *supra* note 20, at III-171. Another reason the Supreme Court decided to make claim construction a judicial, rather than a jury, decision was to “bring claim construction out into the open.” With claim construction in the province of judges, there is “voluminous jurisprudence” regarding how to construe patent terms and claims. *Id.*

32. See generally John M. Golden, *Working Without Chevron: The PTO as Prime Mover*, 65 DUKE L.J. 1657 (2016). Among these many major changes have been:

(1) the emergence of the U.S. Court of Appeals for the Federal Circuit as the primary, day-to-day judicial expositor of patent law; (2) the U.S. Supreme Court’s temporary withdrawal from and subsequent return to being a regular active player in substantive patent law; and (3) the rise of jurisdictions, such as the Eastern District of Texas and District of Delaware, as favorite fora for patent disputes.

*Id.* at 1660–61 (footnotes omitted). Professor Golden notes, “from a relatively modest Jacksonian agency with limited responsibilities after the initial examination and granting of patent applications, the [PTO] has emerged as an adjudicatory forum that competes with courts in reviewing the validity

reexamination statute in the Patent and Trademark Law Amendments Act of 1980.<sup>33</sup> This statute, also known as the Bayh-Dole Act, was intended to “restore confidence in the validity of patents and thereby spur investment in new technologies” through the creation of a “system of administrative reexamination of doubtful patents.”<sup>34</sup> As the first federal statute to create a patent reexamination process, this statute is the predecessor of later reexamination statutes, including the AIA.<sup>35</sup>

Proceedings under the Bayh-Dole Act were *ex parte*, meaning that after a third party filed a petition for reexamination, only the patent owner could participate in the proceeding, if instituted.<sup>36</sup> Furthermore, the statute limited examiners to reviewing issues of prior art, lack of novelty, and obviousness, and to admitting “patents, printed publications, and affidavits” as evidence, thereby preventing claims of fraud, abandonment, and concealment from being heard.<sup>37</sup> These patent reexaminations took several years to complete.<sup>38</sup> Consequently, many defendants did not view this process as a viable option, especially given that they often ended up litigating reexaminations anyway.<sup>39</sup>

Roughly two decades later in 1999, Congress passed the Intellectual Property and Communications Omnibus Reform Act, also known as the American Inventors Protection Act.<sup>40</sup> It created an *inter partes* reexamination process by which a third party could request reexamination of an issued patent, and the requesting party could respond to any responses submitted by the patent owner.<sup>41</sup> Although the American Inventors Protection Act expanded the reexamination process to include *inter partes* reexamination, petitioners seldom used *inter partes* reexamination to challenge patent validity outside of litigation.<sup>42</sup> This unpopularity can be explained by the process’s co-option by accused infringers

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of original patent grants.” *Id.* at 1658 (footnotes omitted). He highlights that the PTO has “grow[n] into an agency with a multibillion-dollar annual budget, [and] over ten thousand employees.” *Id.* at 1661.

33. Patent and Trademark Law Amendments Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (2012)).

34. Eric J. Rogers, *Ten Years of Inter Partes Patent Reexamination Appeals: An Empirical View*, 29 SANTA CLARA COMPUT. & HIGH TECH. L.J. 305, 310 (2013) (quoting H.R. REP. NO. 96-1307, pt. 1, at 3 (1980)).

35. *Id.*

36. See LEMLEY ET AL., *supra* note 20, at III-161.

37. *Id.*; see also Rogers, *supra* note 34, at 316–17.

38. LEMLEY ET AL., *supra* note 20, at III-161.

39. *Id.*; see also Rogers, *supra* note 34, at 319–20. Congress’s first attempt at creating an *ex parte* reexamination review board also drew heavy criticism as “[m]any people felt that the [*ex parte* reexamination] was an unattractive alternative to litigation because a capably represented [patent owner], by using a litigation-sized budget, could tilt the odds heavily in his or her favor.” Rogers, *supra* note 34, at 310.

40. Consolidated Appropriations Act, Pub. L. No. 106-113, 113 Stat. 1501A-552 (1999).

41. See Rogers, *supra* note 34, at 310.

42. *Id.* at 311.

as a litigation tactic to forestall an injunction against them.<sup>43</sup> Subsequently, district court judges have criticized inter partes reexamination.<sup>44</sup>

During the 2000s, patent reform efforts again gained momentum. The focus of such reforms called for “a more robust administrative review process paralleling the European Patent Office’s opposition system.”<sup>45</sup> After several years, those efforts resulted in the AIA.<sup>46</sup> The AIA established three review procedures: inter partes review (IPR), post-grant review (PGR), and covered-business-method review (CBM).<sup>47</sup> Inter partes reexaminations were replaced with IPRs, and PGR and CBM reviews were established for the first time.<sup>48</sup> The IPR statute allows anyone, except the patent owner, to petition the Patent Office to review the patentability of any claim in a patent under Sections 102 (novelty) and 103 (obviousness) of the 1952 Patent Act based on patents and printed publications.<sup>49</sup>

Similarly, PGRs allow anyone other than the patent owner to challenge the patentability of any claim in a patent, but the request must be filed within nine months of the patent’s issuance.<sup>50</sup> PGR grounds for patent review, however, are broader than those for an IPR, as a petitioner can challenge patentability under Sections 101, 102, 103, and 112 of the Patent Act, including double patenting.<sup>51</sup> The petitions are reviewed by a panel of three administrative patent judges in what is now known as the Patent Trial Appeal Board (previously, the Board of Patent Appeals and Interferences (BPAI)).<sup>52</sup>

As with prior patent reform efforts,<sup>53</sup> Congress intended to create an efficient alternative to district court litigation and to improve the quality of the patent

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43. *Id.* at 319.

44. *Id.* at 320–21.

45. See LEMLEY ET AL, *supra* note 20, at III-160.

46. 157 CONG. REC. S5326, 5327 (daily ed. Sept. 6, 2011) (statement of Sen. Leahy).

47. See *supra* note 2 and accompanying text.

48. See LEMLEY ET AL, *supra* note 20, at III-163; see also Golden, *supra* note 32, at 1666 (“[These proceedings under the AIA] notably empower the PTAB to conduct more trial-like proceedings than those previously conducted by the PTO. Further, [these] reviews permit a broader range of potential validity challenges than were previously available in PTO post-issuance proceedings.” (footnotes omitted)).

49. 35 U.S.C. § 311(a), (b) (2012).

50. *Id.* § 321.

51. Jason Mock, *Post-Grant Proceedings at the USPTO and the Rising Tide of Federal Circuit Appeals*, 25 FED. CIR. B.J. 15, 20 (2015).

52. See LEMLEY ET AL, *supra* note 20, at III-161 (The PTAB is the “successor to the pre-AIA [BPAI].”); see also Golden, *supra* note 32, at 1663 (“By statute, the PTAB’s membership consists of the PTO’s Director and Deputy Director, the Commissioners for Patents and for Trademarks, and administrative patent judges.”). The administrative judges are appointed by the Secretary of Commerce in consultation with the Director. Golden, *supra* note 32, at 1663.

53. See Rogers, *supra* note 34, at 310 (“Congress’ purpose in establishing the reexam procedure [under the Bayh-Dole Act] in 1980 was to ‘strengthen[] investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents.’” (quoting H.R. REP. NO. 96-1307, pt. 1, at 3 (1980))).



system.<sup>54</sup> Similar to district court litigation, “most invalidity decisions require that the PTO first engage in claim construction.”<sup>55</sup> But unlike district court litigation, which uses “ordinary and customary meaning” (OCM) to construe the claims of a patent,<sup>56</sup> the PTAB uses the broadest reasonable interpretation (BRI) standard for claim construction.<sup>57</sup> Unsurprisingly, claim construction plays an important role in the PTAB’s decision to institute a trial and in rendering its final decision, much like in district court litigation.<sup>58</sup>

Since IA proceedings began in 2012, there have been a striking number of petitions filed with the PTAB.<sup>59</sup> To handle the inflow of cases, the PTAB tripled the number of judges on the Board.<sup>60</sup> Some commentators have stated that the number of petitions, in comparison to the number of requests filed under the previous administrative framework, underscores the PTAB’s role in patent law.<sup>61</sup>

The PTAB issues hundreds of final decisions each year.<sup>62</sup> To build and maintain their robust patent portfolios, many companies appeal these decisions to the Federal Circuit.<sup>63</sup> Because of the sharp increase in the number of PTAB

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54. See LEMLEY ET AL., *supra* note 20, at III-162; see also H.R. REP. NO. 112-98, at 48 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 78. Lemley cites the Committee, which stated: “The Committee believes that this new, early-stage process for challenging patent validity and its clear procedures for submission of art will make the patent system more efficient and improve the quality of patents and the patent system.” H.R. REP. NO. 112-98, at 48 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 78.

55. Mannigé, *supra* note 7, at 163.

56. *Id.* at 160.

57. *Id.* at 163; see also 37 C.F.R. § 42.100(b) (2016) (“A claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.”).

58. See James Stein et al., *Spotlight on Claim Construction Before PTAB*, 11 BUFF. INTELL. PROP. L.J. 73, 74–75 (2015) (“Claim construction plays a key role both in the institution decision and in the ultimate final written decision. . . . PTAB has to construe the claims to review the patentability of a challenged claim against the grounds of unpatentability asserted in the petition.”). As a result of the ability of challengers to a patent to institute proceedings prior to the patent even being granted, “the new AIA post-grant proceedings mean that PTAB is a whole new audience that must be taken into account when drafting patent applications.” *Id.* at 75.

59. See Golden, *supra* note 32, at 1667 (“From mid-2014 through the third quarter of 2015, filings for *inter partes* post-issuance proceedings before the PTAB arrived at a rate of about 150 per month . . . . The demand for resolution of such *ex parte* appeals is relentless: as of September 2015, the PTAB faced a backlog of over twenty thousand pending *ex parte* appeals.”).

60. See *id.* at 1667–68 (“The BPAI had eighty-one judges in 2010 . . . . By August 2015, the PTAB had 235 members, almost triple the BPAI’s 2010 membership.”).

61. See, e.g., *id.* at 1666–67 (“[T]he number of cases already under PTAB review attest to its substantial role in the post-AIA power structure of U.S. patent law.”).

62. See Mock, *supra* note 51, at 28 (“[T]he PTAB has been issuing hundreds of decisions annually, and it will likely continue to do so.”).

63. See *id.* at 28 (“Considering the gravity of these decision to patent owners’ portfolios, many, if not most, of these decisions will likely be appealed to the Federal Circuit.”); see also U.S. COURT OF APPEALS FOR THE FED. CIRCUIT, FILINGS OF PATENT INFRINGEMENT APPEALS FROM

decisions, some commentators have questioned whether the Federal Circuit can balance its current caseload with these new PTAB appeals.<sup>64</sup> Thus, for the sake of efficiency and justice, the Federal Circuit must apply the correct standard of review to the PTAB's factual findings.

### C. The Substantial Evidence Standard of Review

The Federal Circuit began applying the substantial evidence standard to appeals from the Patent Office following the Supreme Court's decision in *Dickinson v. Zurko*.<sup>65</sup> Before *Zurko*, the Federal Circuit reviewed the Board's factual findings for clear error.<sup>66</sup> *Zurko* started as an appeal to the Federal Circuit from a final determination by the BPAI that a patent applicant's method to increase the security of computers was obvious in view of the prior art.<sup>67</sup>

On appeal, the Federal Circuit held the Board's factual findings regarding obviousness were "clearly erroneous."<sup>68</sup> However, to clarify the issue regarding the standard of review, the Federal Circuit heard the matter en banc.<sup>69</sup> After examining the legal and policy precedents, a per curiam Federal Circuit held that "the stricter . . . standard [of clearly erroneous] was legally proper."<sup>70</sup> In justifying its reliance on the clear error standard, the Federal Circuit determined that Congress excluded the Board from the APA.<sup>71</sup> Additionally, the Federal

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THE U.S. DISTRICT COURTS, [http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/FY16\\_Caseload\\_Patent\\_Infringement\\_2.pdf](http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/FY16_Caseload_Patent_Infringement_2.pdf) (last visited Feb. 9, 2018).

64. See, e.g., Mock, *supra* note 51, at 28 ("Th[e] interplay between the PTAB and the Federal Circuit could lead to the court being overwhelmed by the number of appealable decisions coming out of the Patent Office, giving rise to the question of whether the system of post-grant proceedings, as currently constructed, is sustainable in the long term.").

65. See *Dickinson v. Zurko*, 527 U.S. 150, 152 (1999).

66. See, e.g., *In re De Blauwe*, 736 F.2d 699, 703 (Fed. Cir. 1984) ("[T]he clearly erroneous standard . . . is applicable to fact findings." (citing *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 220 (Fed. Cir. 1983))); see also *In re Zurko (Zurko I)*, 142 F.3d 1447, 1457 (Fed. Cir. 1998) (stating that *De Blauwe* was the "first opinion of [the Federal Circuit] indicating that the clearly erroneous standard is applied to Board of Appeal fact finding.").

67. *Zurko*, 527 U.S. at 153.

68. *In re Zurko*, 111 F.3d 887, 889 (Fed. Cir. 1997) (citing *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993)).

69. See *Zurko*, 527 U.S. at 153.

70. *Id.* at 154; accord *In re Zurko*, 142 F.3d at 1457–59 (upholding the application of the Patent Act's clearly erroneous standard for factual findings of the Board because Congress, in passing the Administrative Procedure Act, did not indicate any departure from that standard).

71. See *In re Zurko*, 142 F.3d at 1452. The Federal Circuit held:

This history suggests that Congress drafted the APA to apply to agencies generally, but that because of existing common law standards and the availability of trial *de novo* pursuant to section 4915 of the Revised Statutes, the predecessor of 35 U.S.C. § 145, Congress did not intend the APA to alter the review of substantive Patent Office decisions.

*Id.*

Circuit relied on the principal of stare decisis,<sup>72</sup> which made the Federal Circuit reluctant to apply a different standard of review in light of the Board's roughly twenty-year record of reviewing factual findings for clear error.<sup>73</sup>

Dickinson, the Commissioner of the PTO at the time, appealed the Federal Circuit's decision, and the Supreme Court granted certiorari to address whether Section 706 of the APA applies to Federal Circuit reviews of the PTO's findings of fact.<sup>74</sup> The Court rejected the Federal Circuit's rationale and held that the appropriate standard of review to be used by the Federal Circuit, or any appellate court reviewing an agency decision, "must [be] the framework set forth in § 706" of the APA.<sup>75</sup> Specifically, the Court stated that the Federal Circuit must review "an agency's reasoning to determine whether it is 'arbitrary' or 'capricious,' or, if bound up with a record-based factual conclusion, to determine whether it is supported by 'substantial evidence.'"<sup>76</sup> As such, the Court concluded that the Federal Circuit, in reviewing the Board's decisions regarding findings of fact, must apply the standards of review articulated in Section 706 of the APA.<sup>77</sup> The Court further stated that because the Federal Circuit is a "specialized court," its review of factual findings is "through the lens of patent-related experience,"<sup>78</sup> and thus, review by a court with technical patent expertise would "play a more important role in assuring proper review than would a theoretically somewhat stricter standard."<sup>79</sup>

On remand, the Federal Circuit concluded that "[t]he Board's conclusion of obviousness was based on a misreading of the references relied upon and, therefore, lacks substantial evidence support."<sup>80</sup> Consequently, the Federal Circuit again reversed the Board's final decision—even with the application of a different standard of review on remand.<sup>81</sup>

As a result of the Supreme Court's decision in *Zurko*, the Federal Circuit had to decide in *In re Gartside* whether it would apply the arbitrary and capricious or substantial evidence standard of review articulated in Section 706.<sup>82</sup> The Federal Circuit explained that the arbitrary and capricious standard was a "default standard" that only applied when the substantial evidence standard did

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72. *Id.* at 1457 (invoking "the principle of *stare decisis*," the idea that "Courts do not set aside long-standing practices absent a substantial reason").

73. *See id.*

74. *See Zurko*, 527 U.S. at 152, 154.

75. *Id.* at 152.

76. *Id.* at 164 (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 89–93 (1943); accord 7 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 43:74 (2017)).

77. *See Zurko*, 527 U.S. at 164–65.

78. *Id.* at 163.

79. *See id.*

80. *In re Zurko (Zurko II)*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

81. *Zurko I*, 142 F.3d 1447, 1452, 1459 (Fed. Cir. 1998).

82. *In re Gartside*, 203 F.3d 1305, 1312 (2000) ("We feel compelled to decide that question, in order to secure the standard of review through which we will test the decision of the Board in this case.").

not.<sup>83</sup> The Federal Circuit then determined that the substantial evidence standard applied to the Board's factual findings because the Patent Act required the Federal Circuit to review Board adjudications on the record. Thus, Board adjudications fell within the language of the APA's substantial evidence standard.<sup>84</sup> Therefore, the Federal Circuit decided that the substantial evidence standard should apply, not the arbitrary and capricious standard.<sup>85</sup> As a result, the Federal Circuit reversed course from its previous decision that the APA did not apply to the Board.<sup>86</sup> The Federal Circuit has since defined the substantial evidence standard of review as "something less than the weight of the evidence but more than a mere scintilla of evidence."<sup>87</sup>

The Federal Circuit continues to apply its holding in *Gartside* despite the many changes that have occurred to the Patent Act since 2000.<sup>88</sup> Given the more trial-like nature of adjudications before the PTAB, it is problematic that courts are reviewing PTAB decisions under a standard developed for reviewing agency adjudications rather than a more searching standard developed for analyzing district court claim construction factual findings.

*D. The Adoption of the Clear Error Standard for the Review of District Court Findings of Fact Made During Claim Construction*

As noted above, the Supreme Court recently addressed which standard of review applies when a district court decides questions of fact and whether findings of fact incidental to claim construction are questions of fact. In *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*,<sup>89</sup> the Supreme Court seemingly clarified these two longstanding and controversial questions regarding the Federal Circuit's standard of review for patent cases on appeal from the federal district courts. In *Teva*, a pharmaceutical company filed a patent infringement claim against several competitors that had attempted to market a generic version of the multiple sclerosis drug Copaxone.<sup>90</sup> The Supreme Court first explained that its holding in *Markman* applies even when the construction of a specific

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83. Substantial evidence of review is the most deferential standard that provides only "[t]he narrowest scope of judicial review," whereas the substantial evidence standard "involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency's decision." *Id.*

84. *Id.* at 1313–14.

85. *Id.* at 1315.

86. *Id.* at 1316.

87. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

88. See MATTHEWS, *supra* note 76, at § 43:74 ("In accordance with the *Zurko* decision and the APA, the Federal Circuit has ruled that because findings and rulings by the PTO board are based on a full documentary record, it will review the board's fact findings under the "substantial evidence" standard rather than the more deferential arbitrary and capricious standard."); accord *In re Cuozzo Speed Technologies*, 793 F.3d 1268, 1280 (Fed. Cir. 2015); *Merck & C.I.E. v. Gnosis*, 808 F.3d 829, 833 (Fed. Cir. 2015).

89. 135 S. Ct. 831 (2015).

90. *Id.* at 835.

claim term involves underlying evidentiary findings.<sup>91</sup> The Court summarized the issue quite succinctly:

In *Markman v. Westview Instruments*, we explained that a patent claim is that “portion of the patent document that defines the scope of the patentee’s rights.” We held that “the construction of a patent, including terms of art within its claim,” is not for a jury but “exclusively” for “the court” to determine. That is so even where the construction of a term of art has “evidentiary underpinnings.” *Today’s case involves claim construction with “evidentiary underpinnings.”*<sup>92</sup>

The Court also had to determine whether the Federal Circuit “should use [the *de novo* or clearly erroneous standard of review] when it reviews a trial judge’s resolution of an underlying factual dispute.”<sup>93</sup> In *Teva*, the Supreme Court held that although the ultimate construction of a legal claim is a legal conclusion warranting *de novo* review, the standard of review for a district court’s ruling on a subsidiary factual matter made during a district court’s construction of a patent claim cannot be overturned unless the factual findings are “clearly erroneous.”<sup>94</sup> The Supreme Court rested its decision primarily on Federal Rule of Civil Procedure 52(a)(6),<sup>95</sup> explaining that this rule does not contain any exceptions for patent cases.<sup>96</sup>

Furthermore, the Court determined that any factual disputes regarding extrinsic evidence during claim construction in district court are questions of fact.<sup>97</sup> In other words, even when a district court judge weighs the credibility of competing extrinsic factual contentions presented at a claim construction hearing, these findings are solely findings of fact and not findings of law because

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91. *Id.* (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996)).

92. *Teva*, 135 S. Ct. at 835 (emphasis added).

93. *Id.*

94. *Id.* at 836.

95. According to the rule, “[f]indings of fact, whether based on oral or other evidence, must not be set aside unless clearly erroneous, and the reviewing court must give due regard to the trial court’s opportunity to judge the witnesses’ credibility.” FED. R. CIV. P. 52(a)(6).

96. *Teva*, 135 S. Ct. at 836–837; see generally Keith Slenkovich, Katherine Lin & Michael Van Handel, *Teva Pharmaceuticals v. Sandoz: New Rules for Claim Construction Review*, BPLA NEWSLETTER (Boston Patent Law Ass’n, Quincy, Mass.), Mar. 15, 2015, <http://www.bpla.org/?NewsL20150202Teva>.

97. *Teva*, 135 S. Ct. at 841. The Supreme Court explained the justification for its holding as follows:

In some cases, . . . the district court will need to look beyond the patent’s intrinsic evidence and consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. . . . In cases where [such] subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the “evidentiary underpinnings” of claim construction that we discussed in *Markman* . . . .

*Id.*

*Markman* unequivocally articulated that claim construction is “exclusively” within the domain of the trial court to determine.<sup>98</sup>

In settling these questions, the Court expressly overruled the Federal Circuit’s decision in *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*,<sup>99</sup> in which the Federal Circuit held that “patent claim construction receives *de novo* determination on appeal, that is, review for correctness as a matter of law.”<sup>100</sup> Subsequently, the Federal Circuit applied the *Teva* holding in *In re Cuozzo Speed Technologies*,<sup>101</sup> which involved an appeal of a claim construction determination in an inter partes review.<sup>102</sup> As such, the Federal Circuit decided to apply *Teva*’s *de novo* standard of review to the ultimate claim construction finding by the PTAB, but has continued following *Zurko*’s substantial evidence standard as to the PTAB’s findings of underlying factual disputes.<sup>103</sup>

#### *E. Arguments in Favor of and Against the Substantial Evidence Standard of Review*

##### *1. A Relevant Analysis Justifying the Federal Circuit’s Continued Use of the Substantial Evidence Standard*

Since *Teva*, scholars have attempted to justify the Federal Circuit’s continued use of the substantial evidence standard of review for PTAB findings of fact made incidental to claim construction. For example, in a Note written by Alana Canfield Mannigé, she advocated that questions of fact made incidental to claim construction in IPRs should be reviewed for substantial evidence in accordance with the Supreme Court’s decision in *Zurko*.<sup>104</sup> Mannigé based her conclusion on Section 706 of the APA and the requirement that administrative agency decisions in “formal” proceedings be reviewed for substantial evidence.<sup>105</sup> To be considered formal under the APA, a proceeding must be “determined ‘on the record’ after the ‘opportunity for an agency hearing.’”<sup>106</sup>

Mannigé argues that although the AIA does not explicitly identify IPRs as formal and IPRs do not require decisions to be made “on the record,” the Federal

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98. *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

99. 744 F.3d 1272 (Fed. Cir. 2014).

100. *Id.* at 1276.

101. 793 F.3d 1268, 1280 (Fed. Cir. 2015).

102. *Id.* at 1279. In applying *Teva*, the Federal Circuit majority did not expound upon whether the Supreme Court’s ruling would have any effect on the Circuit’s standard of review for inter partes reviews. The majority stated, “we review underlying factual determinations concerning extrinsic evidence for substantial evidence and the ultimate construction of the claim *de novo*.” Because there is no issue here as to extrinsic evidence, we review the claim construction *de novo*.” *Id.* at 1280 (internal citations omitted).

103. *Id.*

104. Mannigé, *supra* note 7, at 169–70.

105. *Id.* at 169 (citing 5 U.S.C. § 706(2)(E) (2012)).

106. 5 U.S.C. § 554.

Circuit will nonetheless treat IPRs as formal proceedings.<sup>107</sup> Thus, she argued, “questions of fact during IPR should be reviewed for ‘substantial evidence.’”<sup>108</sup> Analogizing a similar argument made in the context of PGRs, she argued that IPRs should likewise “be treated as formal proceedings because they possess many of the hallmarks of formal adjudication, such as discovery and oral argument.”<sup>109</sup> To support these assertions, Mannigé referred to the Federal Circuit’s conclusion in *In re Gartside* that substantial evidence should apply to appeals from PTO interference proceedings—a proceeding that is considered less formal than PGRs.<sup>110</sup> Thus, factual findings regarding claim construction in *inter partes* proceedings and other PGRs should be reviewed in the same manner.<sup>111</sup>

Adding to the chorus of criticism, Professor Paul J. Verkuil argued that the clearly erroneous standard discussed in *Teva* significantly resembles the substantial evidence standard currently used by courts when reviewing factual findings from an administrative agency.<sup>112</sup> Professor Verkuil observed that the two standards statistically result in nearly identical outcomes despite both Congress’ and the Supreme Court’s attempts to meaningfully distinguish the two.<sup>113</sup> Professor Amanda Peters echoes this sentiment, arguing that when comparing the application of the substantial evidence and clear error standards of review, “there is effectively no difference between [the two standards]” because they are both “so similar in their wording and application.”<sup>114</sup> Likewise, Mannigé noted the Supreme Court’s commentary in *Zurko*:

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107. Mannigé, *supra* note 7, at 169.

108. *Id.*

109. *Id.* at 169–70 (citing Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1981–86 (2013)) (arguing that Congress’ requirement that the Patent and Trademark Office permit oral arguments and discovery during post-grant review proceedings suggests that Congress wanted post-grant reviews to be treated like formal adjudications governed by the Administrative Procedure Act).

110. *Id.* at 170 (citing *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000)).

111. Mannigé states:

Even more telling is that in *In re Gartside*, the Federal Circuit decided that the substantial evidence standard of formal proceedings applies to appeals from PTO interference proceedings, which are less formal than the new AIA post-grant proceedings. In *In re Gartside*, the Federal Circuit had based its conclusion partly on the fact that appeals from interferences were required to be reviewed “on the record” developed by the PTO. The AIA has a similar requirement for IPR, requiring review to be based “on the record” developed by the PTO.

*Id.* (footnotes omitted) (citing *In re Gartside*, 203 F.3d at 1313).

112. See generally Paul R. Verkuil, *An Outcomes Analysis of Scope of Review Standards*, 44 WM. & MARY L. REV. 679 (2002) (discussing *Teva Pharms. USA, Inc., v. Sandoz, Inc.*, 135 S. Ct. 831, 836 (2015)).

113. *Id.* at 692–97 (“[Statistical] outcomes . . . sometimes converge between close cousins like the substantial evidence standard and clearly erroneous tests.”).

114. Amanda Peters, *The Meaning, Measure, and Misuse of Standards of Review*, 13 LEWIS & CLARK L. REV. 233, 245–46 (2009).

The difference [between the standards of review] is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome.<sup>115</sup>

As explained below, however, the different standards of review can result in distinctive outcomes depending on the factual record. This issue is not merely an academic concern.

## 2. *The Arguments for the Federal Circuit's Use of the Clear and Convincing Standard of Review*

The continued use of the substantial evidence standard by the Federal Circuit in light of *Teva* has not occurred without controversy.<sup>116</sup> Among the critics of the standard's continued use are sitting judges in the Federal Circuit. Specifically, in its denial of the petition for rehearing en banc in *Merck*,<sup>117</sup> several judges questioned whether the continued adherence to the substantial evidence standard is the appropriate standard of review for any PTAB factual determinations.<sup>118</sup> Judge O'Malley, for example, in concurring with the per curium denial of a rehearing, remarked that the “application of the substantial evidence standard of review [wa]s . . . seemingly inconsistent with the purpose . . . of the AIA.”<sup>119</sup> Nevertheless, she stated that she was “bound by binding Supreme Court precedent,” and therefore concurred with the majority's reliance

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115. Mannigé, *supra* note 7, at 170–71 (quoting *Dickinson v. Zurko*, 527 U.S. 150, 162–63 (1999)).

116. *See id.* at 161 (“[T]his Note argues that the appropriate standard of review [for questions of fact] is the substantial evidence standard.”). Some commentators are uncertain as to whether the standard of review in which the Federal Circuit now reviews factual findings will make a substantive difference. *See, e.g.*, Stephanie A. Quick, *The New Standard of Claim Construction After Teva*, *LANDSLIDE MAG.*, Sept.–Oct. 2016, at 49, 50–51 (“Until the Federal Circuit reviews more claim construction orders, it remains to be seen how this “new” standard will affect patent litigation.”).

117. *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829 (Fed. Cir. 2015), *reh'g denied per curium*, 820 F.3d 432 (Fed. Cir. 2016).

118. *Merck*, 820 F.3d at 433–38 (O'Malley, Wallach & Stoll, JJ., concurring in the denial of the petition for rehearing en banc) (Newman, J., dissenting from the denial of the petition for rehearing en banc) (per curium).

119. *Id.* at 433 (O'Malley, Wallach & Stoll, JJ., concurring in the denial of the petition for rehearing en banc).



on the substantial evidence standard.<sup>120</sup> Her concurrence is particularly noteworthy, as she was previously a district court judge.<sup>121</sup>

Perhaps the Federal Circuit's most outspoken critic of the substantial evidence standard of review is Judge Newman. According to Judge Newman, the standard conflicts with the AIA's purpose of "providing quick and cost-effective alternatives to litigation."<sup>122</sup> Because the Federal Circuit is the only court permitted to review PTAB decisions, she argued that it was improper for the Circuit "to review the PTAB decision under the highly deferential 'substantial evidence' standard."<sup>123</sup> Some commentators agree and have relied on her opinions to highlight the importance of using the appropriate standard of review.<sup>124</sup>

According to Judge Newman, the use of the clear error standard is consistent with the use of a lower evidentiary burden of proof used in AIA proceedings.<sup>125</sup> The PTAB only requires a preponderance of the evidence to prove invalidity of a patent.<sup>126</sup> Dissenting in *Merck*, Judge Newman acknowledged that although

120. Judge O'Malley added:

Because Congress failed to expressly change the standard of review employed by this court in reviewing Board decisions when it created IPR proceedings via the AIA, we are not free to do so now. . . . I write separately, however, because I agree with the dissent to the extent it argues that a substantial evidence standard of review makes little sense in the context of an appeal from an IPR proceeding.

*Id.* (O'Malley, Wallach & Stoll, JJ., concurring in the denial of the petition for rehearing en banc).

121. *Judges*, U.S. CT. APPEALS FED. CIR., <http://www.cafc.uscourts.gov/judges/kathleen-momalley-circuit-judge> (last visited November 23, 2017).

122. *See In re Cuzo Speed Techs., LLC*, 793 F.3d 1268, 1284 (Fed. Cir. 2015) (Newman, J., dissenting); *Merck*, 808 F.3d at 845 (Newman, J., dissenting) ("The PTAB is not an examining body, but an adjudicatory body, an objective arbiter between opposing parties."); accord 157 CONG. REC. S1052, S1053 (daily ed. Mar. 1, 2011) (statement of Sen. Whitehouse) ("Administrative processes that should serve as an alternative to litigation have also broken down, resulting in further delay, cost, and confusion."); 157 CONG. REC. S5326, S5327 (daily ed. Sept. 6, 2011) (statement of Sen. Leahy) ("This bill will establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs, while make sure no party's access to court is denied.").

123. *Merck*, 808 F.3d at 840 (Newman, J., dissenting). She invoked the words of the Supreme Court:

Reviewing courts are not obliged to stand aside and rubberstamp their affirmation of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute. Such review is always properly within the judicial province, and courts would abdicate their responsibility if they did not fully review such administrative decisions.

*Id.* at 839–40 (Newman, J., dissenting) (quoting *N.L.R.B. v. Brown*, 330 U.S. 278, 291–92 (1965)).

124. *See, e.g.*, Richard G. Gervase, Jr. & Peter J. Cuomo, *Fed. Cir. Defers to PTAB Finding of Obviousness in First Pharma IPR Reviews* (*Merck v. Gnosis*), MINTZ LEVIN (Dec. 21, 2015), <https://www.mintz.com/legal-insights/alerts/>.

125. *Merck*, 808 F.3d at 841 (Newman, J., dissenting).

126. 35 U.S.C. § 316(e) (2012) ("In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."); *id.* § 326(e) ("In a post-grant review instituted under this chapter, the petitioner

judicial review of agency findings upon the preponderance standard was “not the general APA rule, [it] has been adopted by statute in other situations.”<sup>127</sup> Moreover, she added that sister circuits “have interpreted the preponderance standard to require review for ‘clear error’ on appeal.”<sup>128</sup>

Judge Newman argued that the APA included the substantial evidence standard only because the administrative agencies reviewing these decisions utilized “the expertise of specialized agencies.”<sup>129</sup> However, in her view, Congress passed the AIA because it determined that the Patent Office was making too many mistakes.<sup>130</sup> Judge Newman contended that this standard of review “is critical to the legislative balance of the [AIA].”<sup>131</sup>

Judge Newman’s opinions, particularly with respect to the burden of proof, highlight the underlying flaws in the majority’s adoption of such a deferential standard of review for factual findings made incidental to claim construction.

### 3. Other Arguments Grounded in the Language of the APA Favor the Clearly Erroneous Standard

Following the Federal Circuit’s denial for rehearing, Merck & Cie filed a petition for a writ of certiorari to the U.S. Supreme Court, which was subsequently denied.<sup>132</sup> In its petition, Merck & Cie argued that the substantial evidence standard of review was inapplicable to all factual findings made by the PTAB. Specifically, it emphasized that Section 559 of the APA contains two distinct exceptions to the standards of review enumerated in Section 706 of the APA.<sup>133</sup>

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shall have the burden of proving a proposition of unpatentability under a preponderance of the evidence.”).

127. *Merck*, 808 F.3d at 841 (Newman, J., dissenting). Judge Newman points to the Service Contract Act, where the preponderance of the evidence standard of review was employed by statute as opposed to the substantial evidence standard required under the APA. Judge Newman contends that this the legislature can adopt different standards of review in “special situations.” *Id.* (Newman, J., dissenting) (citing 41 U.S.C. § 6507(e) (2012)).

128. *Id.* (Newman, J., dissenting) (stating that “determination by the administrator . . . must be affirmed unless it is not supported by a preponderance of the evidence.” (citing *Amcors, Inc. v. Brock*, 780 F.2d 897, 901 (11th Cir. 1986))).

129. *Id.* (Newman, J., dissenting).

130. *Id.* at 840–41 (Newman, J., dissenting). Judge Newman demonstrates Congress’ disapproval of the quality of the patents coming out of the Patent Office. *Id.* (Newman, J., dissenting) (“This will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation.” (citing 157 CONG. REC. S1326 (daily ed. Mar. 7, 2011) (statement of Sen. Sessions))). The IPR process, specifically, was created partially as a response to the increasing number of non-practicing entity, or “patent troll” litigations, whereby defendants could challenge the validity of an asserted troll patent without incurring the high cost of the formal litigation process in the District Court. *See Mannigé, supra* note 7, at 159.

131. *Merck*, 808 F.3d at 841 (Newman, J., dissenting).

132. *Merck & Cie v. Gnosis, S.P.A.*, 137 S. Ct. 279 (2016) (mem.).

133. Petition for Writ of Certiorari at 2, *Merck*, 137 S. Ct. 279 (No. 16-125).

The first exception was addressed in both *Zurko* and *Gartside* and applies whenever “additional requirements are imposed by a pre-APA statute or a settled practice recognized by law.”<sup>134</sup> The second exception is referred to as the “express-reference requirement” and applies whenever “a post-APA statute ‘expressly’ excludes the APA’s review standards.”<sup>135</sup> Although the AIA does not expressly exclude PTAB proceedings from the APA’s review standards, Merck & Cie argued that the second exception in Section 559 may still apply. Because a court could find implicit invocation of the desire for a more searching standard of review by examining the AIA’s “policy, objectives, and design,”<sup>136</sup> Congress did not need “magical passwords” to invoke the express-reference exception.<sup>137</sup> Therefore, according to Merck & Cie, the Supreme Court should exempt the AIA proceedings from the APA’s substantial evidence standard and instead apply the clear error standard. This, Merck & Cie argued, would effectuate Congress’ intent with the AIA “to restore the public’s confidence in the patent system” and provide parties an alternative to district courts.<sup>138</sup>

In short, Merck & Cie argued that Congress intended the PTAB’s administrative judges to “quickly and efficiently” reach “*correct* determinations as to patent validity based on evidence presented by opposing parties in a trial-like environment.”<sup>139</sup> Because the overarching goal is correctness, “appellate review of PTAB fact-findings cannot be premised on mere substantial evidence.”<sup>140</sup> Merck & Cie argued that because the “substantial error standard does not address whether the *correct* decision was made, but merely whether there is some evidence in the record to support the findings,” it was the improper standard to apply in PTAB cases.<sup>141</sup> It argued, rather, that “Congress intended IPR fact-findings to be review under a more rigorous standard,” like that of the clear error standard of review.<sup>142</sup>

## II. THE FEDERAL CIRCUIT SHOULD ADOPT THE CLEAR ERROR STANDARD OF REVIEW FOR FACTUAL FINDINGS MADE BY THE PTAB INCIDENTAL TO CLAIM CONSTRUCTION

Judge Newman and other commentators have persuasively argued that the application of the substantial evidence standard to review factual findings made

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134. *Id.* at 2–3.

135. *Id.* at 2 (citing 5 U.S.C. § 559 (2012)).

136. *Id.* at 4 (citing *Lockhart v. United States*, 546 U.S. 142, 148 (2005) (Scalia, J., concurring)).

137. *Id.* at 4 (quoting *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)).

138. *Id.* at 4–5.

139. *Id.* at 5, 11 (“[D]etermining the proper appellate review standard for fact-findings in IPR proceedings is critical to effectuate Congress’s objectives for the AIA.”).

140. *Id.* at 5 (“Such deference to the agency—which itself employs no internal, second-tier review in IPR proceedings—severely compromises the balance that Congress sought.”).

141. *Id.*

142. *Id.*

incidental to claim construction fails to consider Congress' intent in passing the AIA.<sup>143</sup> Merck & Cie's argument that AIA proceedings should not fall within the scope of Section 706 is similarly persuasive. Unfortunately, because the Supreme Court, in denying Merck & Cie's petition for a writ of certiorari, declined to clarify the standard of review,<sup>144</sup> the issue remains uncertain in the context of AIA proceedings.<sup>145</sup> Although some argue the Supreme Court settled the matter of appellate standards of review between district courts and the PTO,<sup>146</sup> controversies over law and policy remain and must be resolved to ensure the reliable administration of the system created under the AIA.

*A. The Current Scholarship Supporting the Continued Reliance on the Substantial Evidence Standard Fails to Account for the Other Exemption Provisions of the APA that are Explicitly Discussed in Merck & Cie's Petition for Writ of Certiorari*

The current scholarship fails to account for the exemption provisions of the APA. For example, Alana Canfield Mannigé justified the Federal Circuit's continued reliance on *Zurko* by arguing that the APA implicitly requires judicial review of PTAB factual findings during claim construction to be made under the substantial evidence standard.<sup>147</sup> As noted, Mannigé based her argument on Section 706(2)(e), which states that courts review factual findings for substantial evidence when made in proceedings deemed "formal" under the APA.<sup>148</sup> Analogizing review of inter partes claim construction to Professor Wasserman's analysis of IPRs, she argued that because the Federal Circuit, in *In re Gartside*, applied the substantial evidence standard to appeals from PTO interference proceedings, any AIA proceeding that is more formal than PTO interference proceedings should also be afforded the substantial evidence standard of review.<sup>149</sup> But, as explained below, the formality of PTAB proceedings should exempt the PTAB from the APA's standards of review for factual findings.

The fact that these inter partes PTAB proceedings "possess many of the hallmarks of formal adjudication" support the conclusions in Merck & Cie's petition for writ of certiorari.<sup>150</sup> Merck & Cie's reference to the other exception of Section 706 carved out in Section 559 of the APA is more persuasive than Mannigé's argument justifying the continued application of the substantial evidence standard. Merck & Cie argued that the express-reference exception

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143. See discussion *infra* Section II.B.

144. See *Merck & Cie v. Gnosis, S.P.A.*, 808 F.3d 829 (Fed. Cir. 2015), *cert. denied*, 137 S. Ct. 297 (2016).

145. See Gervase & Cuomo, *supra* note 124.

146. See discussion *supra* Section I.C, E.1.

147. See Mannigé, *supra* note 7, at 169–71.

148. *Id.* at 169–70; accord discussion *supra* Section I.E.1.

149. Mannigé, *supra* note 7, at 169–70.

150. Compare *id.* at 169, with *Petition for Writ of Certiorari*, *supra* note 133, at 12.

can exempt a reviewing court from the APA standards of review if a post-APA statute “expressly” states that the APA standards of review are excluded.<sup>151</sup>

Although the AIA does not contain an express provision excluding the AIA from the APA, the Supreme Court said that “statutes enacted by one Congress cannot bind a later Congress, which remains free . . . to exempt the current statute from the earlier statute.”<sup>152</sup> Indeed, as Merck & Cie pointed out, the Supreme Court has gone even further and held that despite the use of the word “express” in the APA, Congress does not need to use “magical passwords” to later exempt itself from a subsequent statute; thus, it can exempt itself though “fair implication.”<sup>153</sup> That fair implication arises from the legislative history indicating that the AIA and its IPR procedures were meant to establish a “patent system that w[ould] improve patent quality”<sup>154</sup> by correcting agency mistakes that “resulted in too many low quality patents.”<sup>155</sup>

Due to the formal nature of IPRs, a proper analysis must account for Congress’ inclusion of this formality into PTAB proceedings, which were inherently designed to be an alternative to district court litigation.<sup>156</sup> In seeking correct decisions regarding the validity of patents, Congress intended to create a mechanism that could ensure the correction of “agency mistakes that had resulted in too many low quality patents.”<sup>157</sup> Therefore, Congress intended AIA reviews to be an alternative to litigation, and as such, they should be exempted from the APA’s proscribed standards of review. Accordingly, it is illogical to conclude that Congress intended for a reviewing court to apply the substantial evidence standard, which asks whether there was enough information to plausibly support the PTAB’s conclusion.<sup>158</sup> In other words, if the PTAB is supposed to serve as a viable alternative to district court litigation over

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151. Petition for Writ of Certiorari, *supra* note 133, at 15–16.

152. *Dorsey v. United States*, 132 S. Ct. 2321, 2331 (2012).

153. *Id.* at 2331–32 (citing *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)); *see also* Petition for Writ of Certiorari, *supra* note 133, at 15; *accord* *Lockhart v. United States*, 546 U.S. 142, 148 (2005) (Scalia, J., concurring) (“A subsequent Congress . . . may exempt itself from such requirements by “fair implication”—that is, *without* an express statement.” (quoting *Warden v. Marrero*, 417 U.S. 653, 659–60 n.10 (1974))).

154. H.R. REP. NO. 112-98, pt. 1, at 40 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 69.

155. Petition for Writ of Certiorari, *supra* note 133, at 19 (citing CONG. REC. H10276 (daily ed. Sept. 7, 2007) (statement of Rep. Goodlatte) (commenting that the AIA’s proceedings were an “additional check on the issuance of bogus patents”)).

156. *See, e.g.*, H.R. REP. NO. 112-98, pt. 1, at 45–48; 157 CONG. REC. S5326, S5326-27 (daily ed. Sept. 6, 2011) (statement of Sen. Leahy); 157 CONG. REC. S1052, S1053 (daily ed. Mar. 1, 2011) (statement of Sen. Whitehouse).

157. *See* Petition for Writ of Certiorari, *supra* note 133, at 19 (citing 153 CONG. REC. H10276 (daily ed. Sept. 7, 2007) (statement of Rep. Goodlatte) (“The PTO, like any other large government agency makes mistakes. [The AIA, as proposed,] creates a post-grant opposition procedure to allow the private sector to challenge a patent just after it is approved to provide an additional check on the issuance of bogus patents.”)).

158. *See id.* at 20 (citing 3 STEVEN ALAN CHILDRESS & MARTHA S. DAVIS, FEDERAL STANDARDS OF REVIEW § 15.04 (4th ed. 2010)).

patentability, courts should review PTAB decisions using the same standard district courts use for factual findings.

Additionally, as critics have noted, the PTAB construes patent claims in a manner that uses the “broadest reasonable interpretation,”<sup>159</sup> which the Federal Circuit has frequently upheld.<sup>160</sup> This is the same standard of review patent examiners apply.<sup>161</sup> However, applying a standard of review that provides additional deference to the PTAB squarely contradicts Congress’ intent to ensure that correct patentability conclusions are reached. Accordingly, the appropriate standard to ensure *correct* patentability conclusions is the clear error standard.

*B. The Current Scholarship Fails to Grasp the Marked Differences Between the Substantial Evidence and Clear Error Standards of Review*

Lastly, the arguments denying any substantive difference between the substantial evidence and clearly erroneous standards of review are overly inclusive. Such arguments rely almost exclusively on the Supreme Court’s remarks in *Zurko* that the substantial evidence and clearly erroneous standards

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159. 37 C.F.R. § 42.100(b) (2017) (“A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.”). In the PTO’s official commentary, regulators stated that the “broadest reasonable interpretation” (BRI) standard was consistent with the congressional intent of the enabling statute, adding: “This rule is also consistent with longstanding established principles of claim construction before the Office.” Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680, 48,688 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 42). The PTO elaborated:

For nearly thirty years, the United States Court of Appeals for the Federal Circuit has continued to require the Office to give patent claims their broadest reasonable construction consistent with the specification in patentability determination proceedings. . . . The “broadest reasonable interpretation” standard has been well established nearly thirty years in the judicial precedent for construing patent claims in patentability determination proceedings before the Office.

77 Fed. Reg. at 48,697.

160. See *In re Cuozzo Speed Tech., LLC*, 793 F.3d 1268, 1276 (Fed. Cir. 2015) (“[T]he broadest reasonable interpretation standard has been applied by the PTO and its predecessor for more than 100 years in various types of PTO proceedings.”). The Federal Circuit explained its reliance on the BRI standard as follows:

This court has approved of the broadest reasonable interpretation standard in a variety of proceedings . . . . Indeed, that standard has been applied in every PTO proceeding involving unexpired patents. . . .

There is no indication that the AIA was designed to change the claim construction standard that the PTO has applied for more than 100 years. . . .

Moreover, Congress in enacting the AIA was well aware that the broadest reasonable interpretation standard was the prevailing rule.

. . . .

We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA.

*Id.* at 1276–78.

161. See U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2111.01 (9th ed. 2014).

of review are very similar.<sup>162</sup> However, the Court's comment can be seen more as an aberration than precedent. For example, the Supreme Court has determined in other cases that the substantial evidence standard of review affords such a high degree of deference to an administrative agency decision that "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence."<sup>163</sup> In contrast, the Court reiterated in *Teva* that "clear error review is 'particularly' important where patent law is at issue because patent law is 'a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.'"<sup>164</sup>

In practice, applying the clearly erroneous standard rather than the substantial evidence standard can, and sometimes does, yield different results. Dissenting in *Merck*, Judge Newman applied the clearly erroneous standard of review and arrived at a different conclusion than the panel majority.<sup>165</sup> Upon a closer look at the prior art, Judge Newman revealed that although substantial evidence supported the majority's conclusion, such evidence does not necessarily ensure that the PTAB reached the *correct* determination.<sup>166</sup>

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162. See *Dickinson v. Zurko*, 527 U.S. 150, 162–63 (1999) ("[T]he difference [between the clear error and substantial evidence standards] is a subtle one—so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome.").

163. See *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 619–20 (1966) ("We have defined 'substantial evidence' as 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" (quoting *Consol. Edison Co. v. Nat'l Labor Relations Bd.*, 305 U.S. 197, 229 (1938))); accord *Petition for Writ of Certiorari*, *supra* note 133, at 20.

164. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 838 (2015) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 610 (1950)).

165. *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 842–43 (Fed. Cir. 2015) (Newman, J., dissenting).

166. In applying the clear error standard, Judge Newman concluded:

The evidence of record does not support the PTAB's apparent assumption that any folate would be effective against elevated homocysteine. No reference teaches that L-5-MTHF has this activity. A *prima facie* case cannot be based on the inventor's successful investigations.

The PTAB states that "Serfontein calls for a 'suitably active metabolite of folate' in preparations used to correct folate deficiency and treat diseases associated with elevated levels of homocysteine." This statement appears to enlarge Serfontein, who uses folate for "lowering levels of homocysteine or . . . counteracting the harmful effects associated with homocysteine."

The PTAB states that "Marazza specifically identifies chirally-pure L-5-MTHF as an active metabolite of folate suitable for use as a therapeutic agent in folate deficient states." The PTAB combines the Serfontein and Marazza references because "the *close similarity of purpose* and disclosure between these references would have provided sufficient rationale for one of ordinary skill in the art to have combined the teachings therein." However, there is no suggestion to select and make such combination with a reasonable expectation of success in treating elevated homocysteine. The only source of this concept is hindsight reconstruction using the teachings of these inventors.

Had the Federal Circuit applied the clearly erroneous standard, as suggested by Judge Newman, the Federal Circuit would have determined that the PTAB cited no source for finding a motivation to combine the prior art references.<sup>167</sup> In other words, by following the substantial evidence standard, the majority opinion disregarded the evidence weighing against the PTAB's finding that a reasonable expectation of success existed to combine the references.<sup>168</sup> By failing to consider this evidence, the Federal Circuit demonstrated that "[d]eferential review on a standard that looks only at one side of the evidence is less likely to uncover [the PTAB's] errors in the balance and burden of proof."<sup>169</sup>

*C. The Disparate Appellate Standard of Review Between the Federal District Court and the PTAB May Lead to Unfair Outcomes*

PTAB trials have been immensely popular, and statistics suggest that they will continue to be in the future.<sup>170</sup> In fact, studies suggest that the number of appeals may double by 2020.<sup>171</sup> Moreover, PTO statistics show that the PTAB is generally favorable to petitioners,<sup>172</sup> with roughly two-thirds of IPR trials that

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*Id.* (Newman, J., dissenting) (internal citations omitted).

167. *See id.* (Newman, J., dissenting) ("Only hindsight [could have] provide[d] such prophesy."). Instead, the majority opinion applied the substantial evidence standard of review and determined that there was no need to scrutinize the validity of the factual finding made by the PTAB. *Id.* at 842 (Newman, J., dissenting) ("[T]he majority decides that 'substantial evidence' supports the PTAB's finding of a motivation to combine the information in the Serfontein and Marazza references.").

168. Such evidence included clinical observations that raised questions of uncertainty in combining the two references, Merck & Cie's commercial success, and the evidence showing a "long-felt need, failure of others, industry praise, licensing, and copying." *Id.* (Newman, J., dissenting).

169. *See id.* (Newman, J., dissenting).

170. *See* Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, IPWATCHDOG (Mar. 24, 2014), <http://www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642/>; *accord* Golden, *supra* note 32, at 1669.

171. *See* Mock, *supra* note 51, at 30–34. Based on his analysis, Jason Mock warns:

[T]he number of appeals could exceed 2,000 as early as 2018, and would gradually continue to increase as it reaches a new steady state shortly after 2023. If these projections are correct, they indicate that the Federal Circuit could expect its number of appeals to roughly double within the next five years. This would be a monumental burden on the court, which could result in issues ranging from the allocation of additional resources for the judges and clerks to potentially lengthening the mean disposition for time for appeals from 10.6 months to well over a year.

*Id.* at 34 (footnotes omitted).

172. *See* U.S. PATENT & TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD STATISTICS 10 (Oct. 31, 2016), [https://www.uspto.gov/sites/default/files/documents/aia\\_statistics\\_october2016.pdf](https://www.uspto.gov/sites/default/files/documents/aia_statistics_october2016.pdf); *see also* Jordan Klimek, *Patents as Regulations: How the America Invents Act and the Seminole Rock Doctrine Could Change Claim Construction After Teva v. Sandoz*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 307, 325 (2015) ("PTAB proceedings, especially IPR, have the advantage of tilting the procedural playing field toward patent challengers."); *accord* Cutler, *supra* note 6.



end in final written decisions finding all instituted claims unpatentable.<sup>173</sup> An additional sixteen percent of IPR trials that end in final written decisions find that some, but not all, of the instituted claims are unpatentable.<sup>174</sup> As such, AIA proceedings will likely remain an attractive forum for parties to challenge the validity of a patent.

The overwhelming success of these proceedings has led some practitioners to speculate that rather than simply eliminating deficient patents, the PTAB is instead being used as a weapon by companies “seeking to punch holes in a competitor’s patent portfolio.”<sup>175</sup> This success, and arguable abuse of the system by some petitioners, may be due not only to the lower burden of proof in these proceedings, but also to the highly deferential substantial evidence standard of review, which insulates final decisions that are favorable to petitioners. The Federal Circuit has disproportionately affirmed PTAB decisions because the court fails to employ a more searching standard to review factual findings made by the PTAB incidental to claim construction.<sup>176</sup>

However, if the Federal Circuit adopts the clearly erroneous standard of review to factual findings made incidental to claim construction, it will have the opportunity to save patents that the PTAB improperly invalidated. The PTAB provides petitioners with an alternative to district courts that is faster, more cost-effective and requires a lesser burden of proof. Given the power of these newly-created proceedings, it is important to ensure that these proceedings are conducted fairly and in full consideration of the underlying facts often at the heart of claim construction rulings.

*D. The Federal District Court and PTAB Standards of Review for Factual Findings Made Incidental to Claim Construction Should Be Harmonized*

There are many ways in which the Federal Circuit or the PTAB could modify the current standards of review for factual findings. However, it is the role of Congress to enact a comprehensive and binding solution. Congress can amend the statutes to harmonize the standards of review in the PTAB and district courts. Given Congress’ enhanced ability to conduct research and hear varying viewpoints, Congress is best seated to modify the current trajectory of the PTAB and Federal Circuit.

In fact, Congress has looked more closely at IPR practice. Most notably, in the 114th Congress, Senators Grassley, Leahy, Cornyn, Schumer, Lee, Hatch, and Klobuchar introduced the Protecting American Talent and Entrepreneurship Act of 2015 (PATENT Act).<sup>177</sup> Particularly, Section 11 of the current draft of

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173. See U.S. PATENT & TRADEMARK OFFICE, *supra* note 172, at 10.

174. *Id.*

175. See Cutler, *supra* note 6.

176. See discussion *supra* Section II.A.

177. Protecting American Talent and Entrepreneurship Act of 2015, S. 1137, 114th Cong. (2015).

the PATENT Act provides that the PTAB may choose not to institute an IPR if the review would not “serve the interests of justice.”<sup>178</sup> This provision could potentially protect patent holders against abusive practices by competitors. Additionally, the PATENT Act would bar “an inter partes review from being instituted on the basis that the evidentiary standard before the USPTO differs from that used in a U.S. Court.”<sup>179</sup>

Perhaps most importantly, the PATENT Act calls for claims in AIA proceedings to be construed according to their ordinary and customary meaning, rather than the broadest, reasonable interpretation standard utilized by the PTAB.<sup>180</sup> Because the PTAB and the district courts under this bill would be construing patents using the same approach, *Teva*'s clearly erroneous standard of review should extend to Federal Circuit review of PTAB factual findings incidental to claim construction.

The PATENT Act is evidence that some members of Congress are aware of the issues and are attempting to improve proceedings at the PTAB. If legislation like the PATENT Act were passed, the Federal Circuit could accord the PTAB decisions the same deference it accords district court decisions. Thus, Congress should ensure the PATENT Act to explicitly provide that the APA does not apply to AIA proceedings.

### III. CONCLUSION

Congress enacted the AIA, in part, to provide an efficient way to eliminate deficient patents. However, the nature of the AIA proceedings and the deferential review of PTAB decisions have resulted in the elimination of nearly all patents, including some that would otherwise survive scrutiny in a district court litigation. Changes to the system can and should be made to ensure that a proper balance is achieved because patent owners currently have an approximately seven percent chance of a Federal Circuit reversal of a PTAB decision.<sup>181</sup> As explained above, the applied standard of review for factual findings made by the PTAB during claim construction should be revised so that the Federal Circuit can correct unsupported PTAB decisions that improperly invalidate valid patents. Ample support exists for the adoption of the clear error standard of review of factual findings made incidental to claim construction.

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178. Cong. Research Serv., *Summary: S.1137—114th Congress (2015–2016)*, CONGRESS.GOV (Sept. 08, 2015), <https://www.congress.gov/bill/114th-congress/senate-bill/1137?q=%7B%22search%22%3A%5B%22s.1137%22%5D%7D&r=1>.

179. *Id.*

180. *Id.*

181. See David C. Seastrunk et al., *Federal Circuit PTAB Appeal Statistics—November 2016*, FINNEGAN: AMERICA INVENTS ACT BLOG (Nov. 18, 2016), <http://www.aiablog.com/cafc-appeals/federal-circuit-ptab-appeal-statistics-november-2016/>.