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## Indefiniteness as an Invalidity Case

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## INDEFINITENESS AS AN INVALIDITY DEFENSE

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## INTRODUCTION

Should a good patent be deemed invalid because it is not perfect?<sup>1</sup> Assume the good patent satisfies all the important elements of patentability: it claims novel,<sup>2</sup> nonobvious,<sup>3</sup> and patent-eligible<sup>4</sup> subject matter; sufficiently discloses the claimed invention at the time of application;<sup>5</sup> contains embodiments that enable a skilled artisan to practice the invention;<sup>6</sup> and discloses the best version of the invention.<sup>7</sup> The good patent's only imperfection resides in a slightly imprecise term.<sup>8</sup> But the imprecision does not cause demonstrable confusion about the scope or content of the invention claimed.<sup>9</sup> The perceived defect appears entirely without real-world consequence.<sup>10</sup>

Invalidating such a good patent for inconsequential imperfection seems unadvisable.<sup>11</sup> No deterrence rationale justifies allowing such

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1. *Cf.* *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (“[W]e protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal.”).

2. 35 U.S.C. § 102 (2012).

3. *Id.* § 103.

4. *Id.* § 101.

5. *Id.* § 112.

6. *Id.* § 112(a).

7. *Id.* *But see id.* § 282(b)(3)(A) (specifying that an assertion of insufficient disclosure of best mode no longer represents an invalidity defense even as it remains a requirement for issuance).

8. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002) (finding some modicum of uncertainty “as the price of ensuring the appropriate incentives for innovation”); *Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124 (1873) (finding that “every reasonable doubt” should be resolved in favor of the patentee).

9. Patentability requires definite claims so that inventors neither accidentally infringe nor avoid innovating by over-estimating the monopoly asserted. *See Merrill v. Yeomans*, 94 U.S. 568, 573 (1876).

10. In *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc. (Teva II)*, which provides the focus of this Note, an inconsequential defect proved outcome-determinative in an assessment of patent validity. *See* 876 F. Supp. 2d 295, 400-01 (S.D.N.Y. 2012) (finding patents valid despite theoretical indefiniteness), *rev'd*, 723 F.3d 1363, 1375 (Fed. Cir. 2013) (finding patents invalid as indefinite), *vacated*, 135 S. Ct. 831, 836 (compelling deferential review for district court subsidiary fact-finding related to claim construction), *remanded to* 789 F.3d 1335, 1345 (Fed. Cir. 2015) (finding patents invalid as indefinite without locating clear error in district court subsidiary fact-finding).

11. *See* David L. Schwartz, *Retroactivity at the Federal Circuit*, 89 IND. L.J. 1547, 1549, 1556 (2014) (noting that judicial parsing of semantic differences encourages patent prosecutors to waste considerable time considering a judicial readership in addition to an

insubstantial error to be fatal.<sup>12</sup> Nonetheless, in the course of infringement litigation, such a minor defect might lead a court to invalidate the good patent as indefinite.<sup>13</sup>

Providing the statutory hook for definiteness jurisprudence, the law requires a valid patent to contain “one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”<sup>14</sup> When invoking indefiniteness as an invalidity defense, an accused infringer may escape liability by arguing that the claim language appears ambiguous and by convincing the court to invalidate the patent at issue.<sup>15</sup>

Historically, courts tended to invalidate a patent as indefinite only if a claim term proved insusceptible to construction—meaning the evidence in the record failed to enable the court to discern how a person of ordinary skill in the art (POSA) would interpret the disputed claim language.<sup>16</sup> As claim construction jurisprudence tolerates some imprecision, the good patent would not be felled by

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innovative readership, and discussing the dampening effect of invalidation for insignificant drafting errors, which render inventors disinclined to invest in patenting given its unpredictability).

12. In fact, patent law permits the court to correct certain obvious errors in the course of claim construction so as to avoid invalidating such good patents. *See, e.g.*, *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1359 (Fed. Cir. 2011) (viewing the erroneous phrase “detect analyze” as reasonably corrected by placing “and” between the two verbs or by deleting one of the verbs); *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1352-53 (Fed. Cir. 2009) (reversing the district court’s decision to refrain from adding a comma between fluorine and chlorine).

13. *See infra* Part II.

14. 35 U.S.C. § 112(b) (2012).

15. *See infra* Part II.

16. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). Imagine a pharmaceutical patent claims an “enhanced combination” of two active ingredients, and the patent owner argues that the court should construe the phrase as indicating a “synergistic” effect. For a case upon which this example is loosely based, see *Andrulis Pharm. Corp. v. Celgene Corp.*, No. 13-1644(RGA), 2015 WL 3978578, at \*3 (D. Del. June 26, 2015), *aff’d*, 2016 WL 3755929 (Fed. Cir. July 14, 2016) (mem). The defendant might succeed in invalidating the patent as indefinite by arguing that the phrase remains susceptible to several other equally reasonable but contradictory interpretations, preventing the court from locating a consistent meaning for the phrase. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (formalizing the steps for claim construction).

indefiniteness that operates to invalidate a patent when claim terms cannot be construed.<sup>17</sup>

The true threat to the good patent arises when alleged infringers invoke indefiniteness as an invalidity defense after a court has carefully construed a given claim term.<sup>18</sup> This iteration of indefiniteness as an invalidity defense proves problematic because—when no longer tethered to claim construction, which places great emphasis on reading the patent from the perspective of POSA—the definiteness assessment may result in the invalidation of a patent on the basis of imprecision that causes no actual confusion.<sup>19</sup>

A recent case reveals the hazards posed by permitting defendants to raise indefiniteness as an invalidity defense following claim construction. In *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* (*Teva V*), the Federal Circuit,<sup>20</sup> on remand from the Supreme Court, invalidated a fully functional and generally unambiguous group of related patents because of a small, inconsequential defect.<sup>21</sup> Although the district court did not lend legal significance to the alleged indefiniteness given the absence of practical effect, the Federal Circuit assessed definiteness separate from claim construction, without discrete reference to the consequences of any error discovered.<sup>22</sup> Even after the Supreme Court demanded greater deference to the district court's subsidiary fact-finding related to claim construction in *Teva IV*,<sup>23</sup> the Federal Circuit found Teva's

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17. See *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) (“[T]he specification may define claim terms ‘by implication’ such that the meaning may be ‘found in or ascertained by a reading of the patent documents.’” (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582, 1584 n.6 (Fed. Cir. 1996))).

18. Imagine the court did construe “enhanced combination” as indicating a “synergistic” relationship between the two ingredients. See *supra* note 16. The defendant would then invoke indefiniteness to argue for invalidation by asserting that the claim remained ambiguous despite the court's construction. See *infra* Part II.

19. See *infra* Part III.

20. A specialized appeals court hearing all patent appeals from federal district courts. See 28 U.S.C. § 1295(a)(4)(C) (2012) (establishing the limits of the Federal Circuit's jurisdiction).

21. 789 F.3d 1335, 1345 (Fed. Cir. 2015) (invalidating patents as indefinite); see *id.* at 1346 (Mayer, J., dissenting) (“[A] person of ordinary skill in the art of polypeptide synthesis would infer from the use of the SEC method disclosed in the specification of the ‘808 patent that the term ‘molecular weight’ referred to peak average molecular weight.”).

22. *Id.* at 1345 (majority opinion) (“The district court fact findings regarding how one of skill in the art would understand the way in which a curve created with chromatogram data reflects molecular weights was not clearly erroneous.”).

23. *Teva Pharm. USA, Inc. v. Sandoz, Inc.* (*Teva IV*), 135 S. Ct. 831, 841 (2015).

patents invalid without identifying clear error in the district court's fact-finding.<sup>24</sup>

Such dissonance between the Federal Circuit and district courts is not new.<sup>25</sup> The frequency with which the Federal Circuit reverses district court rulings deviates from the norm.<sup>26</sup> For federal appeals courts generally, the civil case reversal rate ranges from 12 to 15 percent.<sup>27</sup> But the Federal Circuit's reversal rate for patent cases averages around 28 percent.<sup>28</sup> The Federal Circuit most often reverses district courts because of disagreements related to claim construction.<sup>29</sup> In fact, excluding reversals implicating claim construction, the Federal Circuit's patent reversal rate would average only 18 percent.<sup>30</sup> Further, reversals premised on indefiniteness of the sort that was dispositive in *Teva V* averages almost 40 percent, while claim construction reversals overall hover closer to 30 percent.<sup>31</sup>

High reversal rates in patent cases on appeal have been the aim of much scholarly inquiry.<sup>32</sup> The commentary supplies two main explanations for why the Federal Circuit so often reverses district court patent rulings.<sup>33</sup> Either the Federal Circuit has failed to sufficiently articulate the standards for claim construction such that district courts are unable to abide by those standards, or the Federal Circuit has refused to grant district court rulings the

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24. *Teva V*, 789 F.3d at 1345.

25. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996) (removing claim construction from the province of the jury to enable vertical uniformity); cf. David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223, 248-49 (2008).

26. Compare David L. Schwartz, *Pre-Markman Reversal Rates*, 43 LOY. L.A. L. REV. 1073, 1094 fig.B (2010), with Ted Sichelman, *Myths of (Un)certainty at the Federal Circuit*, 43 LOY. L.A. L. REV. 1161, 1172 n.46 (2010).

27. Sichelman, *supra* note 26, at 1172 n.46.

28. Schwartz, *supra* note 26, at 1094 fig.B.

29. See Sichelman, *supra* note 26, at 1175 fig.1 (compiling reversal rate figures from both primary and secondary sources). But see Jeffrey A. Lefstin, *Claim Construction, Appeal, and the Predictability of Interpretive Regimes*, 61 U. MIAMI L. REV. 1033, 1038 (2007) (criticizing statistical methods used by those that crunch the reversal rate numbers).

30. Sichelman, *supra* note 26, at 1175 fig.1.

31. See *id.*

32. See, e.g., Schwartz, *supra* note 25; Schwartz, *supra* note 26; Sichelman, *supra* note 26.

33. See Lefstin, *supra* note 29, at 1035.

deference that information asymmetry demands.<sup>34</sup> Both factors converge for Federal Circuit reversals premised on definiteness.<sup>35</sup> As currently conceived, the requirement enables the appellate court to reverse the lower court's invalidity assessment without opining as to evident claim construction errors, yielding opinions that display only superficial deference and fail to clarify claim construction jurisprudence.<sup>36</sup>

Unlike the other requirements for patentability, definiteness appears inseparable from claim construction.<sup>37</sup> Either a claim term is not susceptible to construction, and thus the patent is indefinite, or the claim term is susceptible to construction and the patent is definite.<sup>38</sup> And yet, the Supreme Court recently reaffirmed definiteness as a conclusion of law separate from claim construction.<sup>39</sup> By forcing this separation, the law enables the Federal Circuit to find no error in lower court claim construction while simultaneously invalidating a patent as indefinite if the claim lacks "reasonable certainty"—a phrase coined by the Supreme Court in 2014 that continues to beg for content.<sup>40</sup> In the context of invalidating a patent as indefinite when competing interpretations prevent the court from construing disputed claim language, "reasonable certainty" may provide sufficient guidance.<sup>41</sup> But "reasonable certainty" provides little guidance as to how the ambiguity of claim language should be assessed after claim construction.<sup>42</sup>

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34. *See id.*; *see also* FED. R. CIV. P. 52(a)(6) ("[T]he reviewing court must give due regard to the trial court's opportunity to judge the witnesses' credibility.").

35. *See infra* Part II.

36. *See infra* Part III.

37. *Compare infra* Part II, *with infra* Part I.B.4.

38. *See* John R. Allison & Lisa Larrimore Ouellette, *How Courts Adjudicate Patent Definiteness and Disclosure*, 65 DUKE L.J. 609, 619 (2016) ("For some time, the Federal Circuit had required that a claim need only be susceptible to construction and not 'insolubly ambiguous' to satisfy the definiteness requirement." (quoting *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005), *abrogated by* *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014)).

39. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014) (replacing "insolubly ambiguous" with "reasonable certainty" as the phrase that pays for definiteness under 35 U.S.C. § 112(b) (2012)).

40. *See infra* Part III.

41. *See infra* Part I.A.

42. *See infra* Part III.

Through a close examination of *Teva*, this Note argues that the definiteness requirement should rarely be deployed to invalidate a patent for ambiguity following claim construction.<sup>43</sup> If ambiguity remains, then the court failed to properly construe the disputed language.<sup>44</sup> To support this conclusion, Part I overviews the role of invalidity defenses in patent litigation to show how claim construction appears distinct from a court's evaluation of enablement, anticipation, and written description, but remains identical with an assessment of definiteness. Part II closely examines *Teva V* on remand from the Supreme Court to reveal the extent to which the problematic aspects of definiteness jurisprudence cannot be ameliorated by heightened deference for lower court subsidiary fact-finding. Part III discusses the lessons learned from *Teva* to propose a new test for definiteness where "consequentially ambiguous" would replace "reasonable certainty" as the phrase that pays in order to provide a more robust link between definiteness and claim construction.

## I. THE MECHANICS OF PATENT LITIGATION

United States law prohibits the unauthorized making, using, or selling of any "patented invention."<sup>45</sup> The strategies invoked during litigation revolve around what constitutes a "patented invention."<sup>46</sup> An alleged infringer will succeed if she persuades the court that her activities do not fall within the limited number of activities protected by the patents at issue.<sup>47</sup> Alternately, an alleged infringer will succeed if she is able to convince the court that the patent is entirely invalid and thus incapable of precluding her ostensibly infringing activity.<sup>48</sup> Typically, alleged infringers raise both defenses—

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43. *See infra* Part III.

44. *See infra* Part III.

45. 35 U.S.C. § 271(a) (2012).

46. *See id.*

47. *See id.* § 282(b)(1).

48. *See id.* § 282(b)(2). Given the defensive nature of such tactics, nonmeritorious claims of patent invalidity abound. *See* John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1786 fig.3 (2014). When facing an invalidity defense, patentees won on summary judgment in district courts at a rate of 26 percent despite the fact that a patentee's burden for summary judgment in the face of an invalidity assertion is very high. *See id.* at 1787, 1790 ("A patentee must



asserting that the infringing product or process is not identical to the invention claimed in the patent and asserting that, regardless of the subject matter covered by the claims, the patent cannot protect any invention because the patent itself proves deficient.<sup>49</sup>

One of the first steps in any patent litigation involves the patent owner and the defendant jointly submitting a list of challenged claim terms with each side presenting competing interpretations of each term.<sup>50</sup> The patent owner's interpretation of the claim terms must be broad enough to support the argument that the allegedly infringing product or process falls within the scope of the claimed invention.<sup>51</sup> The defendant interprets claim terms more narrowly to argue that the patent does not cover the infringing product or process.<sup>52</sup> The persuasiveness of the defendant's invalidity arguments hinges on which interpretation prevails.<sup>53</sup>

Demonstrating the delicate dance of patent litigation, a patent owner's interpretation of a disputed claim term may increase the likelihood that the patent will be invalidated.<sup>54</sup> If the court con-

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show a lack of disputed issues of material fact for *all* elements of the claimed invention, while the accused infringers merely need to show a lack of disputed issues of material fact for *any* element of the claimed invention.”).

49. *See, e.g., PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1311 (Fed. Cir. 2008) (finding a lack of written description support for broad claiming of a consumer interface where the application described only a particular type of consumer interface as an aspect of the invention possessed).

50. *See, e.g., Scripps Clinic & Research Found. v. Genetech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991) (“[T]he construction of claims is simply a way of elaborating the normally terse claim language: in order to understand and explain, but not to change, the scope of the claims.”).

51. 35 U.S.C. § 271 (providing the statutory basis for the “all elements” rule for direct infringement, induced infringement, and contributory infringement); *see also Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014) (stating that “infringement exists if at least one claim of an asserted patent reads on a product or process that the accused infringer has introduced into the U.S. marketplace” and distinguishing “classic patent infringement” from “an infringement inquiry provoked by an ANDA filing under the Hatch-Waxman system”).

52. *See, e.g., Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1309 (Fed. Cir. 2015) (discussing claim construction in the context of clinical efficacy as a functional limitation).

53. *See, e.g., Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (“Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.”).

54. *See, e.g., Eiselstein v. Frank*, 52 F.3d 1035, 1038-39 (Fed. Cir. 1995) (finding written description support for claims related to nickel alloy, which appeared unsupported by ranges recited in the application, because the application indicated that the range should be reviewed as approximate).

strues the patent as covering a broad range of activities, then that construction may strengthen the defendant's assertions of anticipation, nonenablement, insufficient written description, or indefiniteness.<sup>55</sup> Accordingly, before the court may assess patent validity, the court must determine how to interpret disputed claim terms—the process known as “claim construction.”<sup>56</sup>

### A. Claim Construction

Patents contain two parts: the specification, followed by individual claims.<sup>57</sup> The specification describes the invention as a whole, providing important contextual information as a prelude to the individual claims.<sup>58</sup> The claims delimit the territory of the monopoly asserted and function to put potential infringers on notice.<sup>59</sup> Claims particularize what is to receive patent protection.<sup>60</sup>

When engaged in claim construction, the court does not simply choose between the patent owner's interpretation or the defendant's interpretation.<sup>61</sup> Rather, the court triangulates between opposing

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55. See, e.g., *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (indicating that a patent will be invalidated if one process or composition claimed appears anticipated even if the patent claims cover other processes or compositions).

56. See, e.g., *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1285-86 (Fed. Cir. 2014) (en banc) (“Claim construction is often a preliminary proceeding in the district court, before trial of infringement, validity, damages, etc. At the threshold, the court establishes the metes and bounds of the claims that define the patent right. The questions of claim construction are not questions of weight of evidence or credibility of witnesses, but of the claim scope as set forth in the patent documents. Claim construction is the interpretation of a legal document that establishes a property right that applies throughout the nation.”), *vacated sub nom.* *Lighting Ballast Control LLC v. Universal Lighting Techs., Inc.*, 135 S. Ct. 1173 (2015).

57. See 35 U.S.C. § 112 (2012).

58. See *id.* § 112(a).

59. See *id.* § 112(b).

60. See *Merrill v. Yeomans*, 94 U.S. 568, 573 (1876) (“The genius of the inventor ... should not be restrained by vague and indefinite descriptions of claims in existing patents from the salutary and necessary right of improving on that which has already been invented.”).

61. See, e.g., *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1359 n.4 (Fed. Cir. 2012) (en banc) (finding no error in the lower court's claim construction, which was “based on the assertion that neither party argued the construction arrived at by the district court,” because the court is not “bound by the arguments of the parties”).

interpretations of disputed terms to determine how POSA would understand the terms as of the effective filing date of the patent.<sup>62</sup>

While factual conflicts traditionally fall within the purview of the jury, the task of claim construction now resides exclusively with the judge, even when such construction involves the resolution of issues with “evidentiary underpinnings.”<sup>63</sup> Delineated by the Supreme Court in 1996, this division of labor is relatively new.<sup>64</sup> To justify empowering judges to engage in the fact-intensive process of claim construction, judges and scholars compare claim construction to judicial construction of other written instruments, like contracts or deeds.<sup>65</sup>

Unsurprisingly, the increasing complexity of claim construction mirrors the increasingly complex subject matter of patents.<sup>66</sup> As formalized in *Phillips v. AWH Corp.*, the claim construction process begins with judicial consideration of the “ordinary and customary meaning” of the terms in a given claim.<sup>67</sup> Where a claim term has several common meanings, the judge may consult the patent

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62. *See id.* at 1358, 1359 n.4; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (indicating that the court should construe disputed terms from the perspective of POSA “at the time of the invention, i.e., as of the effective filing date of the patent application”).

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

64. In the 1990s, approximately 75 percent of patent infringement cases enlisted the jury as the fact-finder. *See* J. Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 NW. U. L. REV. 1, 18-21 (2013). However, now that juries do not resolve fact matters related to claim construction and infringement cases hinge on claim construction, only 2 percent of appealed district court decisions reviewed by the Federal Circuit involve a jury. *See id.*

65. *Teva IV*, 135 S. Ct. 831, 837 (2015). The alternative—and heterodox—comparison on offer views patent claim construction as analogous to statutory interpretation, which begs complicated questions given that the Patent and Trademark Office (PTO) does not enjoy interpretive authority in the way that other agencies do. *See* 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, 314 (2015).

66. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003) (describing variances in claim construction associated with mechanical, software, biotechnological, or pharmaceutical patents).

67. 415 F.3d at 1312; *see* Peter S. Menell, Matthew D. Powers & Steven C. Carlson, *Patent Claim Construction: A Modern Synthesis and Structured Framework*, 25 BERKELEY TECH. L.J. 711, 718 (2010) (“The Federal Circuit’s en banc decision in *Phillips v. AWH Corp.* stands as the most authoritative synthesis of claim construction doctrine.”); Kristen Osenga, *Linguistics and Patent Claim Construction*, 38 RUTGERS L.J. 61, 66-67 (2006) (describing difficulties inherent in “using existing words to describe a new invention” (footnote omitted)).

specification for guidance as to the proper meaning.<sup>68</sup> What inventors intended to protect when filing the patent may also inform the court.<sup>69</sup> In construing claim terms, the court adopts the perspective of POSA.<sup>70</sup>

Operation of claim construction thus involves two categories of evidence: intrinsic evidence—which includes the patent specification and the Patent and Trademark Office (PTO) prosecution history—and extrinsic evidence, such as expert testimony.<sup>71</sup> While the court may rely on information sources other than the claims themselves, claim construction must not import this evidence in a way that would limit the scope of the claim terms as written.<sup>72</sup> As one might imagine, relying on evidence to construe claim terms without importing unsupported meaning into the claim terms proves precarious.<sup>73</sup>

### *B. Assessing Patent Validity*

All patents vetted and issued by the PTO enjoy the presumption of validity.<sup>74</sup> But the threshold for rebutting this presumption is low,<sup>75</sup> which may be by design given that patent examiners are

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68. *Phillips*, 415 F.3d at 1314; see *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (“[I]f an apparatus claim recites a general structure (e.g., a noun) without limiting that structure to a specific subset of structures (e.g., with an adjective), we will generally construe the claim to cover all known types of that structure that are supported by the patent disclosure.”); *Sjolund v. Musland*, 847 F.2d 1573, 1581-82 (Fed. Cir. 1988).

69. “Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.” *Renishaw*, 158 F.3d at 1250.

70. 35 U.S.C. § 103(a) (2012).

71. See *Phillips*, 415 F.3d at 1317. But see *Lefstin*, *supra* note 29, at 1051 (viewing the dichotomy between intrinsic and extrinsic evidence as overly simplistic and positing four categories of claim construction evidence: intrinsic, formal extrinsic, informal extrinsic, and informative).

72. See, e.g., *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

73. See *Osenga*, *supra* note 67, at 75-76 (“Where is the line between reading the claims in light of the specification and reading in limitations from the specification? Where is the line between using extrinsic evidence to educate the court versus to inform claim construction?... Who is the [POSA] and how do we know what he thinks? How does one determine the ordinary and customary meaning of a claim term?”).

74. See 35 U.S.C. § 282(a) (“A patent shall be presumed valid.”).

75. See *id.* (specifying that “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity” but failing to provide guidance as to the evidentiary threshold for carrying such a burden).

famously overworked and examine vast numbers of patents every year, and only 2 percent of patents are ever subject to litigation.<sup>76</sup> Accordingly, in assessing patent validity in the context of litigation, the court never assumes that an issued patent should have been granted.<sup>77</sup>

Once a court has completed claim construction—construing all the terms at issue in a given patent for plain meaning or in light of intrinsic and extrinsic evidence—the court will move on to an assessment of patent validity.<sup>78</sup> As the court resolves most fact matters in the course of claim construction, the court often assesses these requirements as matters of law and without the aid of a jury.<sup>79</sup>

Current statutory provisions enable a defendant to challenge the validity of an issued patent in federal court on several grounds.<sup>80</sup> The discussion that follows overviews four categories of validity challenges to demonstrate the extent to which indefiniteness as a validity challenge appears aberrant in its inseparability from claim construction. First, when a defendant challenges validity by asserting nonenablement, the court examines the extent to which the claims as construed enable POSA to practice the claimed invention.<sup>81</sup> Second, for validity challenges based on anticipation, the court examines the extent to which the claims as construed relate to subject matter that appeared nonnovel or obvious as of the effective filing date of the patent.<sup>82</sup> Third, when a defendant asserts insufficient written description, the court compares the claims as

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76. See Mark A. Lemley, Essay, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1507 (2001).

77. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 111 (2011) (specifying that the Federal Circuit has long invoked “clear and convincing” as the evidentiary standard and without interruption by Congress, but noting that “if the PTO did not have all material facts before it, its considered judgment may lose significant force”).

78. See Anderson & Menell, *supra* note 64, at 11-19.

79. See *id.* at 23.

80. See 35 U.S.C. § 282(b) (2012) (specifying that the defense of invalidity may be based on conditions of patentability (patent-ineligible, nonnovel, or obvious subject matter) or raised under 35 U.S.C. § 112 (nonenablement, insufficient written description, or definiteness), but excluding best mode as grounds for a validity challenge). While representing another obscure and fascinating corner of the patent law landscape, validity challenges based on patent-ineligible subject matter reside outside the scope of this Note and are not discussed. See 35 U.S.C. § 101; *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (invalidating a method-patent covering software as drawn toward an abstract idea).

81. See 35 U.S.C. §§ 112(a), 282(b)(3)(A); *infra* Part I.B.1.

82. See 35 U.S.C. §§ 102, 103, 282(b)(2); *infra* Part I.B.2.

construed with the information disclosed in the specification at the time of filing to determine whether the application demonstrated possession of the invention as claimed in the patent.<sup>83</sup> Finally, for validity challenges based on indefiniteness, the court evaluates the claims as construed for “reasonable certainty”—an ironically indefinite task that, this Note argues, detracts the good patent and offers evidence against an assessment of definiteness separate from claim construction.<sup>84</sup> What follows is a discussion of each of these four categories.

### 1. *Enablement*

If the claims as construed by the court relate to subject matter that the patent fails to fully enable, then the defendant will prevail in invalidating the patent and will not be held liable for infringement.<sup>85</sup> A valid patent must enable POSA to practice the invention claimed without “undue experimentation.”<sup>86</sup> Through the process of claim construction, the court determines the subject matter claimed by the challenged patent.<sup>87</sup> The patent must enable POSA to make the invention and must describe the invention’s utility, but it need not “guarantee that the invention works for a claim to be enabled.”<sup>88</sup> To evaluate whether the patent proves sufficiently enabling, the court will assess all information disclosed in the patent, including the specification’s description of the invention, the specification’s listed embodiments, and any other enabling information disclosed in any of the claims of the issued patent.<sup>89</sup> The court is free to mix and match construed claims to locate sufficient disclosure, and the

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83. See 35 U.S.C. §§ 112(a), 282(b)(3)(A); *infra* Part I.B.3.

84. See 35 U.S.C. §§ 112(b), 282(b)(3)(A); *infra* Part I.B.4.

85. See 35 U.S.C. §§ 112(a), 282(b)(3)(A).

86. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988); see, e.g., *Plant Genetic Sys., N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003) (en banc) (holding that transgenic corn products did not infringe cell claims where a patent was found to be invalid for lack of enablement).

87. See *supra* Part I.A.

88. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014); see also *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308, 1310 (Fed. Cir. 2015).

89. See *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (“Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.”).

court analyzes the enabling impact of construed claims in the aggregate.<sup>90</sup>

## 2. *Anticipation*

If the claims as construed by the court relate to subject matter found to be nonnovel or obvious, then the defendant will prevail in challenging the patent as anticipated.<sup>91</sup> A valid patent claims a novel and nonobvious invention.<sup>92</sup> Patents provide a limited private monopoly to induce further innovation, and that end is not served by granting patents for insignificant advances.<sup>93</sup> If one reference or activity discloses every element of the claimed invention prior to the patent's priority date, then the patent should be invalidated as non-novel.<sup>94</sup> If several related references disclose every element of the claimed invention, then the patent should be invalidated as obvious.<sup>95</sup> The court's anticipation analysis remains distinct from claim construction because the court evaluates whether the claims as construed relate to subject matter fully disclosed prior to the patent's priority date.<sup>96</sup>

## 3. *Written Description*

While an applicant may add, subtract, or otherwise alter the claims after the filing date, the content of the patent's specification

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90. It is not incumbent upon the inventor to enable replication in a single claim or to identify those particular parts of the patent pertinent to enablement. *See* Lefstin, *supra* note 29, at 1055-56.

91. *See* 35 U.S.C. § 282(b)(2) (2012).

92. *See id.* §§ 102, 103.

93. *See* Hotchkiss v. Greenwood, 52 U.S. (How. II) 248, 267 (1850) (involving patentability of porcelain knob with metal fastening mechanism; affirming a patent was invalid where "absence of ... skill and ingenuity" was evidenced by "the improvement [being] the work of the skillful mechanic, not that of the inventor"). *But see* John F. Duffy, *Inventing Innovation: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 7 (2007) (noting that seemingly trivial technological innovations may have great economic significance).

94. *See* 35 U.S.C. § 102 (precluding patenting where a "claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public").

95. *Id.* § 103.

96. *See In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) ("[O]nce an invention is in the public domain, it is no longer patentable by anyone." (quoting *In re Hall*, 781 F.2d 897, 898 (Fed. Cir. 1986))).

remains unalterable after filing.<sup>97</sup> Given that the effective filing date serves to shield patent owners from validity challenges based on anticipation,<sup>98</sup> the law requires that an issued patent's claims find sufficient written description support in the application relied on for priority.<sup>99</sup> The court will view a patent as having sufficient written description support when the application's specification demonstrates possession of the subject matter covered by the patent in light of the claims as construed by the court.<sup>100</sup>

Demonstrating possession means enabling POSA to anticipate the limitation later articulated in the claims.<sup>101</sup> Even if the specific embodiments of the invention disclosed in the application do not suggest the claim limitation, the patent will be upheld as valid if the application otherwise enabled POSA to anticipate the limitation later articulated in the claims.<sup>102</sup> Unlike the court's evaluation of definiteness, the written description assessment requires the court to engage in a task separate from claim construction—namely, comparing the challenged claims as construed to the description of the invention offered in the specification.<sup>103</sup>

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97. 35 U.S.C. § 132(a) (allowing for amendments to the claim language but prohibiting the introduction of “new matter”).

98. *See supra* Part I.B.2.

99. 35 U.S.C. § 112(a).

100. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (requiring the application relied on for priority to “reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date”); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (indicating that actual possession does not suffice and requiring the specification to communicate possession); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

101. *See, e.g., Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

102. *See, e.g., Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009) (en banc) (“[A] patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed.”); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (indicating that a patent should “not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language”).

103. *See, e.g., Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1358-61 (Fed. Cir. 2011) (en banc) (invalidating a patent as lacking sufficient written description when a claim covered “macrocyclic lactone analogs” and the specification disclosed rapamycin analogs “that bind FKBP12 and possess the same pharmacologic properties as rapamycin” because, while the latter included the former, the pool of potential analogs proved too numerous for POSA to discern that the patent owner possessed “macrocyclic lactone analogs” at the time of filing).



#### 4. *Definiteness*

To be valid as definite, a patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the [applicant] ... regards as his invention.”<sup>104</sup> During the patent application process, the PTO finds a claim indefinite if it appears “amenable to two or more plausible claim constructions.”<sup>105</sup> Until 2014, the Federal Circuit embraced an indefiniteness threshold higher than that of the PTO, finding a patent invalid as indefinite only if a claim proved “insolubly ambiguous”—a test that would not invalidate a patent where a claim term appeared susceptible to more than one plausible construction so long as one construction appeared most plausible.<sup>106</sup> Before 2014, the Supreme Court deemed a patent invalid as indefinite when a claim resided in “[a] zone of uncertainty.”<sup>107</sup> Then, in 2014, the Court announced a new test for definiteness,<sup>108</sup> wherein a patent would be invalid as indefinite in the event that a claim “fail[ed] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”<sup>109</sup>

Notably, unlike the other requirements, the court’s evaluation of definiteness appears identical with claim construction.<sup>110</sup> The definiteness test does not require the court to engage in a comparative task, which renders definiteness distinct from other varieties of validity assessment. The court’s assessment of enablement involves

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104. 35 U.S.C. § 112(b).

105. *Ex parte Miyazaki*, No. 2007-3300, 89 U.S.P.Q.2d (BNA) 1207, 1211 (BPAI Nov. 19, 2008).

106. *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (finding a claim to be “insolubly ambiguous” when “no narrowing construction can properly be adopted”). Some scholars and commentators believe the “insolubly ambiguous” standard was too permissive of indefiniteness. *See, e.g.*, Sanjeev Mahanta, *Indefiniteness*, 54 IDEA 479 (2012).

107. *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

108. As the Federal Circuit pointedly stated on remand in *Biosig Instruments, Inc. v. Nautilus, Inc.*, “The Court has accordingly modified the standard by which lower courts examine allegedly ambiguous claims; we may now steer by the bright star of ‘reasonable certainty,’ rather than the unreliable compass of ‘insoluble ambiguity.’” 783 F.3d 1374, 1379 (Fed. Cir. 2015).

109. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

110. The “reasonable certainty” test for definiteness is conditioned on the decipherability of the claim at issue “read in light of the specification delineating the patent, and the prosecution history,” which sounds like a recitation of what constitutes claim construction. *Biosig*, 783 F.3d at 1379 (quoting *Nautilus*, 134 S. Ct. at 2124); *see supra* Part I.A.

the distinct task of assessing whether the patent enables POSA to make and use the subject matter to which the claims as construed relate.<sup>111</sup> Likewise, the court's assessments of anticipation and written description involve distinctly comparative tasks—wherein the court evaluates the extent to which the claims as construed relate to subject matter already in the public domain as of the priority date or relate to subject matter not sufficiently disclosed in the application.<sup>112</sup> Meanwhile, current definiteness jurisprudence permits the court to assess residual ambiguity following claim construction for “reasonable certainty,” which begs the question: If uncertainty remains following claim construction, perhaps the conclusions drawn during claim construction require reexamination and not the claims themselves?<sup>113</sup>

## II. LESSONS FROM *TEVA V. SANDOZ*

*Teva* followed the typical path of patent litigation. A brand name drug company, Teva, held several product-by-process patents covering Copaxone, a multiple sclerosis medication.<sup>114</sup> Several generic drug companies, Sandoz among them, sought to manufacture and market generic versions of Copaxone before Teva's patent term expired, and Teva sued for patent infringement.<sup>115</sup> The generic companies defended against the infringement allegation by claiming that Teva's patents were invalid as indefinite.<sup>116</sup>

The nine patents at issue in *Teva* contained the same specification—describing the manufacturing process for Copaxone—and each contained individual claims detailing every element of the manufacturing process that should be considered by other drug manufacturers as the patented invention not to be infringed.<sup>117</sup> “Molecular weight” represented the contentious phrase the litigants called on the district court judge to construe.<sup>118</sup> Both sides presented conflict-

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111. *See supra* Part I.B.1.

112. *See supra* Parts I.B.2-3.

113. *See infra* Part II.A.

114. *Teva IV*, 135 S. Ct. 831, 835 (2015).

115. *Id.*

116. *Id.* at 835-36.

117. *Id.*; *see also Teva II*, 876 F. Supp. 2d 295, 305-06 (S.D.N.Y. 2012); *supra* Part I.

118. *Teva IV*, 135 S. Ct. at 835.

ing evidence as to the meaning of “molecular weight” as used in Teva’s patents.<sup>119</sup>

The District Court for the Southern District of New York enlisted both intrinsic evidence and extrinsic evidence to construe the phrase “molecular weight” from the perspective of POSA with specialized knowledge of pharmaceutical manufacturing.<sup>120</sup> In addition to reviewing the patents’ specification, claims, and prosecution histories, the district court heard expert testimony offered by both parties.<sup>121</sup> Sandoz claimed that “molecular weight,” as used in Teva’s patents to describe the active ingredient, copolymer-1, yielded equally to three competing constructions: “peak average molecular weight,”<sup>122</sup> “number average molecular weight,”<sup>123</sup> and “weight average molecular weight.”<sup>124</sup> Teva argued that “molecular weight,” in the context of the patent, could only mean “peak average molecular weight.”<sup>125</sup> The district court agreed with Teva and construed the phrase “molecular weight” as “peak average molecular weight.”<sup>126</sup>

When first reviewing *Teva* on appeal from the district court, the Federal Circuit granted no deference to the district court’s conclusions as to the meaning of “molecular weight” on the grounds that claim construction represented a matter of law to be reviewed *de novo*.<sup>127</sup> The Federal Circuit found that “molecular weight” did indeed yield to three possible interpretations, thus finding the patent invalid as indefinite.<sup>128</sup> Disabusing the Federal Circuit of its proclivity to subject all district court rulings related to claim construction to *de novo* review, the Supreme Court’s subsequent opinion in *Teva IV* refused to carve out a patent-specific exception

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119. *Id.* at 836.

120. *Id.*

121. *Id.*; see also *Teva Pharm. USA, Inc. v. Sandoz, Inc. (Teva I)*, 810 F. Supp. 2d 578, 590-93 (S.D.N.Y. 2011).

122. *Teva IV*, 135 S. Ct. at 836 (indicating “molecular weight as calculated by the weight of the molecule that is most prevalent in the mix that makes up copolymer-1”).

123. *Id.* (indicating “molecular weight as calculated by ... adding up the weight of each molecule and dividing by the number of molecules”).

124. *Id.* (indicating “molecular weight as calculated by taking all the different-sized molecules ... and calculating their average weight while giving heavier molecules a weight-related bonus when doing so”).

125. *Id.*

126. *Id.*

127. *Teva Pharm. USA, Inc. v. Sandoz, Inc. (Teva III)*, 723 F.3d 1363, 1373 (Fed. Cir. 2013).

128. *Id.* at 1369, 1375-76.

to Rule 52(a)(6), deeming subsidiary fact-finding related to claim construction as a fact matter to receive deferential, clear error review.<sup>129</sup> Meanwhile, claim construction itself remains a matter of law.<sup>130</sup> After *Teva IV*, separating subsidiary fact-finding from claim construction appears to hinge on whether the fact derives from intrinsic evidence or extrinsic evidence.<sup>131</sup>

Say a patent claim contains the phrase “leather chair.” If the district court uses plain meaning or intrinsic evidence to define the words “leather” and “chair” to then construe the meaning of the phrase “leather chair,” then the court’s entire decision-making qualifies as a matter of law subject to *de novo* review.<sup>132</sup> If the court relies on expert testimony to construe “leather” as “cow hide” and “chair” as “elevated seat with four legs,” then such subsidiary findings should be subject to deferential review as factual conclusions.<sup>133</sup> But, when the court subsequently concludes that POSA would read “leather chair,” as used in the patent, to mean “elevated seat with four legs covered in cow hide,” such a subsequent conclusion remains a matter of law subject to *de novo* review on appeal.<sup>134</sup>

Unfortunately, “molecular weight” presents a far harder case than “leather chair.”<sup>135</sup> Even still, the Supreme Court’s instructions in *Teva IV* appeared to indicate that the Federal Circuit must find clear error in the subsidiary fact-finding that supported the district court’s construction of “molecular weight” as “peak average molecular weight” in order to find Teva’s patent invalid as indefinite.<sup>136</sup> The

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129. *Teva IV*, 135 S. Ct. at 841.

130. *Id.* at 838.

131. *See id.*; Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1, 4 (2000) (categorizing Federal Circuit claim construction jurisprudence as hypertextualism versus pragmatic textualism).

132. *See Teva IV*, 135 S. Ct. at 840-41.

133. *See id.*

134. *See id.*

135. The construction of “leather chair” as “elevated seat with four legs covered in cow hide” cannot hold a candle to the district court’s construction of “molecular weight” as “peak molecular weight detected using an appropriately calibrated suitable gel filtration column.” *Teva I*, 810 F. Supp. 2d 578, 596 (S.D.N.Y. 2011) (holding followed *Markman* hearings).

136. “We have previously pointed out 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.’” *Teva IV*, 135 S. Ct. at 838 (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 610 (1950)).

Supreme Court conceded that distinguishing fact and law presented a challenge in the patent context, but did not view the obstacle as insurmountable:

[I]f a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*....

...This ultimate interpretation is a legal conclusion. The appellate court can still review the district court's ultimate construction of the claim *de novo*. But, to overturn the judge's resolution of an underlying factual dispute, the Court of Appeals must find that the judge, in respect to those factual findings, has made a clear error.<sup>137</sup>

Nonetheless, as discussed in depth below, the Federal Circuit found Teva's patents indefinite for a second time on remand without locating clear error in the district court's subsidiary fact-finding.

#### A. Teva on Remand

Not long before issuing *Teva IV*, the Supreme Court's opinion in *Nautilus, Inc. v. Biosig Instruments, Inc.* announced a new test for definiteness.<sup>138</sup> Prior to *Nautilus*, the Federal Circuit found a claim indefinite if the claim, as construed by the court, proved "insolubly ambiguous."<sup>139</sup> *Nautilus* granted the Federal Circuit more leeway in evaluating definiteness.<sup>140</sup> Now, any claim that "fail[ed] to inform, with reasonable certainty, those skilled in the art about the scope of the invention" might be classified as indefinite.<sup>141</sup>

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137. *Id.* at 841.

138. 134 S. Ct. 2120, 2124 (2014).

139. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (categorizing a claim as "insolubly ambiguous" when "no narrowing construction can properly be adopted").

140. *See Mahanta, supra* note 106, at 511.

141. *Nautilus*, 134 S. Ct. at 2124.

“Reasonable certainty” is a phrase that begs for content, and the Federal Circuit happily exploited that deficit in deciding *Teva V.*<sup>142</sup> After declaring that the district court made no clear error in fact-finding efforts that supported the construction of “molecular weight” as “peak average molecular weight,” the Federal Circuit simply stated that “there is not reasonable certainty that molecular weight should be measured using [peak average molecular weight],” and thus held the patent invalid as indefinite.<sup>143</sup> By finding no clear error in the district court’s subsidiary fact-finding, the Federal Circuit implicitly affirmed that POSA would construe “molecular weight” as “peak average molecular weight.”<sup>144</sup> Then, in holding the patent invalid as indefinite, the Federal Circuit carved out a brave new world wherein a patent can somehow fail to specify the claimed invention with reasonable certainty even though no skilled artisan would perceive the alleged ambiguity supposedly giving rise to such uncertainty.<sup>145</sup>

Neither *Teva*’s patents themselves nor their prosecution history evidenced procedural perfection.<sup>146</sup> The curve values offered in a figure accompanying one patent did not match the range offered in a particular patent claim, but an expert reasonably testified to the fact that a skilled artisan would understand that chromatography caused the peak curves to shift.<sup>147</sup> The prosecution history for another *Teva* patent exhibited a small degree of carelessness.<sup>148</sup> Prior to issuing the patent, the PTO asked for clarity on the phrase “molecular weight,” and *Teva* specified “weight average molecular weight,” contradicting *Teva*’s claim at trial that POSA would read

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142. Even if “insolubly ambiguous” remained the standard, the Federal Circuit may still have found the claims at issue indefinite while simultaneously finding no clear error in the district court’s fact-finding—the already tortured logic would just have been a bit more tortured. *Cf. Mahanta*, *supra* note 106, at 511.

143. *Teva V.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015).

144. *See id.* After all, that is the way the district court resolved the fact matter. *Teva II*, 876 F. Supp. 2d 295, 400 (S.D.N.Y. 2012).

145. *See Teva V.*, 789 F.3d at 1345 (Mayer, J., dissenting).

146. *Teva I*, 810 F. Supp. 2d 578, 588-89 (S.D.N.Y. 2011) (holding followed *Markman* hearings).

147. *Id.* at 589 (“[A] person of ordinary skill in the art would understand that any discrepancy between the peak values read from the chromatogram (7.7 kDa and 12.0 kDa) and the peak of Figure 1 is merely a by-product of the process by which the data from the chromatogram would have been used to generate Figure 1.”).

148. *See id.*

“molecular weight” as “peak average molecular weight.”<sup>149</sup> But testimony at trial supported a finding that Teva’s response to the PTO was accidental error.<sup>150</sup> And the district court determined that any skilled artisan reviewing the patents at issue and their prosecution histories would recognize Teva’s response as careless error and not as grounds for confusion.<sup>151</sup>

### B. Teva’s “Good” Patents

Teva’s missteps were minor, and the perfect should not be the enemy of the good.<sup>152</sup> If a patent is one that properly delimits the claimed invention and puts the innovative community on proper notice of infringement, then, as a public policy matter, the patent should be valid.<sup>153</sup> The district court found that Teva’s patent enabled replication without undue experimentation.<sup>154</sup> Accordingly, even if some inventor found herself reasonably uncertain as to the meaning of “molecular weight,” her confusion would not prevent her from perceiving the scope of the claimed invention—her confusion would not have the effect of leading her to accidentally infringe.<sup>155</sup>

The Federal Circuit could not hope to encourage more effective patenting with this decision because Teva’s patents included claims definite enough to delimit the scope of the claimed invention so as to prevent infringement.<sup>156</sup> Maybe the Federal Circuit aimed to encourage inventors to exercise tremendous care so that future patents would not be voided on the basis of an error no scientist would interpret as meaningful, but to which the court might imbue overriding significance.<sup>157</sup> Maybe the Federal Circuit aimed to

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149. *Teva V*, 789 F.3d at 1346-47 (Mayer, J., dissenting).

150. *Id.* at 1346.

151. *Id.* at 1347 (“Teva’s statement that the use of kilodalton units implied that ‘molecular weight’ meant weight average molecular weight was a non sequitur and, as the district court correctly found, a skilled artisan would not have relied upon it.”).

152. *See Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124 (1873).

153. *See Giordana Mahn, Keeping Trolls Out of Courts and Out of Pocket: Expanding the Inequitable Conduct Doctrine*, 45 LOY. U. CHI. L.J. 1245, 1246-47 (2014).

154. *Teva II*, 876 F. Supp. 2d 295, 386 (S.D.N.Y. 2012).

155. *See id.* at 383 (“The testimony of the experts at trial established that the relevant level of skill in the art was high.”).

156. *See Schwartz, supra* note 11, at 1549.

157. *See supra* note 12; *see also Vederi, LLC v. Google, Inc.*, 744 F.3d 1376, 1382 (Fed. Cir. 2014); *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1372-73 (Fed. Cir. 2007)

admonish patent examiners for accepting as satisfactory responses to definiteness inquiries that prove scientifically erroneous upon close inspection.<sup>158</sup> Maybe the Federal Circuit aimed to discourage the Supreme Court from altering the Federal Circuit's patent validity jurisprudence by wielding the *Nautilus* definiteness test as a weapon that enabled covert *de novo* review of fact-finding attendant to claim construction.<sup>159</sup>

Notwithstanding the Federal Circuit's historic power struggles with the PTO and the Supreme Court,<sup>160</sup> voiding patents on the basis of technical imperfection undermines the public utility of United States patent law.<sup>161</sup> Patents should be valid if fully functional.<sup>162</sup> As currently conceived, the definiteness requirement cuts against the public interest by allowing judicial assessment of patent validity to hinge on insignificant error.<sup>163</sup>

### III. THE FUTURE OF INDEFINITENESS

Many scholars blame claim construction for high reversal rates on appeal in patent cases.<sup>164</sup> A large majority of Federal Circuit reversals implicate claim construction issues.<sup>165</sup> Claim construction as the root cause makes intuitive sense given that district courts engage in claim construction in a manner vastly different from the Federal Circuit.<sup>166</sup> Notably, indefiniteness represents the largest

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(finding error in prosecution history not dispositive where statement was submitted after corrected error).

158. *But see* Schwartz, *supra* note 11, at 1549.

159. *See, e.g.*, John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 519 (2010); Arti K. Rai, Essay, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237, 1238-40 (2012).

160. *See* Duffy, *supra* note 159, at 519; Rai, *supra* note 159, at 1238-40.

161. *See* Schwartz, *supra* note 11, at 1549.

162. *See id.*

163. *See* Sichelman, *supra* note 26, at 1161-63.

164. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1746-48 (2009). *But see, e.g.*, Lefstin, *supra* note 29, at 1038-39.

165. Sichelman, *supra* note 26, at 1175-76; *see also* Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 8-10 (2001).

166. Lefstin, *supra* note 29, at 1051 ("In the course of deciding whether to admit evidence, the trial judge examines that evidence. Though the evidence may eventually be denied admission, the trial judge's exposure to the evidence may influence his or her understanding of the claim language.").



category of adjudicatory challenges to patent validity, outpacing nonobviousness and novelty, which also follow from claim construction.<sup>167</sup> Accordingly, definiteness jurisprudence, rather than claim construction, may deserve the blame for high reversal rates.

#### A. Claim Construction Is Not the Problem

If claim construction deserves the blame, then *Teva IV* presented an excellent solution to the high reversal rate problem.<sup>168</sup> By demanding that the Federal Circuit give greater weight to well-reasoned, fully-informed district court decisions about how to construe a claim, *Teva IV* explicitly remedied any potential imbalance between deference and information asymmetry.<sup>169</sup> By limiting the Federal Circuit's ability to issue reversals based on *de novo* review, *Teva IV* encouraged the Federal Circuit to clarify claim construction jurisprudence by requiring an exposition of any clear error perceived.<sup>170</sup>

Yet, on remand in *Teva V*, the Federal Circuit found Teva's patents invalid as indefinite without locating clear error in the district court's subsidiary fact-finding.<sup>171</sup> The alchemy on display by the Federal Circuit in *Teva V* demonstrates why increased deference for subsidiary fact-finding is unlikely to solve the incongruity in claim construction between district courts and the Federal Circuit, and begs the question: Is claim construction really the problem?

Claim construction attendant to a judicial assessment of definiteness contributes to the Federal Circuit's high reversal rate.<sup>172</sup> Accordingly, retooling the definiteness test may lessen the reversal rate problem. More importantly, the unpredictability of judicial assessment of patent definiteness means that the test for definiteness must be retooled if the requirement is to remain useful and legitimate as an essential element of patentability.<sup>173</sup>

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167. See Allison, Lemley & Schwartz, *supra* note 48, at 1782.

168. Cf. Lefstin, *supra* note 29, at 1050-51.

169. Cf. *id.* at 1050.

170. *Teva IV*, 135 S. Ct. 831, 841 (2015).

171. *Teva V*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015).

172. See Lefstin, *supra* note 29, at 1050-51.

173. See Mahanta, *supra* note 106, at 511.

The definiteness test will remain broken if it continues to stand in isolation from all other elements of patentability.<sup>174</sup> Such reifying of definiteness led the Federal Circuit in *Teva V* to lose sight of why the court should care about indefiniteness.<sup>175</sup> Patents do not distinctly point out claims to honor the ideal of definiteness; patents distinctly claim to prevent infringement and to limit the scope of the monopoly claimed so that other innovators are not wrongly restricted.<sup>176</sup> Congress never intended for definiteness to stand in isolation from all other elements of patentability.<sup>177</sup>

*B. “Consequentially Ambiguous”*

To bring definiteness out of isolation, a pragmatic test might replace “reasonable certainty” with “consequentially ambiguous.” In *Teva V*, the Federal Circuit held that, because “molecular weight” theoretically yielded to three possible meanings, the patent claim remained reasonably uncertain, rendering the patent invalid.<sup>178</sup> Theoretical uncertainty invalidated the patent even though the district court determined that POSA would easily resolve any theoretical ambiguity by drawing on knowledge of the field.<sup>179</sup> The district court’s subsidiary fact-finding would support a conclusion that the phrase appeared inconsequentially ambiguous.

Accordingly, “consequentially ambiguous” might achieve *Teva IV*’s deference aspirations by more forcefully compelling the Federal Circuit to give more weight to well-reasoned fact-finding by the district court.<sup>180</sup> While a theoretical estimation of uncertainty allowed the Federal Circuit to disregard subsidiary fact-finding, district court resolution of fact matters as proof positive (or negative) of the consequences of any perceived ambiguity should be harder to dismiss.<sup>181</sup> Even as jurisprudence from the Federal Circuit would provide content for what qualifies as “consequential” as a

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174. *Cf.* Allison, Lemley & Schwartz, *supra* note 48, at 1788-91.

175. *See Teva V*, 789 F.3d at 1344-45.

176. *Cf. id.*

177. *See* Schwartz, *supra* note 11, at 1549.

178. *See Teva V*, 789 F.3d at 1344-45.

179. *See id.* at 1346-47 (Mayer, J., dissenting).

180. *Cf.* Anderson & Menell, *supra* note 64 (discussing impact of *Markman* hearings on deference and claim construction jurisprudence).

181. *Cf. id.*

legal standard, fact-finding related to consequences could not be as easily ignored as fact-finding related to theoretical uncertainty.<sup>182</sup>

In addition, with a focus on consequence rather than theoretical confusion, “consequentially ambiguous” might impose a burden on the party raising invalidity as a defense to demonstrate how the indefiniteness alleged proved consequential.<sup>183</sup> Currently, asserting indefiniteness as an invalidity defense proves par for the course in patent litigation because such a defense does not require much from the alleged infringer.<sup>184</sup> If the defendant is required to particularize the consequences of the ambiguity perceived, then the court need not consider theoretical ambiguity nor even all consequences of any alleged ambiguity.<sup>185</sup>

The reasonably uncertain test requires the court to double down on hypotheticals when assessing indefiniteness.<sup>186</sup> As discussed, the court engages in claim construction to evaluate what a given claim term would have meant to POSA at the time of the patent application.<sup>187</sup> Subsequently, the court estimates if the patent as construed would carve out the scope of the invention claimed in a “reasonably certain” manner.<sup>188</sup> How POSA might perceive the scope of a given innovation is far more illusive than how POSA would perceive a claim term like “molecular weight.”<sup>189</sup> Moving definiteness from the hypothetical realm back into the real world should provide a solution. After all, in the context of infringement litigation, the defendant is not a hypothetical POSA alleging invalidity on behalf of all other hypothetical POSAs.<sup>190</sup>

If the party raising indefiniteness as a defense had to specify how POSA would misunderstand the scope of the invention given the

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182. *Cf. id.*

183. A safe assumption given that the standard would clarify how exactly “clear and convincing” is context dependent for the burden of persuasion regarding an invalidity defense premised on indefiniteness. *Cf. Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 111 (2011).

184. *Cf. id.*

185. Just as courts rely on the prior art references supplied by the asserting party when an invalidity defense is premised on lack of novelty. *Cf. Campbell v. Spectrum Automation Co.*, 513 F.2d 932, 935-37 (6th Cir. 1975) (showing “clear and convincing” to be a burdensome evidentiary standard for other infringement defenses).

186. *See generally Teva V*, 789 F.3d 1335 (Fed. Cir. 2015).

187. *See supra* Part I.A.

188. *See supra* Part I.B.4.

189. *See supra* Parts I.B.4, II.A.

190. *Cf. Campbell*, 513 F.2d at 935-37.

evident imprecision, then the court would evaluate the viability of that allegedly reasonable misinterpretation rather than rule on how any perceived indefiniteness might hypothetically inhibit perception of the scope of the invention. In the *Teva* cases, such a test would require Sandoz to particularize the indefiniteness defense. Sandoz would have to demonstrate that misperceiving copolymer-1 as having a molecular weight between five to nine kilodaltons when “molecular weight” means “weight average molecular weight” or “number average molecular weight” would actually lead Sandoz to believe they might manufacture a generic version of Copaxone without infringing Teva’s manufacturing patent. Sandoz would not be able to offer such a particularized version of the invalidity defense to the court—or at least not with a straight face.<sup>191</sup> And so, Sandoz would be unable to raise indefiniteness as a defense.<sup>192</sup>

Compelling the party that asserts an invalidity defense to particularize the consequences of the invalidity alleged is not new.<sup>193</sup> When an assertion of invalidity depends on demonstrating lack of novelty, obviousness, or improper patent subject matter, the asserting party must present more particularized evidence than is required when an invalidity defense is premised on indefiniteness.<sup>194</sup> Accordingly, in imposing an added burden on an alleged infringer asserting a recognized defense, the “consequentially ambiguous” test would not be aberrant.<sup>195</sup>

Arguably, “consequentially ambiguous” might cut in favor of patent holders over alleged infringers.<sup>196</sup> And, the notorious

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191. *Cf. Teva V*, 789 F.3d at 1346-47 (Mayer, J., dissenting).

192. *Cf. id.*

193. *See, e.g., In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999); *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997); *Mass. Inst. of Tech. v. AB Fortia*, 774 F.2d 1104 (Fed. Cir. 1985); *In re Wyer*, 655 F.2d 221 (C.C.P.A. 1981).

194. *See supra* Part I.A.

195. *See Therasense, Inc. v. Becton, Dickenson & Co.*, 649 F.3d 1276, 1296 (Fed. Cir. 2011) (requiring a prima facie case of patentee acting with specific intent to deceive the PTO for alleged infringer to raise defense of inequitable conduct; supporting the contention that insignificant error should not be outcome-determinative).

196. Courts already comment on the extent to which the presumption of validity cuts in favor of the patent holder by placing the burden of demonstrating invalidity on the alleged infringer. *See, e.g., Campbell v. Spectrum Automation Co.*, 513 F.2d 932, 935-36 (6th Cir. 1975). But an invalidity defense premised on obviousness or lack of novelty requires much more from the asserting party than does definiteness. *See supra* Part I.

expense<sup>197</sup> of patent litigation already resigns many to licensing from patent holders even where litigation might reveal the patent at issue to be consequentially ambiguous.<sup>198</sup> Yet, the invalidity defense to infringement is often raised in a context like the above—where Goliath fights Goliath and no monetary asymmetry induces a party to license a bad patent to avoid litigation costs.<sup>199</sup> In no world did Teva’s use of the phrase “molecular weight” lead Sandoz to believe that manufacturing Copaxone did not infringe on Teva’s patent.<sup>200</sup> United States patent law should not allow Sandoz to free-ride off Teva’s investment in drug development because of an insignificant error that amounted to a typo.<sup>201</sup> United States patent law should not allow Sandoz to delegate the task of investigating theoretical indefiniteness to federal district courts or to the Federal Circuit.<sup>202</sup> Emphasizing the absurdity, United States definiteness jurisprudence appears out of step with patent validity standards abroad, given that the European Patent Office recently upheld Teva’s Copaxone patents as valid despite the typographical error.<sup>203</sup>

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197. Patent infringement litigation costs an average of \$650,000 for suits where less than \$1 million is at risk and an average of \$2.5 million where \$1 million or more is at risk. AM. INTELLECTUAL PROP. LAW ASS’N, REPORT OF THE ECONOMIC SURVEY: 2011, at 35-36 (2011).

198. Arguably, the unpredictability of invalidations based on indefiniteness may prevent parties from engaging in such rational calculus when doing so would be wealth-maximizing. Cf. Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007) (describing the prospect of injunctive relief as enabling irrational pricing of licenses).

199. Cf. *id.*

200. Cf. *Teva V*, 789 F.3d 1335, 1346-47 (Fed. Cir. 2015) (Mayer, J., dissenting).

201. Cf. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 111 (2011).

202. Cf. *Anderson & Menell*, *supra* note 64, at 4-5; *Sichelman*, *supra* note 26, at 1165, 1168-71.

203. See Kelly Knaub, *CORRECTED: Teva Copaxone Patent Upheld as Valid by EPO*, LAW360 (Dec. 8, 2015, 9:56 PM), <http://www.law360.com/articles/735404/corrected-teva-copaxone-patent-upheld-as-valid-by-epo> [<https://perma.cc/3DMK-Q434>].

## CONCLUSION

In issuing *Teva IV*, the Supreme Court intended to reduce high reversal rates on appeal in patent cases.<sup>204</sup> Analysis of the Federal Circuit's patent reversal rates suggests that reversals based on district court claim construction drive up the overall reversal rate.<sup>205</sup> And reversals based on claim construction that informs an invalidity assessment where indefiniteness proves dispositive drive up the overall claim construction reversal rate.<sup>206</sup> The conceptual nature of the current test for definiteness renders problematic the task of deciphering between the process of claim construction and an assessment of definiteness in light of completed claim construction.<sup>207</sup>

Many scholars and commentators view the convergence of claim construction and definiteness as grounds for emphasizing the significance of claim construction jurisprudence and attendant review standards.<sup>208</sup> But the same logic justifies an increased emphasis on definiteness jurisprudence.<sup>209</sup> After all, the coincidence of claim construction and definiteness must mean that tests for definiteness necessarily inform the operation of claim construction just as claim construction jurisprudence dictates definiteness.<sup>210</sup>

A test like "consequentially ambiguous" would remove definiteness from claim construction's theoretical realm, enabling the two to be more easily distinguished.<sup>211</sup> Disallowing invalidity defenses premised on conceptual indefiniteness would limit the degree to which definiteness is isolated from other patentability requirements, allow for greater deference to district court subsidiary fact-finding, place a higher evidentiary burden on the asserting party more consistent with the "clear and convincing" standard as re-

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204. See Transcript of Oral Argument at 31, *Teva IV*, 135 S. Ct. 831 (2015) (No. 13-854) (revisiting questions centered on uniformity effects).

205. See Sichelman, *supra* note 26, at 1173-76.

206. See *id.*

207. See *supra* Part I.B.

208. See, e.g., Mahanta, *supra* note 106, at 485.

209. See Lefstin, *supra* note 29, at 1049 (discussing unpredictable nature of indefiniteness reversals as more important than frequency of such reversals).

210. Cf. Klimek, *supra* note 65, at 314 (emphasizing differences between PTO and federal courts regarding patent validity assessment).

211. See *supra* Part III.B.

quired by the presumption, and align the evidentiary standard for indefiniteness with that of the other categories of invalidity defenses.<sup>212</sup>

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212. *See supra* Part III.A.

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