# Patents, Presumptions, and Public Notice<sup>†</sup>

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Patents are peculiar legal instruments in that they contain both technical and legal information. This Janus-like nature of the documents is important because they serve the legal purpose of affording the owner the right to exclude others from practicing the invention, and third parties need to be able to assess the scope of that right. At the same time, through the patent's disclosure, the document is intended to contribute to the storehouse of technical knowledge. Superficially, patents are generally viewed through the eyes of the hypothetical person having ordinary skill in the art (PHOSITA), patent law's "reasonable person." Unfortunately, the U.S. Court of Appeals for the Federal Circuit has marginalized the PHOSITA by treating the document, particularly in claim construction and in assessing the sufficiency of the patent's disclosure, as a purely legal document. While this shift is understandable, it is also unfortunate. Possible justifications for the court's move are unpersuasive. For instance, from the ex ante perspective, the court may hope to encourage future applicants to provide better disclosures. As this Article explains, that argument fails because the court's legal standards are too vague and the lapse of time between the application and a competitor's review

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of the patent causes informational asymmetries for which the applicant cannot account. From an ex post perspective, this shift may assist lay judges and juries in evaluating patents, but such a result is the problem—this treatment reduces the technical value of the patent and incentivizes future applicants to treat the disclosure in a legal fashion, not as a technical resource.

To balance the interest in public notice with the technical nature of the patent, this Article posits the use of presumptions. Courts should use the intrinsic evidence—the patent and the prosecution history—to generate a presumptive conclusion as to the construction of the patent or the sufficiency of the patent's disclosure. Then, the court should resort to the extrinsic evidence to determine whether the legalistic conclusion reached should be rejected in light of the understanding of technologists in the relevant field. In this way, the default position for courts is interpretation afforded by the intrinsic record, enhancing public notice. This default, however, can be rebutted when facts regarding the technical import of the document are brought to bear, bringing the viewpoint of the PHOSITA into the calculus.

#### INTRODUCTION

Patents are peculiar legal instruments. A patent affords a patent owner the right to exclude others from making, using, selling, offering to sell, or importing the invention. The scope of these exclusive rights is determined by the patent's claims, single-sentence elaborations of the invention found at the end of the patent. It therefore is a legal document as it sets the metes and bounds of the owner's exclusionary rights.

Yet, a patent is far more than a legal document like a contract or will. The patent must contain enough information to allow a person of ordinary skill in the relevant technology to make and use the invention.<sup>3</sup> Moreover, the patent claims often contain technical language that would be unintelligible to a non–technically trained lawyer.<sup>4</sup> Patents, therefore, are also technical documents, containing information of interest to technologists and scientists. In fact, one of the key purposes of the patent system is to enhance the storehouse of technical knowledge, leading to further innovation.<sup>5</sup>

- 1. 35 U.S.C. § 271(a) (2006).
- 2. 35 U.S.C. § 112, ¶ 2.
- 3. Id. ¶ 1. See generally Jeanne C. Fromer, Patent Disclosure, 94 IOWA L. REV. 539, 545–47 (2009) [hereinafter Fromer, Patent Disclosure]; Timothy R. Holbrook, Possession in Patent Law, 59 SMU L. REV. 123, 127–31 (2006) [hereinafter Holbrook, Possession]; Jeffrey A. Lefstin, The Formal Structure of Patent Law and the Limits of Enablement, 23 BERKELEY TECH. L.J. 1141, 1142–59 (2008); Sean B. Seymore, Heightened Enablement in the Unpredictable Arts, 56 UCLA L. REV. 127, 129–31 (2008) [hereinafter Seymore, Heightened Enablement].
- 4. See generally Peter Lee, Patent Law and the Two Cultures, 120 YALE L.J. 2, 9–17 (2010) (describing district court judges' struggles with technology aspects of patent law).
- 5. See, e.g., United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933) ("An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge."). But see

As a result of patents' Janus-like nature, reading and interpreting them can be challenging, as courts must parse both the legal and the technical to arrive at a conclusion about the scope and validity of the patent. To mediate a patent's dual nature, the patent statute and common law have developed an analog to tort law's "reasonable person": the "person having ordinary skill in the art," generally referred to as the PHOSITA. In almost every area of patent law, the court or jury should view the issues from the perspective of the PHOSITA, not that of a lawyer or layperson. Consequently, the description in a patent need not include information already known by the PHOSITA, which permits applicants to submit simpler patent disclosures. Similarly, other patentability requirements, such as novelty and non-obviousness, are assessed through a technically based perspective. Whether a given device infringes a patent is also determined by considering the perspective of the PHOSITA. The PHOSITA, whoever she may be, is ubiquitous in patent law.

Within the judicial system, however, no one is truly a PHOSITA. Patent litigation cases are tried in front of judges and juries who seldom have technical degrees at all, let alone one relevant to the particular patent at issue. Even at the national court of appeals that hears all cases arising under the patent laws, the U.S.

Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2023–26 (2005) (rejecting the view that patent disclosures disseminate technical knowledge).

- 6. 35 U.S.C. §§ 103, 112; Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997) (comparing tort's "reasonable person" to patent law's person skilled in the art).
- 7. See generally Dan L. Burk & Mark A. Lemley, Is Patent Law Technology-Specific?, 17 BERKELEY TECH. L.J. 1155, 1185–90 (2002); Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law, 89 VA. L. REV. 1575, 1648–51 (2003); Jonathan J. Darrow, The Neglected Dimension of Patent Law's PHOSITA Standard, 23 HARV. J.L. & TECH. 227 (2009); Rebecca S. Eisenberg, Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA, 19 BERKELEY TECH. L.J. 885 (2004); Joseph P. Meara, Just Who Is the Person Having Ordinary Skill the Art? Patent Law's Mysterious Personage, 77 WASH. L. REV. 267 (2002); John O. Tresansky, PHOSITA—The Ubiquitous and Enigmatic Person in Patent Law, 73 J. PAT. & TRADEMARK OFF. SOC'Y 37, 37–38 (1991).
- 8. See, e.g., Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984). But see ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 941 (Fed. Cir. 2010).
- 9. An invention must be new in order to be patented. 35 U.S.C. §§ 101–02. The absence of novelty results in the claimed invention being anticipated. See, e.g., Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). See generally Timothy R. Holbrook, The More Things Change, the More They Stay the Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar, 15 BERKELEY TECH. L.J. 933, 936–37 (2000); Sean B. Seymore, Rethinking Novelty in Patent Law, 60 DUKE L.J. 919, 930–37 (2010).
  - 10. 35 U.S.C. § 103; Holbrook, *supra* note 9, at 937.
- 11. See Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 1256–57 (Fed. Cir. 2007) (concluding that the level of ordinary skill was determinative of obviousness); see also Timothy R. Holbrook, Equivalency and Patent Law's Possession Paradox, 23 HARV. J.L. & TECH. 1, 8–9 (2009) [hereinafter Holbrook, Paradox] (discussing the relationship between disclosure and PHOSITA).
- 12. Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1361 n.3 (Fed. Cir. 2008); Darrow, *supra* note 7, at 236; Holbrook, *Paradox*, *supra* note 11, at 21–27.

Court of Appeals for the Federal Circuit, <sup>13</sup> most of the judges are not technically trained or did not have prior patent experience. <sup>14</sup> The PHOSITA construct, rooted in the scientific or technical, can be difficult for the courts to apply.

Unsurprisingly, the Federal Circuit over time has discounted the role of the PHOSITA. In reviewing the patent document, the court has emphasized the document itself and the relevant patent's prosecution history, the public record of the patent application process at the U.S. Patent and Trademark Office (USPTO or PTO). If It this publicly available intrinsic evidence is clear, the court will refuse to consult other extrinsic evidence, which would be where the technological context of the invention would be revealed. The court favors the intrinsic evidence as a mechanism for enhancing public notice. The intrinsic evidence is accessible to all parties and is not subject to the influence of the litigation process. By emphasizing the patent document in isolation, the Federal Circuit has increasingly viewed patents as merely legal, not technical, texts. To effect this approach, the court has articulated a variety of formalistic legal rules that are far more accessible to a

13. 28 U.S.C. § 1295(a)(1). See generally Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc., 535 U.S. 826 (2002).

- 15. Eisenberg, *supra* note 7, at 889–97 (discussing the marginalization of PHOSITA in the obviousness context).
- 16. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc).
- 17. See Craig Allen Nard, Legal Forms and the Common Law of Patents, 90 B.U. L. REV. 51, 79–82 (2010).
- 18. *Cf. Markman*, 52 F.3d at 978–79 ("Moreover, competitors should be able to rest assured . . . that a judge, trained in the law, will similarly analyze the text of the patent and its associated public record and apply the established rules of construction, and in that way arrive at the true and consistent scope of the patent owner's rights to be given legal effect.").
- 19. See John F. Duffy, Rules and Standards on the Forefront of Patentability, 51 Wm. & MARY L. Rev. 609, 611 (2009); Timothy R. Holbrook, The Supreme Court's Complicity in Federal Circuit Formalism, 20 Santa Clara Computer & High Tech. L.J. 1, 2 (2003)

<sup>14.</sup> Arti K. Rai, Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform, 103 COLUM. L. REV. 1035, 1068-69 (2003). Of the judges currently on the Federal Circuit, five have technical backgrounds and/or had patent experience prior to joining the bench: Judges Newman, Lourie, Gajarsa, Linn, and Moore. See UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, http://www.cafc.uscourts.gov (follow "The Court: Judges" hyperlink). Judge Rader served on the Senate Subcommittee that dealt with intellectual property policy issues. See id. Judge O'Malley, while not having a technical degree, does have considerable experience as a district court judge trying patent cases. See id. Judge Dyk and nominee Edward DuMont litigated patent cases prior to their appointments, See, e.g., TiVo, Inc. v. EchoStar Commc'ns Corp., 516 F.3d 1290 (Fed. Cir. 2008) (nominee DuMont), vacated and reh'g en banc granted, No. 2009-1374, 2010 WL 1948577 (Fed. Cir. May 14, 2010); Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995) (Judge Dyk). The final pending nominee, Jimmie V. Reyna, has neither a technical degree nor patent litigation experience. See Jimmy V. Reyna, WILLIAMSMULLEN, http://www.williamsmullen.com/jreyna. He does have extensive international trade experience, over which the Federal Circuit has jurisdiction. In contrast, examiners at the U.S. Patent and Trademark Office do have technical backgrounds. See Patent Examiner Positions, U.S. PAT. & TRADEMARK http://usptocareers.gov/Pages/PEPositions/Default.aspx.

layperson but minimize the importance of the patent's technical component.<sup>20</sup> Thus, while paying lip service to her continued importance, the Federal Circuit has actually attempted to speak the death of the PHOSITA.

In contrast, the U.S. Supreme Court believes that the reports of the PHOSITA's death are greatly exaggerated.<sup>21</sup> In the context of assessing whether an invention claimed in a patent is non-obvious, and thus worthy of patent protection, the Supreme Court recently breathed new life into the PHOSITA.<sup>22</sup> Elsewhere, the Supreme Court has rejected the Federal Circuit's formalism in favor of more flexible procedural rules. In particular, the Supreme Court has offered a variety of presumption-based rules that balance interests in certainty and fairness.<sup>23</sup> Unfortunately, the Federal Circuit has not taken these lessons to heart with respect to its treatment of the patent document itself.

Patent scholarship has failed to take full account of the Federal Circuit's systemic efforts to emasculate the PHOSITA in the context of the patent document itself. This Article fills this gap in the literature by performing a comprehensive review of the manner in which the Federal Circuit has marginalized the PHOSITA's role as it relates to the patent document, particularly in the manner the court construes patent claims and assesses the sufficiency of patent disclosures, generally known as the written description and enablement requirements. The Article posits that the removal of the PHOSITA's viewpoint of the patent document is unfortunate because it transforms the patent inappropriately into a purely legal document, when in fact that patent is a blend of the technical and the legal. This shift has the unintended result of undermining the disclosure function of the patent system.

In response to this problem, this Article offers a novel methodology to balance the Federal Circuit's interest in certainty with the important consideration of the technical aspects of the patent document. I posit that the use of rebuttable presumptions can balance the interest in certainty with an appropriate place for the PHOSITA. Presumptions allow the court to establish a default position that reflects its policy preference, here preferring reliance on the patent document and public record over extrinsic, technological evidence. Unlike the status quo, however, the intrinsic evidence is not necessarily determinative; the presumptive outcome from consideration of the intrinsic evidence can be rebutted by persuasive technology-based evidence. Absent such evidence, the intrinsic evidence would govern the outcome. In this way, courts would afford primacy to the patent document while still providing the opportunity for the views of the PHOSITA to be considered in the inquiry.

The remainder of this Article proceeds as follows. Part I.A explores the nature of the patent document, detailing how it is both legal and technical in nature. In

[hereinafter Holbrook, *Complicity*]; Nard, *supra* note 17, at 77–99; Rai, *supra* note 14, at 1103–22; John R. Thomas, *Formalism at the Federal Circuit*, 52 Am. U. L. Rev. 771, 792 (2003).

- 20. See Lee, supra note 4, at 29–41.
- 21. With all respect due to Mark Twain.
- 22. See infra Part II.A.
- 23. See infra Part II.A.
- 24. See Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc).

subpart B, I elaborate the Federal Circuit's inappropriate discounting of the PHOSITA in the context of claim construction and the requirements for an adequate patent disclosure. Subpart C then considers potential justifications for the Federal Circuit's approach by considering its ex ante and ex post consequences. From the ex ante perspective, the Federal Circuit could be attempting to create a penalty default that encourages more robust disclosures from patent applicants. The temporal dynamic of the patent system, however, creates various information asymmetries that suggest the court will not achieve this goal. From the ex post perspective, the court could apply a heuristic to aid laypersons in engaging with patent law. This rationalization, however, *is* the problem: the removal of the technical components of the disclosure from its appropriate place in the patent document. Ultimately I reject these possible defenses of the Federal Circuit's approach.

Part II.A then considers the contrasting approach of the Supreme Court in balancing the concerns of certainty and fairness. In particular, I explore how the Supreme Court has both emphasized the role of the PHOSITA and preferred the use of presumptions to balance the potential competing interests of public notice and fairness. Subpart B then explores the theoretical aspects of presumptions and concludes that such a methodology meshes well with the patent law fabric. Subpart C then offers a particularized rebuttable presumption framework for addressing the construction of patent claims and for assessing the adequacy of the patent's disclosure. Subpart D finally considers possible limitations and drawbacks to the presumption methodology. Notwithstanding some potential hurdles, I conclude that the use of rebuttable presumptions provides an effective method for balancing the legal aspect of the patent document with the technical, improving public notice for the patent system.

# I. THE FEDERAL CIRCUIT'S ELEVATION OF THE PATENT DISCLOSURE AND DISCOUNTING OF THE PHOSITA

Almost every doctrine in patent law is tethered to the PHOSITA in some fashion. In large part, the reliance on the PHOSITA is necessary given the nature of the patent document, which has both legal and technical aspects. The Federal Circuit, however, has elevated the legal aspect to preeminence, relegating the technical aspect—and the PHOSITA—to second-class status. The court's embrace of formalistic legal rules that focus strictly on the patent document is tied directly to its interest in promoting interest and certainty in patent law, but it results in an over-discounting of the views of technologists, as represented in the PHOSITA construct. This Part explores the legal and technical nature of patents and the Federal Circuit's unsurprising yet unfortunate preference for treating them as primarily legal documents.

### A. The Janus-Like Nature of the Patent—Technical, Legal, or Both?

Patents are fairly unique forms of property in that they serve a constitutional, utilitarian purpose: to promote the progress of the useful arts.<sup>25</sup> The award of a patent is therefore about more than simply rewarding the inventor for his creation; it also benefits the public by publishing the invention in the patent document. In exchange for the patent, the inventor is obligated to disclose how to make and use the claimed invention.<sup>26</sup> As a result, while the patent is undeniably a legal document (it affords the patentee the right to exclude others from practicing her invention), it is also a technical document (it teaches technical details of the invention to the relevant public).<sup>27</sup>

The legal aspect of the patent becomes apparent when construing the patent's claims. In patent law, the scope of the right to exclude afforded by the patent is determined by the patent's claims. <sup>28</sup> A claim acts as the metaphorical "fence" that determines the scope of the patentee right. <sup>29</sup> The claim, therefore, is the essential feature of the patent used to assess both validity <sup>30</sup> and infringement. <sup>31</sup> For determining infringement and validity of the claims, therefore, one must determine the meaning of the language in the claim. <sup>32</sup> The act of interpreting the claims therefore delineates the legal limits of the right to exclude.

Even a cursory perusal of a patent on a simple technology confirms that these documents also contain technical information. For example, a patent that covers the insulating sleeve on paper coffee cups contains the summary of the invention:

This invention provides recyclable, corrugated containers and container holders which can be made from existing cellulosic materials, such as

<sup>25.</sup> U.S. Const. art. I, § 8, cl. 8. See generally Paul J. Heald & Suzanna Sherry, Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress, 2000 U. Ill. L. Rev. 1119 (discussing the Constitutional purpose and limits of the Patent and Copyright Clause); Timothy R. Holbrook, The Treaty Power and the Patent Clause: Are There Limits on the United States' Ability to Harmonize?, 22 CARDOZO ARTS & ENT. L.J. 1, 4–21 (2004) (discussing potential Constitutional limits on patent law).

<sup>26. 35</sup> U.S.C. § 112, ¶ 1 (2006).

<sup>27.</sup> Sean B. Seymore, *The Teaching Function of Patents*, 85 Notre Dame L. Rev. 621, 624 (2010) [hereinafter Seymore, *Teaching Function*]; Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy ch. 4, at 3–4 (2003).

<sup>28. 35</sup> U.S.C. § 112, ¶ 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.").

<sup>29.</sup> See Holbrook, Paradox, supra note 11, at 8–9.

<sup>30.</sup> Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1334 (Fed. Cir. 2004) (noting that validity is determined on a claim-by-claim basis).

<sup>31.</sup> Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001) (noting that infringement is assessed on a claim-by-claim basis).

<sup>32.</sup> See Phillips v. AWH Corp., 415 F.3d 1303, 1312, 1315 (Fed. Cir. 2005); Dana Corp. v. Am. Axle & Mfg., 279 F.3d 1372, 1376 (Fed. Cir. 2002) ("[A] court may not invalidate the claims of a patent without construing the disputed limitations of the claims and applying them to the allegedly invalidating acts.").

paper. The preferred recyclable, corrugated hot beverage container includes a lip and an internal cavity for containing a hot or cold medium. The container includes fluting means, such as fluting adhesively attached to one or more liners, for thermally spacing the hands of the user from the harsh temperatures of the contents of the container.<sup>33</sup>

Even a patent on the relatively straightforward insulating sleeve is rife with technical jargon. Far more complex technologies of course involve far more technical disclosures.<sup>34</sup> Thus, it is unsurprising that in order to prosecute patents at the USPTO, a patent attorney or agent must have a qualifying technical degree.<sup>35</sup> Patent examiners at the USPTO also are required to have technical degrees.<sup>36</sup> As a result, patents necessarily involve technical information.

Review of the literature on patent disclosures confirms that patents are a somewhat bizarre mix of the technical and legal, with commentators advocating a myriad of preferences for one or the other. For example, Professor Sean Seymore argues that the patent document should take on an even more technical character, bridging the gap between patents and more traditional forms of scientific publication and making the patent document a more effectual teacher to technologists.<sup>37</sup> In his view, the patent document at present is undervalued as a source of technical information. The legalistic "patentese" undermines the document's effectiveness as a technical disclosure yet does little seemingly to enhance its legal nature.<sup>38</sup> Instead of treating a patent increasingly as a purely legal document, he argues that it should take on a greater technical nature by, for example, requiring working embodiments of the invention.<sup>39</sup>

Id.

<sup>33.</sup> U.S. Patent No. 5,205,473 col.1 ll.44–52 (issued Apr. 27, 1993).

<sup>34.</sup> See, e.g., U.S. Patent No. 5,716,827 col.2 ll.41–57 (issued Feb. 10, 1998). Methods resulting in the isolation of substantially homogenous compositions of human hematopoietic stem cells are provided. The methods employ a predetermined separation regimen and bioassays for establishing the generation of each of the hematopoietic lineages from the isolated cells. The human stem cells find use: (1) in regenerating the hematopoietic system of a host deficient in stem cells, (2) in a host that is diseased and can be treated by removal of bone marrow, isolation of stem cells and treatment of individuals with drugs or irradiation prior to re-engraftment of stem cells, (3) producing various hematopoietic cells, (4) detecting and evaluating growth factors relevant to stem cell self-regeneration; (5) the development of hematopoietic cell lineages and assaying for factors associated with hematopoietic development; and (6) treatment of genetic diseases through gene replacement in autologous stem cells.

<sup>35. 37</sup> C.F.R. § 11.7.

<sup>36.</sup> See supra note 14.

<sup>37.</sup> Seymore, Teaching Function, supra note 27, at 641–57.

<sup>38.</sup> Id. at 633-41.

<sup>39.</sup> Id. at 641-46.

Similarly, Professor Jeanne Fromer has expressly noted that the patent document has two audiences, the technical and the legal. 40 Notwithstanding her belief that patents represent the best source of technical information, 41 she recognizes that many technologists do not read the patent disclosure due to the "legalized jargon." Similar to Professor Seymore, she advocates an enhanced role for the patent document and would separate the technical from the legal to better effect the disclosure function of patents. 43

Professor Joseph Miller also has advocated enhancing the technical component of the patent document to improve the interpretation of patents. <sup>44</sup> As he explains, "augmenting the patentee's technological disclosure with carefully selected contextualizing information should help courts more reliably identify disputed claim terms' technologically proper meanings. <sup>45</sup> Professor Miller would create a strong default position based on the ordinary meaning of a term in the relevant art. He proposes that the USPTO require not only the enhanced technical disclosures but also particularized definitions of key relevant terms.

In contrast, Professor John Golden has advocated a partial retreat from viewing the patent as a technical document in favor of recognizing its more legal nature. At least with respect to the interpretation of a patent's claims, Professor Golden advocates for an approach that expressly considers the view of a patent *attorney*, not merely the PHOSITA. Thus he would emphasize the legal nature of the document, informed in part by relevant technological considerations.

Patents themselves, the law, and the literature all confirm that the nature of the patent document is a strange mix of the legal and the technical. Of course, the entity with the most authority in regulating the dichotomous nature of the patent document is primarily a legal actor: the U.S. Court of Appeals for the Federal Circuit, which hears all patent appeals arising under the United States' patent laws. <sup>49</sup> As a result, the court has shifted the emphasis of the patent toward the legal and away from the technical.

<sup>40.</sup> Fromer, Patent Disclosure, supra note 3, at 543.

<sup>41.</sup> *Id.* at 560 ("By process of elimination, the patent document is the principal way for an interested technologist to locate useful information about a patented invention."). *But see* Holbrook, *Possession*, *supra* note 3, at 143–46 (arguing that patents are a poor source of technical information due to limits on use and delays in publication).

<sup>42.</sup> Fromer, *Patent Disclosure*, *supra* note 3, at 560–61.

<sup>43.</sup> Id. at 563-85.

<sup>44.</sup> Joseph Scott Miller, *Enhancing Patent Disclosure for Faithful Claim Construction*, 9 Lewis & Clark L. Rev. 177, 187–88 (2005).

<sup>45.</sup> Id. at 188.

<sup>46.</sup> Id. at 203-07.

<sup>47.</sup> John M. Golden, Construing Patent Claims According to Their "Interpretive Community": A Call for an Attorney-Plus-Artisan Perspective, 21 HARV. J.L. & TECH. 321, 327 (2008).

<sup>48.</sup> Id. at 383-85.

<sup>49. 28</sup> U.S.C. §§ 1295(a)(1), 1338(a) (2006).

# B. The Federal Circuit's Treatment of the Patent as Legal for Purposes of Public Notice

Patents, unlike tangible property, do have a problem: their inchoate nature renders defining the boundaries of the property right difficult. <sup>50</sup> Indeed, scholars have decried the lack of public notice as one of the significant failings of the patent system. <sup>51</sup> The Federal Circuit has long recognized the need for certainty and public notice in the patent system. <sup>52</sup> As a result, the court has tended to adopt somewhat formalistic, bright-line legal rules in various areas of patent doctrine. <sup>53</sup> This interest in public notice, though, begs the question of notice as to *whom*? <sup>54</sup> Who is the relevant public? Unsurprisingly, as a judicial and legal actor, the Federal Circuit has generally directed its efforts at public notice to *lawyers*, elevating the patent document and public record as a legal instrument and marginalizing its technical component, in essence by removing the PHOSITA from active participation in the resolution of certain issues. <sup>55</sup> This dynamic is particularly apparent in the Federal

- 50. See Dan L. Burk & Mark A. Lemley, Fence Posts or Sign Posts? Rethinking Patent Claim Construction, 157 U. PA. L. REV. 1743, 1748–61 (2009) [hereinafter Burk & Lemley, Fence Posts]; Kimberly A. Moore, Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box, 99 MICH. L. REV. 365, 365 (2000); David L. Schwartz, Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases, 107 MICH. L. REV. 223, 227–29 (2008). Because an invention may be something new, it may be difficult to find words to adequately capture the idea, further compounding the boundary delineation problem. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002); Jeanne C. Fromer, Claiming Intellectual Property, 76 U. CHI. L. Rev. 719, 737, 755 (2009).
- 51. James Bessen & Michael J. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk 46–72 (2008); Craig Allen Nard, *A Theory of Claim Interpretation*, 14 Harv. J.L. & Tech. 1, 12–14 (2000).
- 52. See In re Bilski, 545 F.3d 943, 994 (Fed. Cir. 2008) (en banc) (Newman, J., dissenting) (discussing uncertainty surrounding court's standard for patent-eligible subject matter), aff'd, Bilski v. Kappos, 130 S. Ct. 3218 (2010); Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1046–47 (Fed. Cir. 2001) (discussing need for certainty in the on-sale bar); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 586 (Fed. Cir. 2000) (en banc) (discussing reliance on public record to effect public notice), vacated & remanded, 535 U.S. 722 (2002); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1455–56 (Fed. Cir. 1998) (en banc) (discussing need for certainty in claim construction).
- 53. See, e.g., Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec., 417 F.3d 1203, 1214–15 (Fed. Cir. 2005) (elevating two out of thirteen factors, control and customer awareness, as necessary to find experimental use). See generally Holbrook, Complicity, supra note 19, at 2–3; Thomas, supra note 19, at 781–83.
- 54. There is a dearth in the literature about patent law's audience. *See generally* Mark D. Janis & Timothy R. Holbrook, Patent Law's Audience(s) (Jan. 11, 2011) (unpublished manuscript) (on file with author).
- 55. See, e.g., Group One, 254 F.3d at 1047 (setting standard for "on-sale bar" under 35 U.S.C. § 102(b) as formal commercial offer as defined by contract law). But see Timothy R. Holbrook, Liability for the "Threat of a Sale": Assessing Patent Infringement for Offering to Sell an Invention and Implications for the On-Sale Patentability Bar and Other Forms of Infringement, 43 Santa Clara L. Rev. 751, 782–83 (2003) (arguing standard is wrong because it is directed to lawyers, not technologists).

Circuit's jurisprudence in two key areas: the interpretation of a patent claim and the sufficiency of a patent's disclosure. 56

# 1. The Primacy of the Patent Document and Prosecution History in Claim Construction

The determination of the scope of a patent depends upon the interpretation of the patent's claims, which informs both infringement and validity analyses. Disputes over the patent claims, therefore, are central in nearly every patent case. <sup>57</sup> Because claims are actually abstract representations of the invention, they are rife with uncertainty. <sup>58</sup> Considerable effort in litigation is therefore devoted to the process of claim construction. <sup>59</sup> The baseline principle for interpreting a word in a claim is that its meaning is assessed not from a lay perspective, but instead from that of the PHOSITA, giving the term its ordinary and customary meaning in the art. <sup>60</sup> A patent applicant can act as her own lexicographer, however, affording a term with a definition different from its customary one. <sup>61</sup> Both of these assessments are taken from the perspective of the PHOSITA. <sup>62</sup> One would think, therefore, that an important part of the interpretive process would be evaluating how a technologist in the field would interpret the term.

The Federal Circuit, however, has marginalized greatly the role of the PHOSITA in construing patent claims. In construing a claim, the Federal Circuit requires a court to first consider the intrinsic evidence, which consists of the claims themselves (both asserted and unasserted), the specification, and the prosecution history (which is the record of the application process at the USPTO), all of which are in the public domain. Only if this evidence is ambiguous is it appropriate to resort to extrinsic evidence, such as dictionaries, prior art not in the prosecution history, treatises, experts, and the inventor.

By creating this preference for the intrinsic evidence, the Federal Circuit hopes to promote public notice. <sup>65</sup> The evidence considered most relevant is that readily

<sup>56.</sup> Admittedly, these two doctrines can be related, as the scope of the disclosure informs the appropriate scope of the claims. *See generally* Holbrook, *Paradox*, *supra* note 11, at 8–15.

<sup>57.</sup> See Burk & Lemley, Fence Posts, supra note 50, at 1750.

<sup>58.</sup> See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002) ("[T]he nature of language makes it impossible to capture the essence of a thing in a patent application."); BESSEN & MEURER, *supra* note 51, at 56–61; Burk & Lemley, *Fence Posts*, *supra* note 50, at 1751–61.

<sup>59.</sup> See generally Kimberly A. Moore, Paul R. Michel & Timothy R. Holbrook, Patent Litigation and Strategy 322–23 (3d ed. 2008).

<sup>60.</sup> Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

<sup>61.</sup> Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

<sup>62.</sup> Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1355–56 (Fed. Cir. 2004).

<sup>63.</sup> *Phillips*, 415 F.3d at 1314; *Vitronics*, 90 F.3d at 1583; Markman v. Westview Instruments, Inc., 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc).

<sup>64.</sup> Vitronics, 90 F.3d at 1584.

<sup>65.</sup> *Id.* at 1583 ("[C]ompetitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. Allowing the public record to be

available to any member of the public. As the patent is theoretically a self-contained document, with sufficient information in the specification to practice the invention, the resort to extrinsic evidence would seem inappropriate.<sup>66</sup> The problem is, however, that federal judges—even those on the Federal Circuit—are not persons of ordinary skill in the art. They are lawyers, not technologists.<sup>67</sup> While the Federal Circuit has noted that extrinsic evidence may be taken to educate the judge,<sup>68</sup> the court has made clear that it is error to rely on such evidence if the intrinsic evidence is unambiguous.<sup>69</sup> The court rejected one methodology that would have given substantial consideration to dictionaries, which could provide insight as to the ordinary meaning of a term from the perspective of the PHOSITA.<sup>70</sup> Unsurprisingly, the focus on the more legal, intrinsic evidence would be favored by those trained in the law and not necessarily in the sciences.<sup>71</sup>

altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless." (citation omitted)).

- 66. Markman, 52 F.3d at 978 ("The patent is a fully integrated written instrument.").
- 67. See supra note 14.
- 68. *Markman*, 52 F.3d at 980–81; *Phillips*, 415 F.3d at 1318. In *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, the court clarified *Vitronics* by explaining:

Despite the district court's statements to the contrary, *Vitronics* does not prohibit courts from examining extrinsic evidence, even when the patent document is itself clear. Moreover, *Vitronics* does not set forth any rules regarding the admissibility of expert testimony into evidence. Certainly, there are no prohibitions in *Vitronics* on courts hearing evidence from experts. Rather, *Vitronics* merely warned courts not to *rely* on extrinsic evidence in claim construction to contradict the meaning of claims discernible from thoughtful examination of the claims, the written description, and the prosecution history—the intrinsic evidence.

- 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citations and footnote omitted).
  - 69. Vitronics, 90 F.3d at 1584.
- 70. *Phillips*, 415 F.3d at 1320–22 (rejecting the methodology of Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002)).
- 71. The Federal Circuit appears ready to reconsider its standard of review for claim construction. See, e.g., Trading Techs. Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1350-51 (Fed. Cir. 2010) (now-Chief Judge Rader criticizing the de novo standard of review); Amgen Inc. v. Hoechst Marion Roussel, Inc., 469 F.3d 1039 (Fed. Cir. 2006) (en banc) (declining en banc reconsideration of de novo review with several dissents and concurrences); see also Trading Techs., 595 F.3d at 1363-64 (Clark, J., concurring) (district court judge sitting by designation, criticizing de novo review). Prior to recent judges taking senior status or retiring, there seemed to be a sufficient number of judges willing to reconsider the issue en banc. See MOORE ET AL., supra note 59, at 261 (counting number of Federal Circuit judges willing to reconsider the de novo standard). With Judges Schall and Mayer taking senior status in 2009 and 2010, respectively, and Judge Michel retiring altogether in 2010, the ability of the court to reconsider the issue en banc will depend on the new judges. Federal Circuit Judge O'Malley, a former district court judge, has criticized the de novo standard. See Kathleen M. O'Malley, Patti Saris & Ronald H. Whyte, A Panel Discussion: Claim Construction from the Perspective of the District Judge, 54 CASE W. RES. L. REV. 671, 680 (2004) (Judge O'Malley stated, "If we are going to receive evidence from experts in order to determine those things, it is a hard pill to swallow as a district judge that, after seeing the experts, and hearing the experts, our efforts to answer those questions are subject to a completely de novo review and a blank record. It is difficult to accept that there is no

Moreover, the court has taken to using representations made in the specification against the patentee. 72 A patentee is free to be her own lexicographer, providing unique definitions to words that vary from the customary and ordinary meaning in the relevant technological art. 73 Such a rule is not troubling when the patent applicant has offered an express definition of the term; she knows that the public will rely on that definition and not some other found outside of the patent document. <sup>74</sup> The problem arises, however, when the Federal Circuit concludes that the patentee has *implicitly* provided a definition, which generally arises in the specification when the applicant distinguishes earlier technologies from the claimed invention<sup>75</sup> or provides only one version of the patented invention.<sup>76</sup> In this context, the court has nevertheless concluded that the applicant has surrendered subject matter, in essence provided a definition implicitly about what the invention is not.<sup>77</sup> The court finds this surrender, however, without considering whether the PHOSITA would read the same language as giving up subject matter; instead, the court is applying a legal idea—estoppel—to preclude the patentee from obtaining coverage for something that she gave up from the perspective of a lawyer. 78

The Federal Circuit effectively has jettisoned the perspective of the PHOSITA from the claim construction analysis. 79 Moreover, as claim construction is usually dispositive of literal infringement. 80 absent factual issues about the device or

deference given to that factual decision making." (emphasis in original)).

Even if the Federal Circuit changes the standard of review, however, it will not eliminate the problem if the court persists in giving primacy to the intrinsic evidence. Indeed, it is quite possible that deference to the factual extrinsic evidence will not alter the oftcriticized reversal rates because, on appeal, the court can simply rely on the intrinsic evidence, to be reviewed de novo anyway, and ignore extrinsic evidence if it is inconsistent with the intrinsic evidence. See Markman, 52 F.3d at 997-98 (Mayer, J., concurring) (arguing for contract-like analysis, with intrinsic evidence treated as legal and extrinsic evidence as factual).

- 72. See, e.g., CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345-47 (Fed. Cir. 2001); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301 (Fed. Cir. 1999).
  - 73. Vitronics, 90 F.3d at 1582.
  - 74. See, e.g., Trading Techs., 595 F.3d at 1353.
- 75. Phillips, 415 F.3d at 1316 ("T]he specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive."); SciMed, 242 F.3d at 1345–47.
- 76. See, e.g., Nystrom v. TREX Co., 424 F.3d 1136, 1143-46 (Fed. Cir. 2005) (construing term "board" as limited to boards made of wood).
- 77. See Miller, supra note 44, at 205–06 (recognizing and criticizing such implied definitions).
- 78. See Timothy R. Holbrook, Substantive Versus Process-Based Formalism in Claim Construction, 9 Lewis & Clark L. Rev. 123, 142 (2005) [hereinafter Holbrook, Claim Construction].
  - 79. See Holbrook, Possession, supra note 3, at 160.
- 80. Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed. Cir. 1997) ("Where the parties do not dispute any relevant facts regarding the accused product . . . but disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment."); see also Jeanne C. Fromer,

method accused of infringing the patent, the court has also removed the PHOSITA from the literal infringement inquiry as well.

# 2. The Written Description Requirement Replaces the PHOSITA's Judgment With That of the Judge

Claim construction is not the only area in which the Federal Circuit has marginalized the PHOSITA to the point of near irrelevance. More recently, and far more greatly underappreciated in the literature, the Federal Circuit has removed considerations of the PHOSITA from assessing the sufficiency of patent disclosures under the written description and enablement doctrines. This assault on the technical is particularly egregious in this context because it directly threatens the types of disclosures that patent drafters will make in crafting the application. If the courts treat the specification as legal, then drafters will have incentives to reduce the technical aspect of the document in favor of creating a more legalistic text. Page 1972.

In exchange for the grant of a patent's exclusive rights, a patentee must disclose her invention to the public. The courts view the quid pro quo aspect of patents as crucial because it forces the applicant to disclose information about the invention to the public. <sup>83</sup> The disclosure obligations are governed by 35 U.S.C. § 112, ¶1, which states in relevant part:

Contained within this somewhat opaque language are two requirements according to the Federal Circuit: the patent must contain a *written description* of the invention and information sufficient to *enable* the PHOSITA to make and use the invention. <sup>85</sup> Importantly, in contrast to the law of claim construction and infringement, the statute specifically references the importance of the PHOSITA by referencing "any person skilled in the art." Notwithstanding this express statutory provision, the Federal Circuit over time has minimized the importance of the PHOSITA in the area of patent disclosures.

This trend of elevating the disclosure over the knowledge of the PHOSITA has its genesis in the law of written description, the dispute over which has been much discussed in the case law and literature.<sup>86</sup> The written description historically and

Patentography, 85 N.Y.U. L. REV. 1444, 1469-72 (2010).

- 81. See infra notes 86–159 and accompanying text.
- 82. See Seymore, Teaching Function, supra note 27, at 633–41.
- 83. Holbrook, *Possession*, *supra* note 3, at 131–32.
- 84. 35 U.S.C. § 112, ¶ 1 (2006).
- 85. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). But see id. at 1369 (Linn, J., dissenting).
- 86. For case law, see, e.g., LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005); *In re* Wallach, 378 F.3d 1330, 1334–35 (Fed. Cir. 2004); Regents of the

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uncontroversially acted to prohibit an applicant from adding new matter to the patent application. <sup>87</sup> Applicants cannot supplement an application with new material without forfeiting the benefit of an earlier filing date. <sup>88</sup> If an earlier-filed application contains sufficient support for material found in a later application, then the applicant is entitled to priority of the earlier application, potentially permitting her to avoid invalidating prior art. <sup>89</sup> To show adequate support, the specification of the earlier application must demonstrate that the inventor possessed the subject matter claimed in the later application. <sup>90</sup> Similarly, within a given application, the doctrine acted to constrain an applicant's attempts to amend a claim that would effectively add new matter to that application. <sup>91</sup> In that context, the amended claim would be invalid as improperly adding new matter to the application. Thus, the written description requirement "functions to ensure that all claims amended or

Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). See also Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1307-08 (Fed. Cir. 2004) (Rader, J., dissenting from declination of en banc consideration) ("In 1997, this court for the first time applied the written description language of 35 U.S.C. § 112, ¶ 1 as a general disclosure requirement in place of enablement, rather than in its traditional role as a doctrine to prevent applicants from adding new inventions to an older disclosure. . . . Neither Eli Lilly nor this case has explained either the legal basis for this new validity requirement or the standard for 'adequate support."); id. at 1325–27 (Linn, J., dissenting from declining rehearing en banc). For commentary, see, e.g., Duane M. Linstrom, Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as it Applies to Genetic Patents, 40 SAN DIEGO L. REV. 947, 970 (2003); Janice M. Mueller, The Evolving Application of the Written Description Requirement to Biotechnological Inventions, 13 Berkeley Tech. L.J. 615, 617 (1998) [hereinafter Mueller, Evolving Application]; Harris A. Pitlick, The Mutation on the Description Requirement Gene, 80 J. PAT. & TRADEMARK OFF. Soc'y 209, 222-23 (1998); Harold C. Wegner, When a Written Description Is Not a "Written Description": When Enzo Says It's Not, 12 FED. CIR. B.J. 271, 274 (2002); Jennifer L. Davis, Comment, The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents, 20 Santa Clara Computer & High Tech. L.J. 469, 487–88 (2004).

- 87. Anascape, Ltd. v. Nintendo of Am., Inc., 601 F.3d 1333, 1335 (Fed. Cir. 2010) ("To obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent 'in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.""); see also id. at 1342 (Gajarsa, J., concurring) ("Here, the majority's opinion demonstrates a good example in applying the written description in a priority policing context, while leaving invalidity in the capable hands of the enablement doctrine. Though Ariad makes clear that written description is not confined to the priority policing context, I continue to believe such confinement, while not statutorily mandated, streamlines litigation and arguably reconciles some of our written description and enablement precedent."); In re Ruschig, 379 F.2d 990, 995–96 (C.C.P.A. 1967) (holding that when an applicant attempts to claim specific chemical compounds which were broadly disclosed, the question is not enablement, but "whether the specification discloses the compound... specifically, as something [the applicant] actually invented").
  - 88. 35 U.S.C. §§ 120, 132(a) (2006).
  - 89. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564 (Fed. Cir. 1991).
- 90. Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998) ("To meet [the written description] requirement, the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed.").
  - 91. In re Ruschig, 379 F.2d at 995-96.

added after the filing date of the application find adequate 'support' in the originally filed application." <sup>92</sup>

In recent years, the Federal Circuit has expanded the doctrine to provide a basis for invalidating a claim even absent priority or new matter concerns. The inventor must demonstrate sufficient support in the specification to justify the scope of the claim by showing that the inventor was in possession of the entirety of the claimed invention; broad, generic claims tend to be particularly vulnerable to challenge under the written description doctrine. In order to satisfy this aspect of the written description requirement, an applicant must disclose within the patent document support to show that the inventor was in possession of the invention, and particularly the entirety of the broad, generic claim. The inventor can do so by, for example, listing a sufficient number of species to justify protection for an entire class of inventions or identifying common structural or functional aspects of the invention that would permit broad generalization and extrapolation as to the scope of the invention. How many disclosed species or functional generalizations are sufficient is unclear and likely depends on the technology.

This expanded form of the written description requirement originally arose in the context of biotechnology inventions. <sup>97</sup> In particular, early gene patents claimed cDNA sequences based not on the DNA structures themselves, but instead on the proteins coded by those DNA sequences. <sup>98</sup> Given the redundancy of the genetic code, such a claiming technique had the potential to allow one patent to cover millions of DNA sequences. <sup>99</sup> Similarly, claiming "vertebrate" or "mammalian" cDNA generically was too broad when the patent only disclosed a particular species' (rats) cDNA sequence. <sup>100</sup> Over time, the Federal Circuit has loosened this obligation as to biotechnology patents as technology has evolved, allowing, for

<sup>92.</sup> JANICE M. MUELLER, PATENT LAW 123 (3d. ed. 2009).

<sup>93.</sup> See Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc); LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344 (Fed. Cir. 2005).

<sup>94.</sup> See LizardTech, 424 F.3d at 1346; Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568–69 (Fed. Cir. 1997).

<sup>95.</sup> Ariad, 598 F.3d at 1350, 1352–53.

<sup>96.</sup> *Id.* at 1351 ("The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field.").

<sup>97.</sup> See generally Janice M. Mueller, The Evolving Application of the Written Description Requirement to Biotechnological Inventions, 13 BERKELEY TECH. L.J. 615 (1998) (exploring the written description requirement's unique impact on biotechnology and characterizing it as a super enablement requirement).

<sup>98.</sup> Eli Lilly, 119 F.3d at 1567.

<sup>99.</sup> *Cf. In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein.").

<sup>100.</sup> Eli Lilly, 119 F.3d at 1567-68.

example, claiming in terms of function if one of skill in the art would know the set of structures that would perform that function. <sup>101</sup> Moreover, the court more recently has applied the requirement outside of the biotech area, including sofa design <sup>102</sup> and computer software. <sup>103</sup> In *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, <sup>104</sup> the en banc Federal Circuit confirmed that written description is a separate basis for invalidating patent claims and made clear that the doctrine applies equally to all technologies and not specifically to biotech or other, early-stage inventions. <sup>105</sup>

The use of the written description in this fashion has been harshly criticized, both by judges on the court and commentators, as a standardless requirement that effectively grants the Federal Circuit discretion to strike down claims that it simply believes are too broad, regardless of what someone in the technological field might think. He may view the requirement as redundant of the enablement requirement and, indeed, have called it a "super-enablement" requirement, although the Federal Circuit rejected this characterization. He

101. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (adopting PTO Guideline that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics" (alteration in original) (emphasis in original) (quoting Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001))).

102. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479-80 (Fed. Cir. 1998).

103. LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1343–47 (Fed. Cir. 2005).

104. 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

105. *Id.* at 1352 ("It also has not just been applied to chemical and biological inventions.").

106. See LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1378 (Fed. Cir. 2006) (Rader, J., dissenting); Davis, supra note 86, at 487–88 ("[T]he court has not issued clear and consistent standards."); Mark D. Janis, On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines), 2 WASH. U. J.L. & Pol'y 55, 62–71 (2000); Duane M. Linstrom, Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents, 40 SAN DIEGO L. REV. 947, 970 (2003) ("[I]t has also left us with even more uncertainty in the law than before the ruling."); Mueller, supra note 97, at 617; Pitlick, supra note 86, at 222; Arti K. Rai, Intellectual Property Rights in Biotechnology: Addressing New Technology, 34 WAKE FOREST L. REV. 827, 830–31 (1999); Wegner, supra note 86, at 274. But see Lefstin, supra note 3, at 1215–22.

107. Holbrook, *Possession*, *supra* note 3, at 161–63; Christopher M. Holman, *Is* Lilly *Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of* Eli Lilly *and Its Progeny in the Courts and PTO*, 17 ALB. L.J. Sci. & Tech. 1, 80 (2007) (arguing that the courts have failed to articulate a standard for compliance with written description which is distinct from enablement); Wegner, *supra* note 86, at 271.

108. Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1325 (Fed. Cir. 2003) (Rader, J., concurring) ("[T]he only way to distinguish the *Lilly* rule from enablement is to construe *Lilly* as requiring more disclosure than necessary to enable one of skill in the art to make and use the invention, a 'super-enablement' standard."); Mueller, *supra* note 97, at 617.

109. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en

What is striking about the development of the court's written description jurisprudence is that the court rarely, if ever, ventures outside the four corners of the patent document to account for the PHOSITA's perspective. By focusing exclusively on the patent specification only, the court has removed the PHOSITA from the inquiry, notwithstanding its statements that one determines whether the written description requirement is satisfied from the perspective of the PHOSITA. The court does not resort to extrinsic, technical information but instead merely sees a broad, generic claim, reviews the specification to see how many species or correlations are disclosed, and then concludes whether *the court* believes there is adequate support.

#### 3. The Federal Circuit Has Marginalized the PHOSITA in the Enablement Analysis

While the controversy surrounding the written description requirement has been well documented in the case law and the literature, culminating in *Ariad*, the literature has failed to recognize that the Federal Circuit has subtly remolded enablement doctrine to be virtually identical to the law of written description. <sup>111</sup> As a result, even in this incredibly fact-intensive inquiry, the court has removed the viewpoint of the PHOSITA in considering whether the patent adequately enables the claimed invention. <sup>112</sup> This dynamic is particularly striking given the express statutory mandate in § 112 that enablement must be assessed from the viewpoint of a person skilled in the art.

The enablement disclosure obligation ensures that others will be able to practice the invention based strictly on the patent disclosure once the patent expires. Because the patent is published upon issuance (and indeed many applications are published after eighteen months), 113 the enabling disclosure also serves to enhance the storehouse of knowledge before the patent expires. 114 Others can review the document and, while unable to practice the invention without the patentee's permission, can utilize the information therein to generate further advancements or improvements. 115

banc) ("We also reject the characterization, cited by Ariad, of the court's written description doctrine as a 'super enablement' standard for chemical and biotechnology inventions."). The court has recognized that there is a relationship between the two doctrines. LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (observing that written description and enablement are "closely related" and "usually rise and fall together").

- 111. See infra notes 124-59 and accompanying text.
- 112. See infra notes 124–59 and accompanying text.
- 113. 35 U.S.C. § 122(b)(1) (2006).

114. See Fromer, Patent Disclosure, supra note 3, at 553; Holbrook, Possession, supra note 3, at 131; Seymore, Teaching Function, supra note 27, at 624; Katherine J. Strandburg, What Does the Public Get? Experimental Use and the Patent Bargain, 2004 WISC. L. REV. 81, 91.

115. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (explaining that the information disclosed in the patent adds to the public storehouse of knowledge).

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<sup>110.</sup> See, e.g., Ariad, 598 F.3d at 1355 (rejecting patentee's expert testimony as "legally irrelevant"); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 925–26 (Fed. Cir. 2004) (rejecting patentee's expert testimony and relying solely on specification to invalidate the claim).

Historically, the courts recognized that enablement is a highly fact-intensive inquiry, depending on a variety of factors tied directly to the PHOSITA. <sup>116</sup> Specifically, if the PHOSITA can make and use the invention without undue experimentation, then the claimed invention is enabled. <sup>117</sup> By using the perspective of the PHOSITA, the law did not require an applicant to include information that is already well known in the art, permitting simplification of the patent document. <sup>118</sup> In measuring the sufficiency of the specification, therefore, the courts should take into account both the knowledge of one of ordinary skill in the art and the content of the patent specification. <sup>119</sup> As the Federal Circuit has noted, "the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." <sup>120</sup> Some experimentation, therefore, does not preclude a conclusion that the claimed invention is enabled. <sup>121</sup> The courts have identified a number of factors relevant to assessing whether any experimentation would be undue:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance presented,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability or unpredictability of the art, and
- 8) the breadth of the claims. 122

While the enablement requirement is conceptually simple, it is a complicated, fact-intensive inquiry. Further adding to the doctrine's complexity, it is an ever-moving target: as the knowledge of the PHOSITA grows over time, an identical disclosure may shift from not being enabled to being enabled. 123

Although the Federal Circuit has highlighted that the assessment of enablement must include both the knowledge of one of skill in the art and the patent's specification, recent cases have elevated the role of the specification and sharply discounted the importance of the PHOSITA's knowledge. Beginning in *Genentech*,

<sup>116.</sup> In re Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

<sup>117.</sup> Id.

<sup>118.</sup> Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1463 (Fed. Cir. 1984).

<sup>119.</sup> Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) ("The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.").

<sup>120.</sup> AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

<sup>121.</sup> Wands, 858 F.2d at 736-37.

<sup>122.</sup> Id. at 737.

<sup>123.</sup> Holbrook, *Possession*, *supra* note 3, at 129–30; *see also* Holbrook, *Paradox*, *supra* note 11, at 41–42 (discussing how knowledge of PHOSITA alters scope of enablement).

*Inc. v. Novo Nordisk A/S*, <sup>124</sup> the Federal Circuit bemoaned the dearth of disclosure in the relevant specification:

It is true, as Genentech argues, that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. 125

This statement, however, goes too far. Nowhere in § 112 is there a separate obligation to disclose the "novel aspects" of the invention: the statute mandates only that the specification enable the claimed invention to one skilled in the art. <sup>126</sup> If one so skilled does not need the "novel aspects" of the invention (whatever those may be) in order to practice the invention, then seemingly there is no obligation to disclose it

This emphasis on the disclosure, and the discounting of the knowledge of the PHOSITA, has continued. For example, in *AK Steel Corp. v. Sollac and Ugine*, <sup>127</sup> the Federal Circuit confronted the situation where the specification taught away from a particular embodiment. The court reasoned that:

The question more precisely here is whether, with AK Steel's patent specification as an initial guide, the hypothetical skilled artisan's knowledge of the surrounding art and ability to modestly experiment would have been sufficient to enable him to make and use a steel strip containing a Type 1 aluminum coating, with the claimed wetting attributes, at the time of the '549 patent's effective filing date in 1986.

We conclude that the specification is inadequate as a matter of law in that regard primarily because it expressly teaches against it. Worse than being silent as to that aspect of the invention, the specification clearly and strongly warns that such an embodiment would not wet well. In particular, the specification warns that silicon content above 0.5% in the aluminum coating causes coating problems. Such a

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<sup>124. 108</sup> F.3d 1361 (Fed. Cir. 1997).

<sup>125.</sup> Id. at 1366 (citation omitted).

<sup>126. 35</sup> U.S.C. § 112, ¶ 1 (2006) ("The specification shall contain a written description . . . of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable *any person skilled in the art* to which it pertains, or with which it is most nearly connected, to make and use the same . . . ." (emphasis added)).

<sup>127. 344</sup> F.3d 1234 (Fed. Cir. 2003).

statement discourages experimentation with coatings having more than 0.5% silicon, undue or otherwise. It tells the public that higher amounts of silicon will not work. Nothing further need be said about the matter. <sup>128</sup>

Subsequently applying AK Steel, the Federal Circuit in Liebel-Flarsheim Co. v. Medrad, Inc. 129 invalidated a generic claim that covered two embodiments of an invention when the specification disparaged one of those forms. 130 Specifically, the claim at issue covered both jacketed and jacketless syringes, and the specification had suggested problems with jacketless embodiments. As a result, the court held that "where the specification teaches against a purported aspect of an invention, such a teaching 'is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention." In both Liebel-Flarsheim and AK Steel, the court did turn to extrinsic evidence to adduce whether one of skill in the art could make and use the claimed invention, that is, to decide whether the submitted evidence was sufficient to rebut the teaching away from the specification. 132 Neither rested its conclusion entirely on the specification.

More recent cases, however, portend a greater shift away from the knowledge of the PHOSITA and towards requiring disclosure of information in the specification that is already known to the PHOSITA. In particular, in *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, <sup>133</sup> the court noted that:

ATI argues that despite this limited disclosure, the knowledge of one skilled in the art was sufficient to supply the missing information. We do not agree. In *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997), we stated: "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent. The novel aspect of this invention is using a velocity-type sensor for side impact sensing. 134

The court has continued this line of reasoning in more recent cases. The court in *Sitrick v. Dreamworks*, *LLC*<sup>135</sup> relied upon lack of enablement to invalidate a generic claim on summary judgment. The invention allowed a user to integrate

<sup>128.</sup> Id. at 1244.

<sup>129. 481</sup> F.3d 1371 (Fed. Cir. 2007).

<sup>130.</sup> Id. at 1379.

<sup>131.</sup> *Id.* (quoting AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).

<sup>132.</sup> See Liebel-Flarsheim, 481 F.3d at 1379–80; AK Steel, 344 F.3d at 1244–45.

<sup>133. 501</sup> F.3d 1274 (Fed. Cir. 2007).

<sup>134.</sup> Id. at 1283.

<sup>135. 516</sup> F.3d 993 (Fed. Cir. 2008).

<sup>136.</sup> Id. at 1002.

her own video or audio stream into a video game. <sup>137</sup> The district court construed the claims to be generic, encompassing not only video games but also movies, notwithstanding that the specification only described video games. <sup>138</sup> The Federal Circuit affirmed the judgment of invalidity for want of enablement on this basis, noting that "[n]either patent specification in this case teaches how the substitution and integration of a user image would be accomplished in movies." <sup>139</sup> Only after reaching this conclusion did the court consider expert testimony proffered by both parties, relying on the defendant's expert and rejecting the testimony of the patentee's expert as conclusory, unsupported by evidence, and presented by a person not skilled in the relevant art of film making. <sup>140</sup> Such weighing of the evidence in the context of summary judgment suggests that the court was elevating the patent disclosure over the extrinsic evidence.

Similarly, the Federal Circuit affirmed a judgment of invalidity for lack of an enabling disclosure in *ALZA Corp. v. Andrx Pharmaceuticals, LLC.*<sup>141</sup> The invention involved an extended-release version of a drug used to treat Attention Deficit Hyperactivity Disorder (ADHD). The claims were interpreted to cover both osmotic and non-osmotic versions of the drug, but the specification only described osmotic forms. The court specifically rejected the contention that the knowledge of the PHOSITA could be used to supplement the patent's disclosure to enable the full scope of the claims as construed:

To the extent that ALZA argues that the knowledge of a person of ordinary skill in the art satisfies the enablement requirement, we disagree. As this court has repeatedly stated, "the rule that a specification need not disclose what is well known in the art is 'merely a rule of supplementation, not a substitute for a basic enabling disclosure." To satisfy the plain language of § 112, ¶ 1, ALZA was required to provide an adequate enabling disclosure in the specification; it cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification. 144

The court faulted the specification for failing to provide nothing more than a starting point, thus requiring undue experimentation for the non-osmotic form. Although seemingly concluding on the specification alone that the claim was not enabled, the court did consider the expert testimony offered, rejecting the testimony

<sup>137.</sup> Id. at 995.

<sup>138.</sup> Sitrick v. Dreamworks, LLC, No. CV 03-4265-SVW (AJWx), 2006 WL 6116641, at \*4 n.3, \*33 (C.D. Cal. July 20, 2006).

<sup>139.</sup> Sitrick, 516 F.3d at 1000.

<sup>140.</sup> Id. at 1001.

<sup>141. 603</sup> F.3d 935 (Fed. Cir. 2010); see also Sean B. Seymore, Patently Impossible, 64 VAND. L. REV. (forthcoming 2011) (manuscript at 33–34 n.187).

<sup>142.</sup> ALZA, 603 F.3d at 936.

<sup>143.</sup> Id. at 938-39.

<sup>144.</sup> *Id.* at 940–41 (emphasis added) (quoting Auto. Techs. Int'l, Inc. v. BMW of N. Am., 501 F.3d 1274, 1282 (Fed. Cir. 2007), and Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

<sup>145.</sup> Id. at 941.

of the patentee's expert given that it conflicted with other expert testimony and that his skill level was above that of ordinary skill. The court credited the evidence from the accused infringer that the patentee's own employees encountered considerable difficulty in creating a non-osmotic version of the drug. 147

The reasoning in Automotive, Sitrick, and ALZA cannot be reconciled with the language of § 112, ¶ 1. The statute does not create two disclosure obligations, one for most aspects of the invention and a second for "novel aspects" of the invention. The only requirement is that a person of ordinary skill be able to make and use the invention. If an aspect of the invention-even a "novel aspect"-is known in the art, then the specification need not disclose it. 148 The law had been clear that, in fact, the knowledge of the PHOSITA could supplement the disclosure in the patent, as per the statutory language. 149 The knowledge of one of ordinary skill in the art can fill in such gaps. It is not merely "relevant": it is determinative of whether a claim is enabled. 150 To suggest otherwise reduces the enablement inquiry into the identical, inappropriate reasoning used under written description. Neither Automotive, Sitrick, nor ALZA involved situations where there was no disclosure. Instead they involved claims that could cover an alternative embodiment that was not disclosed. There was no evidence to suggest that the particular variations were somehow essential to the patentability of the invention. The only question should have been whether one of skill in the art could have made and used the alternatives covered by the claim without undue experimentation. If one so skilled could have made an electronic sensor in lieu of a mechanical sensor (Automotive), a movie in lieu of a video (Sitrick), or a non-osmotic form in lieu of an osmotic form (ALZA), then the claims should have been enabled. The mere failure to disclose those alternatives should not per se invalidate those claims absent evidence of the knowledge of one of ordinary skill in the art. The sole inquiry is whether one of ordinary skill in the art could make and use the invention.

Perversely, this line of cases in the enablement and the written description doctrines under *Ariad* now inappropriately conflate infringement with validity. The reason the scope of the claim becomes relevant is that the claim must be construed to cover the accused device. If the differences in the accused device were not present, then validity seemingly would not be at issue. For example, if the device in *Automotive* used mechanical sensors, which were disclosed, seemingly there would not have been an enablement challenge because there would not have been a

<sup>146.</sup> Id. at 941-42.

<sup>147.</sup> *Id.* at 942.

<sup>148.</sup> If the novel aspect was known to the PHOSITA, then it may suggest the claim is invalid as lacking novelty or being obvious, but it should have no impact on whether it is enabled.

<sup>149.</sup> See Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) ("[T]he specification need not necessarily describe how to make and use every embodiment of the invention 'because the artisan's knowledge of the prior art and routine experimentation can often fill in the gaps." (quoting AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003))).

<sup>150.</sup> Nat'l Recovery Techs. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999).

dispute over whether the patent covered mechanical sensors.<sup>151</sup> Yet, the scope of the claim should not be dependent on the accused device. One wonders whether the litigants in *Automotive*, *Sitrick*, and *ALZA* could have launched an enablement-based claim even if the accused device was precisely what was disclosed. For example, if the accused device in *Automotive* in fact used a mechanical sensor, could the infringer have made the same enablement challenge? Ultimately, the court is effectively requiring the specification to enable the accused device and not the claim.<sup>152</sup>

Part of the problem is the link between claim construction, claim scope, and disclosure. As the Federal Circuit noted in *Liebel-Flarsheim*:

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, "beware of what one asks for," might be applicable here. 153

The validity of the claim, while clearly tied to claim construction, seemingly should not be tied to the claim construction arguments. In other words, even if the patentee had not asked for—nor perhaps needed to ask for—the broader construction, the claim should be invalid if truly not enabled or unsupported by the written description. <sup>154</sup>

This linkage between the claim construction, the accused device, and the sufficiency of the disclosure is more than ironic, though, because of the asymmetry between conclusions of noninfringement and invalidity. When there is a judgment only of noninfringement, the consequences are between only the patentee and that particular infringer; the patent is still valid, enforceable against other potential infringers, and available to license. <sup>155</sup> With an invalidity determination, however,

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<sup>151.</sup> The same would be true in *Sitrick* if the accused device was a movie instead of a video or in *ALZA* if the accused device was an osmotic form.

<sup>152.</sup> See Holbrook, Paradox, supra note 11, at 11.

<sup>153.</sup> *Liebel-Flarsheim*, 481 F.3d at 1380; *see also* ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 943 (Fed. Cir. 2010); Automotive Techs. v. BMW of N. Am., 501 F.3d 1274, 1285 (Fed. Cir. 2007).

<sup>154.</sup> See Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1322–23 (Fed. Cir. 2003) (Rader, J., concurring) ("This case illustrates some of the unintended consequences of this judge-made doctrine. Each time a claim encompasses more than the preferred embodiment of the invention described in the specification, a defendant can assert that the patent is invalid for failure to describe the entire invention. Under the expanded written description doctrine, every claim construction argument could conceivably give rise to a validity challenge as well.").

<sup>155.</sup> See, e.g., Bayer AG. v. Biovail Corp., 279 F.3d 1340, 1342 (Fed. Cir. 2002) (addressing enforcement of patent previously found not infringed); see generally Glynn S. Lunney, Jr., *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363, 384 (2001) ("[F]ailing to resolve the validity issue where raised permits potentially invalid claims to 'remain in terrorem of the art' and to serve as a basis for enabling the patent holder to extract license fees, if not monopoly rents." (quoting Royal Typewriter Co. v. Remington Rand, 168 F.2d 691 (2d Cir. 1948))).

the patent is invalid as to the rest of the world, even those not involved in the litigation. <sup>156</sup> Indeed, invalidity judgments have a public-good aspect because third parties can free ride on an invalidity determination by another without incurring the costs of litigation. <sup>157</sup> Thus, it would seem more appropriate, if we do value patents, for the courts to err on the side of offering narrower claim constructions that may result in noninfringement, but nevertheless preserve validity. <sup>158</sup> The patentee should not be punished merely for advocating a legal position. By adopting this catch-22 approach, the Federal Circuit has created an unwarranted bias against patents.

Thus, in one of the most fact-intensive inquiries, where the statute mandates the consideration of the views of the PHOSITA, the Federal Circuit has nonetheless elevated the disclosure within the patent over the knowledge of the PHOSITA. 159

### C. Consequences of Treating the Patent as Purely Legal

The Federal Circuit's marginalization of the PHOSITA seems rather odd given the mixed nature of the patent document. There might be reasons, however, to support the Court's approach. This section weighs the advantages and disadvantages of the Federal Circuit's rules. It does so by first looking at the ex ante consequences: how patent applicants will respond to these rules. This section explores how the rules could provide advantageous incentives for applicants to disclose additional information in their patent applications, but ultimately, given information asymmetries created by the temporal difference between the application date and the ultimate acts of infringement, concludes that the rules are too strict and ultimately unwarranted. Second, this section explores the ex post consequences: what impact these rules will have on the way the courts encounter and wrestle with these legal issues. Arguably, these legalistic rules minimize the need for judicial actors to engage with difficult issues of technology; but ultimately, this abdication of the courts' role is unsatisfying and results in the courts simply impeding their ability to deal with these important issues.

156. Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 350 (1971); see also Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100–01 (1993).

157. See Cardinal Chem., 508 U.S. at 101 ("As this case demonstrates, the Federal Circuit's practice of routinely vacating judgments of validity after finding noninfringement creates a similar potential for relitigation and imposes ongoing burdens on competitors who are convinced that a patent has been correctly found invalid."). See generally Joseph Scott Miller, Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents, 19 BERKELEY TECH. L.J. 667, 677–95 (2004).

158. Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996); see also Holbrook, Claim Construction, supra note 78, at 144. But see Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) ("While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.").

159. *Cf.* Seymore, *Teaching Function*, *supra* note 27, at 653 ("More recently, various legal actors disagree about whether the enablement analysis should begin inwardly with the applicant's disclosure or outwardly by gauging the PHOSITA's knowledge.").

## 1. Ex Ante Consequences: How Will Future Patent Applicants Respond?

Patent applicants are not a static set. Drafters of applications will respond to the changing legal and technical landscape. The question is whether the Federal Circuit's claim construction and disclosure rules will produce advantageous consequences for the patent system.

The formalistic claim construction and disclosure rules articulated by the Federal Circuit could be viewed as information-forcing default penalties. The law and economics literature has long argued in favor of default rules around which parties can transact in the absence of normative reasons to use immutable rules. In the context of default rules, Professors Ian Ayres and Robert Gertner rejected the normal assumption that these defaults should reflect the positions to which the parties would have agreed absent transaction costs. Recognizing that parties often have incentives to behave strategically and not disclose information, Ayres and Gertner argue for penalty defaults that function to force parties to disclose information during the negotiation process or risk paying the default penalty.

The Federal Circuit's rules, particularly those for written description and enablement, can be seen as information-forcing penalty defaults. As Professor R. Polk Wagner has identified, patent applicants have both the incentives and opportunity to withhold information during the patent application process. They have reasons to provide just enough information to satisfy § 112 and no more so that the patentee could retain aspects of the invention as a trade secret, potentially providing a competitive advantage in the market even after the patent is published or expires. Moreover, given the ex parte nature of the application process, there is no adversarial check on the applicant's behavior. Only the ethical obligations of the patent attorney or agent, coupled by the threat of the patent being rendered unenforceable if the attorney or agent commits inequitable conduct, provide direct incentives for honesty and disclosure. Given this incentive for the applicant to strategically withhold information, the Federal Circuit's current rules could be viewed as penalty defaults to the patentee. If the patentee fails to disclose information sufficient to support the breadth of the claim they assert in litigation,

<sup>160.</sup> Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 87–88 (1989). The literature has suggested immutable rules are important to protect either parties to the contract who could not otherwise protect themselves in the negotiation, rooted in parentalism, or parties external to the contract, rooted in combating externalities. *Id.* at 88.

<sup>161.</sup> Id. at 90-91.

<sup>162.</sup> Id. at 91.

<sup>163.</sup> R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, 151 U. Pa. L. Rev. 159, 214–16 (2002).

<sup>164.</sup> See Brenner v. Manson, 383 U.S. 519, 534 (1966) (noting incentive for patent applicants to write applications "so that they disclose as little useful information as possible"); Seymore, *Teaching Function*, supra note 27, at 634 n.62.

<sup>165.</sup> See USPTO Patent Application Rule, 37 C.F.R. § 1.56 (2009) (noting duty of candor and good faith to the USPTO, including duty to disclose material information). The risk of eventual invalidation in litigation would constrain strategic efforts, but given that so few patents reach litigation, that risk would be discounted significantly.

then the penalty is the invalidation of the claim. Thus, the patent applicant now has the ex ante incentive to provide a more robust disclosure. Because the patent applicant is in the best position to disclose the relevant information, she should bear the cost of the failure to disclose.

Unfortunately, this view of the Federal Circuit's doctrine is overly simplistic and overlooks some of the important realities of the patent prosecution process. First, the use of the penalty rule is question begging: part of the problem is that the court is finding the patent specifications inadequate when, from the viewpoint of the PHOSITA, they very well may be sufficient. It is possible that some of these disclosures might be sufficient if one were to consider how a technologist would view the disclosures. Thus the problem is not the failure to disclose but instead the failure of the courts to appreciate the disclosure.

Additionally and relatedly, to have effective ex ante consequences, the penalty default rule needs to be clear for the patent applicant to make an informed decision of whether to expand her disclosure or to accept the risk of the punishment inherent in the penalty default. As the literature on written description has discussed, and as this Article has explained with respect to the Federal Circuit's recent course on enablement, these legal standards are vague. It is difficult, if not impossible, for an applicant to know whether a given disclosure will indeed be sufficient.

There are also temporal aspects to patent law that are more significant than in Ayres and Gertner's contract example. In contract law, the parties negotiate contemporaneously with each other to reach an agreement. In patent law, the patent applicant must attempt to foresee what may happen over the course of the life of the patent while drafting the application. Once the patent issues, however, that language is frozen, and the patentee cannot alter it. In contrast, competitors have the advantage of hindsight, looking at the issued patent and being able to shift their position in light of the language of the patent, language that the applicant may not have intended to create the estoppel-like effect as determined by the Federal Circuit. While the patentee seemingly may have the best information about the invention, the temporal dynamic creates its own information asymmetry and may

166. *Cf.* Wagner, *supra* note 163, at 216–17 (arguing for a stronger, almost absolute bar rule for prosecution history estoppel to force information disclosure during the patent's prosecution).

167. This is not to say that contracts do not involve time-related complexities. Contracts often account for future behavior and may need to be adjusted or interpreted in light of changed circumstances over time during an ongoing relationship between parties. *See generally* Paul J. Gudel, *Relational Contract Theory and the Concept of Exchange*, 46 BUFF. L. REV. 763, 765 (1998). Some terms may be left intentionally ambiguous to be addressed at a later date. *See* Milton C. Regan, Jr. & Palmer T. Heenan, *Supply Chains and Porous Boundaries: The Disaggregation of Legal Services*, 78 FORDHAM L. REV. 2137, 2164–65 (2010). Nevertheless, the focus on the interpretation of the contract is the intent of the parties at the time the contract is formed. *See, e.g.*, Centigram Arg., S.A. v. Centigram Inc., 60 F. Supp. 2d 1003, 1006–07 (N.D. Cal. 1999).

168. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002) ("Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application. The inventor who chooses to patent an invention and disclose it to the public, rather than exploit it in secret, bears the risk that others will devote their efforts toward exploiting the limits of the patent's language . . . .").

place potential infringers in a better position to play around the periphery of the patent. <sup>169</sup> This information asymmetry is confirmed by the fact that written description and enablement challenges in the cases are closely tethered to the accused device, <sup>170</sup> which generally has been created after the patent issued. The penalty default rule approach assumes a level of foreseeability on the part of a patent drafter that is unreasonable.

Moreover, to the extent that most of these cases arise from litigation and not from appeals from the PTO, the court's articulation of the default penalty is too late. By the time the litigation reaches the Federal Circuit, the state of the art will have evolved, particularly in rapidly developing technologies. The rule articulated by the court, therefore, will be applied to relatively old technologies. Current applicants will be seeking protection for new technologies. As the written description and enablement standards are tethered, seemingly, to one of skill in the art, that skill has now changed. The court articulates the default penalty and invalidates the patent claim, punishing the litigant and potentially all extant patent holders who prosecuted their patents under a now invalid disclosure rule, yet those currently at the PTO would have a different, as of yet unarticulated, disclosure obligation. We thus punish the current patent holders with no benefit flowing to the adequacy of current applications' disclosures. In order to work effectively as a penalty default, the Federal Circuit would need to articulate the rule in appeals from the PTO dealing with pending applications. Of course, the only way those appeals reach the Federal Circuit is if the PTO rejects the applications. If the PTO views the disclosures as sufficient, under a potentially erroneous standard, the patents will issue and the standard will not reach the Federal Circuit contemporaneously. The time lag, therefore, undermines the effectiveness of written description and enablement as a penalty default.

Finally, it is not clear that the Federal Circuit's approach is efficient. The law expressly now requires applicants to disclose that which is already well known in the art.<sup>171</sup> By stating that the knowledge of the PHOSITA cannot supplement the disclosure as to the novel features of the invention, the Federal Circuit has now incentivized vast overdisclosure, adding cost to the drafting of patent applications and costs to the examiners who must examine these more voluminous applications.

<sup>169.</sup> The doctrine of equivalents could be used to combat the asymmetry, but the Federal Circuit's use of the specification in estoppel-like fashion also applies to the doctrine of equivalents. See, e.g., SciMed Life Sys. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1345–47 (Fed. Cir. 2001); see also Holbrook, Paradox, supra note 11, at 26–27. If the patentee has surrendered literal claim scope, then almost invariably she will be precluded from asserting the doctrine of equivalents; thus, the traditional protection for patentees to combat the temporal dimension of patent law generally is unavailable to patentees in this situation. See, e.g., L.B. Plastics, Inc. v. Amerimax Home Prods., Inc., 499 F.3d 1303, 1309 (Fed. Cir. 2007) ("We have held that when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives.").

<sup>170.</sup> See supra notes 153–59 and accompanying text.

<sup>171.</sup> See supra notes 133-50 and accompanying text.

Given that so few patents are actually litigated <sup>172</sup> and that many are valueless, <sup>173</sup> increasing the upfront costs of *all* patent applications seems rather inefficient.

At a minimum, the elevation of the patent document presupposes a level of foreseeability for a patent drafter that seems rather inappropriate. Competitors will always have the advantage of hindsight, reading the patent document after the fact and being able to find flaws in the disclosure that may not have been apparent at the time of the application, and particularly in light of the competitor's own design.<sup>174</sup> With the court's tethering of claim construction and the disclosure doctrines, patent applicants are at an extreme disadvantage. The likely consequence is patents of reduced value. Indeed, the Federal Circuit's assault on scope via the disclosure doctrines and the removal of the doctrine of equivalents rebuts the argument that the Federal Circuit is overly pro-patent. Instead, the court is provalidity for patents with narrow scope.

# 2. Ex Post Consequences of the Federal Circuit's Rules: Courts' Engagement with Technological Facts

Another potential justification for the Federal Circuit's treatment of the patent document is ex post in nature, facilitating the ability of courts to deal with patent issues. By focusing on the public record, the court theoretically is reducing the various costs associated with reviewing the patent. The court is correct that, as a self-contained document, review of the patent itself (and the prosecution history) should be sufficient for third parties to apprise themselves of the scope of the patent and its teachings.

Along these lines, Professor Peter Lee has argued that these formalistic rules are not terribly surprising as they operate as heuristics that help lay persons—judges and juries—avoid having to engage in the complex technologies involved in these cases. Thus the doctrines reduce information costs for judges and juries alike by transforming the technical concepts into more ordinary, or perhaps more legal, concepts that are more readily accessible to various judicial actors. The simpler legal rules "limit[] the degree to which judges must understand technologies and their context." 176

Unfortunately, this advantage is ultimately its disadvantage: it confirms that the technical is being ignored in favor of the more familiar legal. As discussed above, patent drafters will have the incentive to shift the patent document to more of a legal discussion (assuming they can accurately predict the court's legal rules), increasing the gap between patents and other forms of technical knowledge.

<sup>172.</sup> Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1500–08 (2001).

<sup>173.</sup> See generally Kimberly A. Moore, Worthless Patents, 20 BERKELEY TECH. L.J. 1521 (2005).

<sup>174.</sup> The use of the specification to preclude claim scope is particularly troubling in contrast to the use of the prosecution history because the surrender may have been inadvertent. Holbrook, *Claim Construction*, *supra* note 78, at 142–43.

<sup>175.</sup> Lee, *supra* note 4, at 25–41.

<sup>176.</sup> Id. at 41.

Moreover, if the court's interest is in promoting notice, it is only promoting notice to lawyers. Third parties likely have persons skilled in the relevant fields to assist in assessing the content and scope of patents. Thus, they are more informed about the patent's true teachings. Courts, in contrast, are not persons of skill in the art, and by limiting the relevant evidence, the Federal Circuit is actually handicapping their understanding.

These harsh formalistic rules that have divorced the PHOSITA from the analysis, however, are not necessary to afford appropriate weight to the court's policy preferences, such as public notice. As the next section shows, the Federal Circuit should take a cue from the Supreme Court about the importance of the PHOSITA and her role through the use of rebuttable presumptions.

### II. BALANCING THE LEGAL AND THE TECHNOLOGICAL—THE USE OF PRESUMPTIONS

The tension that runs due to the dualistic nature of the patent document is of considerable concern. The Federal Circuit's interest in public notice, and consequent elevation of the patent itself over the PHOSITA, is understandable 177 yet troubling. It ignores that documents do contain technical aspects to them, and that the representations made in them as a technical matter may not have the same import that the courts are affording them as a legal matter.

Another court has not been as receptive to this approach as the Federal Circuit—the U.S. Supreme Court. Review of Supreme Court patent jurisprudence counsels two important points that the Federal Circuit has failed to take into account. First, the Supreme Court's recent foray into the law of obviousness demonstrates, and reinvigorates, the importance of the PHOSITA. Second, although the Supreme Court failed to apply its own methodology in the context of the obviousness inquiry, the Supreme Court has previously resolved the tension between public notice and consideration of the technical through the use of presumptions. 179

Rebuttable presumptions can be an effective way of mediating concerns of certainty with the technical aspect of the patent document that necessarily entails consideration of extrinsic evidence. These presumptions "reflect substantive policy choices regarding where the risk of error should lie upon completion of the very uncertain business of fact finding." Here, the policy choice is a preference for the intrinsic evidence over that of the extrinsic. The default rule, therefore, is that the intrinsic evidence will govern the determination of issues such as claim construction and satisfaction of the disclosure obligations. Nevertheless, if sufficient extrinsic evidence is presented to show that the PHOSITA would not read the intrinsic evidence in such fashion, then such a presumptive view of the patent would be rebutted.

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<sup>177.</sup> The Supreme Court has long emphasized the public notice function of a patent. *See* McClain v. Ortmayer, 141 U.S. 419, 424 (1891) ("The object of the patent law in requiring the patentee to [distinctly claim his invention] is not only to secure to him all to which he is entitled, but to apprise the public of what is still open to them.").

<sup>178.</sup> See infra notes 183–99 and accompanying text.

<sup>179.</sup> See infra notes 200–21 and accompanying text.

<sup>180.</sup> David L. Faigman, *Madisonian Balancing: A Theory of Constitutional Adjudication*, 88 Nw. U. L. Rev. 641, 658 (1994).

This section explores the Supreme Court's take on the role of the PHOSITA and the use of presumptions. It then articulates a presumption-based approach to claim construction and evaluation of the sufficiency of the patent disclosure. By generally precluding resort to the extrinsic evidence absent some sort of ambiguity, the Federal Circuit has offered an overly formalistic approach to these issues. The presumption-based approaches offered here provide a better, more manageable method for balancing the patent document as a legal and a technical text.

### A. The Lessons (and Missed Opportunity) of the Supreme Court's KSR Decision

For the first twenty years of the Federal Circuit's existence, the Supreme Court rarely intervened in matters of substantive patent law. <sup>181</sup> That situation dramatically changed after 1997, when the Supreme Court re-entered the world of patent law. <sup>182</sup>

One of the most significant interventions by the Supreme Court involved the law of obviousness. In *KSR International Co. v. Teleflex Inc.*, <sup>183</sup> the Supreme Court reviewed the law of obviousness under 35 U.S.C. § 103 for the first time in over thirty years. <sup>184</sup> In doing so, it rejected the rather formalistic approach to the obviousness inquiry that the Federal Circuit had developed. <sup>185</sup>

Prior to KSR, the Supreme Court's seminal decision in Graham v. John Deere Co. 186 provided the framework for analyzing the obviousness of an invention, providing four factors to be considered: the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations, such as commercial success, the failure of others, and long-felt but unsolved need. 187 This determination allows the combination of pieces of prior art, such as looking at a scientific article and an earlier patent. If all of the "pieces" of the invention could be found in various references, then likely the invention would be viewed as obvious. The problem with such a construction, however, is that the patent application itself can serve as a roadmap; it is much easier to find the pieces when the patent lays it all out for the fact finder. Such hindsight reconstruction is problematic because, once someone has created the invention, it may seem trivial and apparent after the

<sup>181.</sup> See Mark D. Janis, Patent Law in the Age of the Invisible Supreme Court, 2001 U. ILL. L. REV. 387.

<sup>182.</sup> See generally John F. Duffy, The Festo Decision and the Return of the Supreme Court to the Bar of Patents, 2002 SUP. CT. REV. 273; Timothy R. Holbrook, The Return of the Supreme Court to Patent Law, 1 AKRON INTELL. PROP. J. 1 (2007) [hereinafter Holbrook, Supreme Court].

<sup>183. 550</sup> U.S. 398 (2007).

<sup>184.</sup> The last time the Supreme Court addressed the issue of obviousness was in 1973. *See* Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976); *see generally* Holbrook, *Complicity*, *supra* note 19, at 5–9 (cataloging pre-1995 Supreme Court cases reviewing Federal Circuit judgments and noting a dearth of cases dealing with substantive patent law).

<sup>185.</sup> See Holbrook, Complicity, supra note 19, at 3; Thomas, supra note 19, at 773.

<sup>186. 383</sup> U.S. 1 (1966).

<sup>187.</sup> Id. at 17-18.

fact. 188 The inventive act may have been to make the combination of known elements. 189

Because of concern over this hindsight bias, the Federal Circuit began requiring some reason that would be known to one of skill in the art to make the combination. To be obvious, the prior art, the knowledge of the one skilled in the art, or the nature of the problem must provide a teaching, suggestion, or motivation (TSM) to combine relevant pieces to obtain the claimed invention. The Federal Circuit had found an invention to be non-obvious, notwithstanding the presence of each and every claim limitation in various pieces of prior art, simply because the prior art lacked a motivation to combine those references. Many commentators felt that the Federal Circuit effectively had lowered the standard of non-obviousness, resulting in the grant and enforcement of patents on trivial innovations.

The Supreme Court agreed with these critiques and rejected application of the TSM in a rigid form. <sup>194</sup> In so doing, the Supreme Court chastised the Federal Circuit for emasculating the PHOSITA and provided a far more vigorous view of her importance:

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. . . . Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents

188. See, e.g., U.S. Patent No. 5,194,299 (filed Dec. 31, 1986) (patent covering Post-It Notes®); see generally Gregory N. Mandel, Another Missed Opportunity: The Supreme Court's Failure to Define Nonobviousness or Combat Hindsight Bias in KSR v. Teleflex, 12 LEWIS & CLARK L. REV. 323, 336–42 (2008) (discussing experimental studies and flaws in the current obviousness inquiry); Gregory N. Mandel, Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational, 67 OHIO ST. L.J. 1391 (2006) (performing experimental studies that show the presence of the hindsight bias in assessing the obviousness of an invention).

189. See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004); Timothy R. Holbrook, *Extraterritoriality in U.S. Patent Law*, 49 Wm. & MARY L. REV. 2119, 2160 (2008) [hereinafter Holbrook, *Extraterritoriality*].

190. *In re* Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999); *In re* Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

191. Dembiczak, 175 F.3d at 999; Rouffet, 149 F.3d at 1357.

192. Carella v. Starlight Archery & Pro Line Co., 804 F.2d 135, 140 (Fed. Cir. 1986); *see also* Teleflex, Inc. v. KSR Int'l Co., 119 Fed. App'x 282, 286–90 (Fed. Cir. 2005) (reversing summary judgment of invalidity based on misapplication of TSM analysis), *rev'd*, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007).

193. See Adam B. Jaffe & Josh Lerner, Innovation and Its Discontents 34–35 (2004); A Patent System for the 21st Century 89–90 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004); Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy 6–7 (2003).

194. KSR, 550 U.S. at 419 ("But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.").

together like pieces of a puzzle. . . . A person of ordinary skill is also a person of ordinary creativity, not an automaton. <sup>195</sup>

Commentators have noted the Supreme Court's invigoration of the PHOSITA in this context. 196

The Supreme Court's resuscitation of the PHOSITA suggests that the Court disagrees with the Federal Circuit's broader efforts to remove or minimize her knowledge from other patent law doctrines.<sup>197</sup> The Supreme Court nevertheless missed an opportunity to provide a more structured framework to balance concerns of notice with a role for the PHOSITA.<sup>198</sup> As those before and after *KSR* have suggested, one appropriate way of performing this balance is through the use of presumptions.<sup>199</sup> The Court need only look to its other patent law jurisprudence to find a tool to permit appropriate balancing: the use of presumptions.

195. Id. at 420-21.

196. Darrow, *supra* note 7, at 248; Daralyn J. Durie & Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 Wm. & Mary L. Rev. 989, 999–1004 (2008); Amy L. Landers, *Ordinary Creativity in Patent Law: The Artist Within the Scientist*, 75 Mo. L. Rev. 1, 3–4 (2010); Joseph Scott Miller, *Remixing Obviousness*, 16 Tex. INTELL. PROP. L.J. 237, 244 (2008); Seymore, *Heightened Enablement*, *supra* note 3, at 134–35.

197. See Lee, supra note 4, at 42. Lee characterizes the Supreme Court's jurisprudence as taking a "holistic turn," rejecting the Federal Circuit's rules for more standard-like analyses. *Id.* I agree with this only partially because early Supreme Court cases expressed the same interest in certainty as the Federal Circuit. See Holbrook, Complicity, supra note 19, at 5–9. Earlier cases articulated the use of presumptions to balance these interests, a methodology the Court unfortunately has failed to embrace as of late. See infra notes 198–221 and accompanying text.

198. *Cf.* Holbrook, *Supreme Court*, *supra* note 182, at 21. The Supreme Court's more recent pronouncements, while rejecting the Federal Circuit's formalism, have failed to offer much guidance as to their holistic approach. *See* Lee, *supra* note 4, at 63–64.

For example, the Supreme Court rejected the Federal Circuit's bright-line rule regarding patent exhaustion. Under the Federal Circuit's prior law, only unrestricted sales of the patented good exhausted the patentee's exclusive rights; any limits on the right of the purchaser on use of the invention resulted in a license, which did not exhaust the patent rights. *See* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 706–08 (Fed. Cir. 1992). The Supreme Court rejected this rule, but offered little guidance as to when exhaustion is triggered, noting only that "[t]he authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article." Quanta Computer, Inc. v. LG Elecs., Inc., 553 U.S. 617, 638 (2008).

Similarly, the Supreme Court rejected the Federal Circuit's rule for assessing subject matter eligibility of a claimed process. The Federal Circuit required a process be "tied to a particular machine or apparatus" or "transform[] a particular article into a different state or thing." *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc), *aff'd sub nom.* Bilski v. Kappos, 130 S. Ct. 3218 (2010). The Supreme Court noted that the "machine-ortransformation" test was helpful but was not the sole test; instead, it relied on vague notions of the unpatentability of abstract ideas, natural phenomena, and laws of nature. *Bilski*, 130 S. Ct. at 3227.

199. Brief for International Business Machines Corp. as Amicus Curiae Supporting Neither Party, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) (No. 04-1350), 2006 WL

In other patent-related cases, the Court has recognized the need for certainty but has also counseled against overly harsh, formalistic rules. <sup>200</sup> In the interest of balancing certainty with fairness, the Court has articulated rebuttable presumptions in a variety of contexts. In the context of prosecution history estoppel, the Court has articulated two presumptions. Prosecution history estoppel is a legal limitation on what is known as the doctrine of equivalents, which allows the patent to cover a device that is not *exactly* the same as what is claimed but is "close enough." <sup>201</sup> An exception to this coverage may arise if, during the prosecution of the patent application at the USPTO, the applicant narrows a claim that *would* have covered the asserted equivalent literally but, after the amendment, no longer does. <sup>202</sup> The Supreme Court has noted that "[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases . . . . The difference which [the patentee] thus disclaimed must be regarded as material."

In *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*,<sup>204</sup> the Supreme Court concluded that this estoppel only arises when an applicant amended the claims for a reason related to patentability.<sup>205</sup> The relevant prosecution history in the case, however, was silent as to why the applicant amended the claim. In the situation where the reason for the amendment is not known, the Court held that courts should presume such amendments were made for reasons related to patentability.<sup>206</sup> As the Court reasoned:

The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives proper deference to the role of claims in defining an invention and providing public notice, and to the primacy of the PTO in ensuring that the claims allowed cover only subject matter that is properly patentable in a proffered patent application. <sup>207</sup>

In so doing, the Court rejected a more formalistic, clearer rule—that any amendment created an estoppel.<sup>208</sup> Instead, the Court created this presumption in

2430566, at \*18 (arguing that "references should be presumed combinable by a person having ordinary skill in the art where the references are within the scope of the 'analogous art'"; in such circumstances, there need not be a motivation to combine the references); Timothy R. Holbrook, Commentary, *Obviousness in Patent Law and the Motivation to Combine: A Presumption-Based Approach*, WASH. U. L. REV. SLIP OPINIONS (Mar. 21, 2007), http://lawreview.wustl.edu/commentaries/obviousness-in-patent-law-and-the-motivation-to-combine-a-presumption-based-approach; Miller, *supra* note 196, at 250–56; Joshua D. Sarnoff, Bilcare, KSR, *Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law*, 25 CARDOZO ARTS & ENT. L.J. 995, 1000 (2008).

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<sup>200.</sup> Cf. Holbrook, Supreme Court, supra note 182, at 9, 21–23.

<sup>201.</sup> See Holbrook, Paradox, supra note 11, at 14.

<sup>202.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733–34 (2002); Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1462 (Fed. Cir. 1998).

<sup>203.</sup> Exhibit Supply Co. v. Ace Patents Corp., 315 U.S. 126, 136–37 (1942).

<sup>204. 520</sup> U.S. 17 (1997).

<sup>205.</sup> Id. at 30-32.

<sup>206.</sup> Id. at 33.

<sup>207.</sup> Id. at 33-34.

<sup>208.</sup> Id. at 30 ("But petitioner reaches too far in arguing that the reason for an amendment

order to demonstrate certain policy preferences—deference to the claims and primacy of the PTO—but did not let those preferences result in absolute rules. Those preferences instead are rebuttable in light of other concerns.

The Supreme Court followed up its presumption in *Warner-Jenkinson* with a second in the context of prosecution history estoppel. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, <sup>209</sup> the Supreme Court rejected the Federal Circuit's rule of prosecution history estoppel that absolutely precluded any equivalents if the claim was narrowed for reasons related to patentability. <sup>210</sup> In its place, recognizing the need for certainty, the Supreme Court created a rebuttable presumption: by making a narrowing amendment for reasons related to patentability, the applicant presumptively has surrendered all equivalents. <sup>211</sup> This presumption can be rebutted if the asserted equivalent was unforeseeable, it bore only a tangential relationship to the reason for the amendment, or there is some other reason that the applicant should not be considered to have surrendered the equivalent. <sup>212</sup> The Court emphasized:

This presumption is not, then, just the complete bar by another name. Rather, it reflects the fact that the interpretation of the patent must begin with its literal claims, and the prosecution history is relevant to construing those claims. When the patentee has chosen to narrow a claim, courts may presume the amended text was composed with awareness of this rule and that the territory surrendered is not an equivalent of the territory claimed. In those instances, however, the patentee still might rebut the presumption that estoppel bars a claim of equivalence. The patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.<sup>213</sup>

The *Festo* presumption, therefore, places primacy on the public record, with the default being a complete surrender of equivalents due to the claim amendment. Courts are only to diverge from that default if it is certain that the patent applicant really did not surrender the equivalent, which does require departure from considering solely the public record.<sup>214</sup>

A similar line of analysis is seen in a non-patent, yet patent-related, decision by the Supreme Court. In *TrafFix Devices, Inc. v. Marketing Displays, Inc.*, <sup>215</sup> the Supreme Court explored the intersection of patent and trademark law, specifically reviewing whether the existence of a utility patent precluded the use of the design of an article as source-identifying trade dress. <sup>216</sup> Eschewing a bright-line rule that

during patent prosecution is irrelevant to any subsequent estoppel.").

213. Id. at 741.

<sup>209. 535</sup> U.S. 722 (2002).

<sup>210.</sup> Id. at 740.

<sup>211.</sup> Id. at 740-41.

<sup>212.</sup> Id.

<sup>214.</sup> See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc).

<sup>215. 532</sup> U.S. 23 (2001).

<sup>216.</sup> Id. at 29.

would preclude trademark protection if the good was covered by a patent, the Court instead created an evidentiary presumption:

A utility patent is strong evidence that the features therein claimed are functional. If trade dress protection is sought for those features the strong evidence of functionality based on the previous patent adds great weight to the statutory presumption that features are deemed functional until proved otherwise by the party seeking trade dress protection. Where the expired patent claimed the features in question, one who seeks to establish trade dress protection must carry the heavy burden of showing that the feature is not functional, for instance by showing that it is merely an ornamental, incidental, or arbitrary aspect of the device. <sup>217</sup>

The use of this approach emphasizes the policy that the contents of an expired patent generally are free to be copied by the public and thus ineligible for trade dress protection. Nevertheless, there are occasions when affording trade dress protection would be appropriate, notwithstanding the existence of the expired utility patent, if the feature is nonfunctional and the design serves a source-identifying function. The use of the evidentiary presumption established the policy preference—free competition and copying—which could be altered in light of countervailing considerations.

Thus, the lessons of the Supreme Court have shown that (1) the PHOSITA is an important consideration in patent law generally and (2) that the use of rebuttable presumptions are an appropriate way to balance competing policy concerns.<sup>220</sup> The

<sup>217.</sup> Id. at 29-30.

<sup>218.</sup> Id. at 29.

<sup>219.</sup> *Id.* at 29–30; Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205, 212–13 (2000) (noting that a product design can serve as a trademark if it is source-identifying); *see also In re* Pennington Seed, Inc., 466 F.3d 1053, 1060 (Fed. Cir. 2006) (characterizing *TrafFix* holding as a "rebuttable presumption" of functionality).

<sup>220.</sup> Professor Lee advocates a different methodology, drawing on patent law's enablement doctrine; Supreme Court decisions should enable any particular test or standard articulated. See Lee, supra note 4, at 63-71. My thesis could be viewed as a narrower form of this argument because a presumption-based approach seemingly would be enabling. Overall, however, Professor Lee's proposal has one serious flaw. Enablement in patent law is based on the idea that the patent document is self-contained and self-referential—the specification must explain how to make and use the invention contained within the patent itself. A Supreme Court decision, and any rule articulated therein, must necessarily be of general applicability because it must be applied to unforeseen future cases. It is difficult to see how a singular Supreme Court decision could enable a court to readily decide a host of future cases involving ever-evolving technologies. Thus, the Supreme Court would have to write considerable dicta in order to guess what cases may come down the line. While Professor Lee's insights are commendable, the proposed prescription is a bit unsatisfying. Another approach may be for the Supreme Court to take clusters of cases in a particular area with different factual contexts to create greater certainty around legal standards. See Carolyn Shapiro, The Limits of the Olympian Court: Common Law Judging Versus Error Correction in the Supreme Court, 63 WASH. & LEE L. REV. 271, 313-27 (2006). To be fair, Professor Lee expressly disclaims offering any "substantive guidelines for determining when the

presumption establishes a default norm, which here would be the importance of the patent document and prosecution history. Only after a presumptive conclusion is reached would expert testimony be considered to determine if it is persuasive enough to overcome the intrinsic record. The use of the presumption, therefore, would require consideration of extrinsic evidence, which typically is the manner by which the views of the PHOSITA enter the calculus. The use of the presumption may also act as a counterbalance to overreliance on expert testimony, one risk when laypersons encounter technical information. <sup>221</sup>

### B. The Theories of Presumptions and Their Applicability to Patent Law

The Supreme Court's embrace of presumptions is quite fortuitous, even though the Court did not engage in a theoretical account of the use of presumptions in patent law, because they are an appropriate tool to balance the interest in notice with consideration of the technical or scientific. This section explores the theoretical basis for presumptions and explains why they are appropriate in the realm of patent law.

Presumptions used in the law generally reflect social or policy choices that the courts or legislatures want to emphasize. Commentators have identified a number of reasons why the use of presumptions arise, including a reflection of the probability of causation or to force a party to disclose information that it is more likely to possess. In a sense, the presumption establishes a default position that will stand absent the introduction of more information.

Presumptions, while ubiquitous in the law, <sup>224</sup> vary widely in application. <sup>225</sup> Indeed, the use of the term "presumption" has been inexact in the law. <sup>226</sup> No single rule is able to capture the entire universe of what courts and legislatures have

Supreme Court should intervene in patent affairs." Lee, *supra* note 4, at 76. In contrast, the proposals in this article do seek to offer such guidance to both the Supreme Court and the Federal Circuit.

221. *See* Lee, *supra* note 4, at 24–25.

222. See Ronald J. Allen, Presumptions in Civil Actions Reconsidered, 66 IOWA L. REV. 843, 845 (1981); Kenneth S. Broun, The Unfulfillable Promise of One Rule for All Presumptions, 62 N.C. L. REV. 697, 702 (1984); Mason Ladd, Presumptions in Civil Actions, 1977 ARIZ. St. L.J. 275, 279; cf. Keyes v. School Dist. No. 1, Denver, Colo., 413 U.S. 189, 209 (1973) ("This burden-shifting principle is not new or novel. There are no hard-and-fast standards governing the allocation of the burden of proof in every situation. The issue, rather, 'is merely a question of policy and fairness based on experience in the different situations." (quoting 9 J. WIGMORE, EVIDENCE § 2486, at 275 (3d ed. 1940))).

223. See Allen, supra note 222, at 845 ("[Presumptions] have been used to construct rules of decision to avoid factual impasse at trial; to allocate burdens of persuasion; to instruct the jury on the relationship between facts; and to allocate burdens of production."); Ladd, supra note 222, at 280–81.

224. Antonio E. Bernardo, Eric Talley & Ivo Welch, *A Theory of Legal Presumptions*, 16 J.L. ECON. & ORG. 1, 2 (2000).

225. See Ladd, supra note 222, at 277 ("Courts and legislatures often carelessly use the term 'presumption."); see also Broun, supra note 222, at 703 (exploring "bursting bubble" presumptions versus presumptions that shift the burden of proof).

226. Professor Allen advocated for eliminating the use of the term "presumption." Allen, *supra* note 222, at 864.

dubbed "presumptions." For example, issued patents are presumed valid, but this presumption merely establishes that the accused infringer bears the burden of proving invalidity as an affirmative defense. Thus, the use of the term presumption does little work, as it simply defines invalidity as an affirmative defense.

In other contexts, the term "presumption" is used to describe the shift of the burden of proof only if certain factual predicates can be demonstrated. The tort doctrine of res ipsa loquitur, for instance, permits a jury to presume the negligence of the defendant if the plaintiff can show that

- (a) the event is of a kind which ordinarily does not occur in the absence of negligence;
- (b) other responsible causes, including the conduct of the plaintiff and third persons, are sufficiently eliminated by the evidence; and
- (c) the indicated negligence is within the scope of the defendant's duty to the plaintiff.<sup>231</sup>

227. Broun, *supra* note 222, at 697–98. Part of the problem with finding a uniform rule is that various policy concerns reflected in the presumption may need to be treated differently given the context, creating variations in the ways in which presumptions function. *Id.* at 708. 228. 35 U.S.C. § 282 (2006).

229. Allen, supra note 222, at 849-50 (objecting to use of term "presumption" in this context). Not all courts agreed with this view of the presumption of validity, however. Before the Federal Circuit was created, some courts treated the presumption of validity as merely shifting the burden of production to the defendant and, once that burden was satisfied, the presumption of validity disappeared under a "bursting bubble" approach. See Sperberg v. Goodyear Tire & Rubber Co., 519 F.2d 708, 713 (6th Cir. 1975) ("The issuance of letters by the Patent Office, because of the statutory presumption of validity, makes a prima facie case for a plaintiff asserting the validity of his patent. This presumption has no independent evidentiary value, however, but only serves to place the burden of proof on a party who asserts invalidity. As the Supreme Court pointed out in Del Vecchio v. Bowers, 296 U.S. 280 (1935), a statutory presumption 'falls out of a case' when the party against whom the presumption works meets his burden of offering evidence sufficient to justify a contrary finding." (citation omitted) (emphasis in original)); Ronald J. Allen, *Presumptions*, Inferences and Burden of Proof in Federal Civil Actions—An Anatomy of Unnecessary Ambiguity and a Proposal for Reform, 76 Nw. U. L. Rev. 892, 897 n.26 (1982) (characterizing *Sperberg* as dealing with burden of production).

230. The Federal Circuit has used the statutory presumption to require proof of invalidity by clear and convincing evidence. *See, e.g.*, Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc., 586 F.3d 1376, 1380 (Fed. Cir. 2009). *But see generally* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007) (arguing that the clear and convincing standard is not appropriate if the asserted prior art was not before the PTO). The Supreme Court will address this issue in the October 2010 term. *See* Microsoft Corp. v. i4i Ltd., No. 10-290, 2010 WL 3392402 (U.S. Nov. 29, 2010). The question presented is "[w]hether the court of appeals erred in holding that Microsoft's invalidity defense must be proved by clear and convincing evidence." Petition for a Writ of Certiorari at i, Microsoft Corp. v. i4i Ltd., No. 10-290 (U.S. Aug. 27, 2010), 2010 WL 3413088, at \*ii.

231. RESTATEMENT (SECOND) OF TORTS § 328D (1965); see also Gideon Parchomovsky &

Patent law has a similar burden-shifting provision, dealing with the proof of infringement for patented processes.<sup>232</sup> If the patent holder can demonstrate both that "a substantial likelihood exists that the product was made by the patented process" and "that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine," then the burden shifts to the accused infringer to prove the product was not produced by the patented process.<sup>233</sup> In these circumstances, the presumption acts as a tool to force the party who is in the better position to have the relevant information to divulge it.<sup>234</sup> In the patent context, the accused infringer will know what process it utilizes more readily than the patentee, particularly if that process is performed overseas,<sup>235</sup> limiting the patentee's ability to obtain discovery. These presumptions can result in a shifting of the entire burden of proof (including both the burden of production and persuasion) or only one aspect (typically the burden of production).

Presumptions may not need to even shift these evidentiary burdens to have the effect of eliciting more information. The presumption-like framework in *TrafFix* does not change the burden in any sense because the trademark owner at all times bears the burden of proving the validity of the trade dress; nevertheless, if the accused infringer can demonstrate the existence of a utility patent, the party asserting the trade dress must come forward with additional evidence to demonstrate that the design is nonfunctional.<sup>236</sup> The prosecution history

Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 286–87 (2008) (referring to res ipsa loquitur as a presumption); *see generally* David Kaye, *Probability Theory Meets Res Ipsa Loquitur*, 77 MICH. L. REV. 1456 (1979). There is variation among the states as to whether the presumption of the res ipsa rule is permissive, allowing the jury to find negligence, or mandatory, shifting the burden of production to the defendant. *See* Broun, *supra* note 222, at 699.

232. See 35 U.S.C. § 295 (2006). This burden shifting appears to be a mandatory presumption.

233. *Id.* This presumption is required by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), although the U.S. statutory provision permissibly differs from the TRIPS article. TRIPS Article 34 permits the burden shift if either the product of the process is new or "if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used." Article 34 only requires signatories to adopt one of these conditions, and the United States has adopted only the latter. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 34, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] ("Members shall provide, *in at least one of the following circumstances*, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process." (emphasis added)).

234. *Cf.* Ladd, *supra* note 222, at 281.

235. Such a scenario can arise because it is an act of infringement to import the product of a patented process, even if the process is performed overseas. 35 U.S.C. § 271(g) (2006); see Holbrook, Extraterritoriality, supra note 189, at 2139–41, 2148–50.

236. TrafFix Devices, Inc. v. Mktg. Displays, Inc., 532 U.S. 23, 30 (2001); see, e.g., Great Neck Saw Mfrs., Inc. v. Star Asia U.S.A., LLC, No. C06-647Z, 2010 WL 2949296, at \*16 (W.D. Wash. July 23, 2010).

presumptions play a similar, information-forcing role. Although the patent holder at all times bears the burden of proving infringement, the *Warner-Jenkinson* and *Festo* presumptions require the patentee to produce additional evidence in order to rebut them.<sup>237</sup> In these contexts, the presumption operates as a litigation-based information forcing tool.<sup>238</sup>

Thus, in the patent context, two key aspects of presumptions are important. The first is using the presumption to implement a policy choice: the default position is often determined through consideration of a policy preference that the courts or the legislatures want to implement.<sup>239</sup> In patent law, both the Federal Circuit and the Supreme Court have noted that the important policy of public notice is served by favoring the publicly available intrinsic evidence.<sup>240</sup> This choice reflects the interest in certainty that is important to the proper functioning of any property regime. Thus, reliance on the intrinsic evidence should create a presumptive conclusion. The conclusion reached from consideration of the intrinsic evidence, however, can be rebutted through consideration of extrinsic, technical information. The presumption, therefore, not only works to effect public notice and certainty but also ensures a modicum of flexibility.

The second reason why presumptions are appropriate in the context of the treatment of the patent document is the information-forcing function they create. Patent applicants do have incentives to withhold certain information and behave strategically, in part due to concerns over competition and in part due to concerns over the legal consequences their disclosures may create. As to the former, patent applicants have the incentive to disclose "just enough" to satisfy the patentability requirements of \$ 112 while retaining other aspects as trade secrets. As to the latter, the Federal Circuit's treatment of the patent document gives an incentive for patent applicants to limit their disclosures to avoid potential estoppel-like consequences. Of course, the court's written description and enablement jurisprudence put applicants in a bit of a catch-22: you must disclose even that which the PHOSITA knows, yet overdisclosure risks surrendering claim scope during the claim construction process. Nevertheless, given that the patentee is more likely to have information relevant to an understanding of the patent document, the

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<sup>237.</sup> One could frame these scenarios more concretely in terms of a presumption framework. Under *TrafFix*, the accused infringer could be viewed as having the burden of producing the utility patent and showing that the asserted trade dress is covered by the patent; the burden of production then shifts back to the trademark owner. Similarly, the accused infringer bears the burden of producing evidence that a narrowing amendment was made during prosecution of the relevant patent. The burden of production then shifts to the patent holder to show that the amendment was made for a reason unrelated to patentability, that the amendment bore only a tangential relationship to the asserted equivalent, or that the equivalent was unforeseeable.

<sup>238.</sup> Allen, *supra* note 222, at 860.

<sup>239.</sup> See Broun, supra note 222, at 702.

<sup>240.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 727 (2002); Warner-Jenkinson Co., v. Hilton Davis Chem. Co., 520 U.S. 17, 29–30 (1997); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996).

<sup>241.</sup> See supra notes 163–66 and accompanying text.

<sup>242.</sup> See supra note 163 and accompanying text.

use of presumptions to create defaults can force the patentee to divulge additional information to the court or risk the loss of patent scope or the invalidation of the patent claim.

# C. The Use of Rebuttable Presumptions Can Help Balance the Legal and Technical Nature of the Patent Document

Generally presumptions can be used to establish a default position that can be shifted in light of additional evidence. In the context of patent law, that preference is to emphasize the primacy of the patent document and the prosecution history, the intrinsic evidence.<sup>243</sup> Determinations of claim construction or the sufficiency of the patent's disclosure should, in the main, be determined by that primarily legal evidence. That default position, however, can be altered by consideration of extrinsic evidence, which can explain the technical component. The following subsection advocates and elaborates the use of presumptions in claim construction, written description, and enablement law.

## 1. Intrinsic Evidence in Claim Construction Should Create a Presumptive Interpretation, Rebuttable by the Extrinsic Evidence

The lessons of the Supreme Court's decisions, and the theoretical justifications of presumptions as promoting certain norms and policies, shows that the Federal Circuit has gone too far in its claim construction jurisprudence. Under the current regime, claim construction operates in a manner akin to the absolute bar approach to prosecution history estoppel rejected by the Supreme Court in Festo.<sup>244</sup> As the Federal Circuit stated in Vitronics, reliance on the extrinsic evidence is inappropriate if the intrinsic evidence is unambiguous.<sup>245</sup> In other words, the extrinsic evidence cannot be used to contradict the clear teachings of the intrinsic evidence. If the intrinsic evidence generates a certain meaning to the claim term, that definition governs regardless of what the extrinsic evidence may suggest.

This methodology is in essence an irrebuttable presumption, akin to the absolute bar of prosecution history estoppel that the Supreme Court rejected. The most appropriate time to consider the extrinsic evidence, contrary to Vitronics, would be when it truly conflicts or is in tension with the intrinsic evidence because it suggests a technologist might read the language differently than a lawyer. The elevation of the patent document is a bit surprising in that the court appears to assume that the patent applicant has somehow perfectly described or represented the nature of the invention. <sup>246</sup> Such an assumption is flawed on a number of levels.

<sup>243.</sup> Phillips v. AWH Corp., 415 F.3d 1303, 1318–19 (Fed. Cir. 2005) (en banc).

<sup>244.</sup> See Festo, 535 U.S. at 737.

<sup>245.</sup> Vitronics, 90 F.3d at 1583; see also Phillips, 415 F.3d at 1324 ("In Vitronics, we did not attempt to provide a rigid algorithm for claim construction, but simply attempted to explain why, in general, certain types of evidence are more valuable than others. Today, we adhere to that approach and reaffirm the approach to claim construction outlined in that

<sup>246.</sup> Cf. Festo, 535 U.S. at 738 ("It does not follow, however, that the amended claim becomes so perfect in its description that no one could devise an equivalent. After

To begin, there is no requirement for the inventor to actually be ordinarily skilled in the art: she could be over- or under-skilled. Thus assuming the PHOSITA would take the specification as scientifically accurate seems incorrect.<sup>247</sup> The PHOSITA could read language of surrender far differently from a scientific perspective than a legal one because she might recognize technical errors in the disclosure or might weigh the importance of the disclosure differently.<sup>248</sup> The patent applicant can even be *wrong* about why the invention works, so long as she nevertheless teaches how to make and use it.<sup>249</sup> Thus, as a technological matter, there is no reason to assume that the disclosure should be the ultimate arbiter of the meaning of the claim.

Instead, the intrinsic evidence should create a presumptive interpretation, rebuttable by extrinsic evidence.<sup>250</sup> This would play out in practice by focusing on the burden of proof. As the burden of proof lies with the patentee in proving infringement, the burden of persuasion at all times would remain with the patentee. If the intrinsic evidence supports the patentee's interpretation, the burden of production would shift to the accused infringer to produce extrinsic evidence to contradict the construction afforded the claim from the intrinsic evidence. Absent any such evidence, the claim construction would stand. If the accused infringer came forward with such evidence, the patentee would need to come forward with her own extrinsic evidence to carry the burden of persuasion.<sup>251</sup>

amendment, as before, language remains an imperfect fit for invention.").

247. Cf. Kelly Casey Mullally, Patent Hermeneutics: Form and Substance in Claim Construction, 59 FLA. L. REV. 333, 367–68 (2007) (arguing that reliance on intrinsic evidence alone risks reducing notice and certainty because of lack of technical context).

248. See, e.g., Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1382 (Fed. Cir. 2000) ("[T]he extrinsic evidence invoked by PowerTrax to show a potential issue of fact relating to the importance of the reliability issue does not trump the clear disclosures and assertions in the patent itself."); Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 141 F.3d 1084, 1095 (Fed. Cir. 1998) (Newman, J., dissenting) ("This new and absolute rule is presented by the majority as rendering irrelevant any evidence of insubstantiality of the differences, or sameness of function/way/result, with reference to the function described in claim clause [5] . . . . The importance of a property mentioned in the specification is a fact to be found and weighed. It is improper to foreclose such evidence by ruling that every unclaimed advantage must be present, whatever its relative significance in practice.").

249. Diamond Rubber Co. v. Consol. Rubber Tire Co., 220 U.S. 428, 435–36 (1911) ("It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative ideas involved."); Newman v. Quigg, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989) ("While it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works, neither is the patent applicant relieved of the requirement of teaching how to achieve the claimed result, even if the theory of operation is not correctly explained or even understood." (citations omitted)).

250. The use of extrinsic evidence could elevate the role of expert testimony in claim construction prepared in anticipation of litigation and the concern of "hired guns" that do not help elucidate the meaning of the claims. *See, e.g., Phillips,* 415 F.3d at 1318; *Vitronics,* 90 F.3d at 1585. As the Supreme Court noted, however, in most cases, credibility and other concerns with experts should be subsumed in the entirety of the claim construction process. Markman v. Westview Instruments, Inc., 517 U.S. 370, 389 (1996). Moreover, if the expert testimony is in equipoise or otherwise unclear, than the presumptive interpretation afforded by the intrinsic evidence would control, mitigating this concern.

251. Importantly, this approach also differs from contract interpretation, which has been

On the other hand, if the intrinsic evidence supported the construction offered by the *accused infringer*, then the patentee would have both the burden of production and persuasion of providing extrinsic evidence contradicting the interpretation provided by the intrinsic evidence. As the burden of proof remains with the patentee, the accused infringer theoretically could stand on the intrinsic evidence alone, although such reliance as a strategic matter would be ill-advised.

There may be occasions when a patent applicant wants to guarantee a particular definition or meaning for a term contained with the patent. In such a circumstance, the applicant should act as a lexicographer and provide an explicit definition for the term. <sup>252</sup> By providing an express definition, this would inform both a lawyer and a technologist as to what the term means, limiting the inquiry to that definition alone. In contrast, courts would no longer be permitted to use implicit definitions through disavowals to narrow claim scope without first considering whether a technologist would view such language in the specification or prosecution history as disclaiming the relevant subject matter. <sup>253</sup>

The Federal Circuit has articulated a variety of "presumptions" in the context of claim construction. For example, claims that use different language are presumptively of different scope.<sup>254</sup> Similarly, the use of the term "means" in a claim creates a presumption that the applicant intends to evoke "means-plusfunction" claiming as governed by 35 U.S.C. § 112, ¶ 6;<sup>255</sup> conversely, failure to use the term "means" creates a presumption against interpreting the claim as a "means-plus-function" claim.<sup>256</sup>

These presumptions, however, are not the same type as those articulated in this article. Use of these presumptions is a bit perplexing. Presumptions are helpful in giving preference to certain types of evidence, which reflects certain normative or

advanced as an appropriate analogy to claim construction. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 997–98 (Fed. Cir. 1995) (Mayer, J., concurring) (arguing for contract-like analysis, with intrinsic evidence treated as legal and extrinsic evidence as factual), aff'd, 517 U.S. 370 (1996). In contract interpretation, resort to parole evidence is appropriate only if the contract language itself is ambiguous. See, e.g., Thomsen v. Famous Dave's of Am., Inc., 606 F.3d 905, 908 (8th Cir. 2010) (applying Minnesota law); Addicks Services, Inc. v. GGP-Bridgeland, LP, 596 F.3d 286, 294 (5th Cir. 2010) (applying Texas law). In claim interpretation, however, more than the patent applicant's intent is relevant; instead, it is that of the exogenous, objective PHOSITA. Thus, the contract analogy also fails.

252. See Phillips, 415 F.3d at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); Markman, 52 F.3d at 980 ("As we have often stated, a patentee is free to be his own lexicographer."); cf. Miller, supra note 44, at 203–07 (advocating requiring lexicon and preferred dictionary sections in patents to guide definitions).

- 253. See supra notes 72–78 and accompanying text.
- 254. This canon of claim construction is known as claim differentiation. *See* Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380–81 (Fed. Cir. 2006) (discussing doctrine's applicability to not only independent and dependent claims but also to two independent claims).
  - 255. See, e.g., Welker Bearing Co. v. PHD, Inc., 550 F.3d 1090, 1096 (Fed. Cir. 2008).
  - 256. E.g., CCS Fitness v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002).

\_ a policy preferences.<sup>257</sup> In the above examples, the only evidence that is relevant in assessing these presumptions is the intrinsic evidence—the patent itself. Indeed, it seems strange to speak of these presumptions in an inquiry that is entirely a legal analysis.<sup>258</sup> While arguably these presumptions might create a hierarchy as to which part of the intrinsic evidence is more relevant, ultimately the court will decide what the intrinsic evidence means. Even the court has recognized that these presumptions are more "rules of thumb" as opposed to presumptions that help govern the relevancy and weight of other evidence, such as how to appropriately weigh the intrinsic versus the extrinsic evidence.<sup>259</sup> Thus, these various presumptions in the canons of claim construction are a bit perplexing and really do not appear to be true "presumptions" in the evidentiary sense.

One corollary to the use of presumptions in claim construction is that it undermines the current status of claim construction as purely legal. Courts are in the business of construing legal documents but not technical ones. These technological considerations, and the presumptions surrounding them, would inevitably be factual in nature, suggesting that the current regime of de novo review of claim construction would need to be rejected.<sup>260</sup>

# 2. A Disclosure of a Limited Number of Species or a Teaching Away Should Create a Presumption of Failure of Written Description or Enablement, Rebuttable by Extrinsic Evidence

In a manner akin to claim construction, the Federal Circuit has essentially foreclosed consideration of the views of the PHOSITA from assessing the adequacy of a patent's disclosure under both the written description and enablement inquiries. Aside from being inconsistent with the clear language of § 112, <sup>261</sup> it creates significant costs to patent drafters to include information that the PHOSITA would know and places them in the odd position of attempting to guess what future litigants may use against them.

<sup>257.</sup> See Broun, supra note 222, at 702.

<sup>258.</sup> Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc).

<sup>259.</sup> Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1332 (Fed. Cir. 2009) ("[C]laim differentiation is a rule of thumb that does not trump the clear import of the specification."); *see also* Autogiro Co. of Am. v. United States, 384 F.2d 391, 404 (Ct. Cl. 1967) ("Claim differentiation is a guide, not a rigid rule. If a claim will bear only one interpretation, similarity will have to be tolerated."); *accord* ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1376 (Fed. Cir. 2009); NOMOS Corp. v. BrainLAB USA, Inc., 357 F.3d 1364, 1368 (Fed. Cir. 2004).

<sup>260.</sup> While there is considerable support for this move, even at the Federal Circuit, it is unclear as a constitutional matter how the court could do so. The Supreme Court, in agreement with the Federal Circuit, removed the jury from the act of claim construction by treating the issue as "purely legal." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996). It is unclear how the courts could then remove the jury from claim construction, yet afford deference to fact finding relevant to claim construction on appeal.

<sup>261.</sup> See supra note 148 and accompanying text.

Instead of using the patent disclosure exclusively, the court should establish presumptions based on the disclosure, subject to rebuttal by extrinsic evidence. <sup>262</sup> Consultation of the specification would create a presumption that disclosure is insufficient, subject to rebuttal by extrinsic evidence. Of course, the posture of written description and enablement challenges in the court is strikingly different than issues of claim construction because the accused infringer bears the burden of proving the claim is invalid. <sup>263</sup> As a result, the Federal Circuit's reliance exclusively on the patent disclosure alone in these cases is particularly troublesome given that the Patent Office has reviewed the disclosure and found it sufficient, which is the reason for the statutory presumption. <sup>264</sup>

A presumption-based methodology can take into account the statutory presumption of validity, as can be seen from the Federal Circuit's approach for assessing whether a party other than the patentee was the first to invent under 35 U.S.C. § 102(g)(2).<sup>265</sup> Generally, under U.S. patent law, the first person to invent is entitled to a patent; the exception, however, is if that person abandoned, suppressed, or concealed it.<sup>266</sup> In those circumstances, then the second-to-invent can be awarded the patent.<sup>267</sup> In the litigation context, this issue arises when an accused infringer challenges the validity of the patent by asserting that someone else was the first to invent (often times the accused infringer herself).<sup>268</sup> The patentee's response is often that the alleged first to invent abandoned, suppressed, or concealed the invention, negating their status as the first to invent and preserving the validity of the patent.<sup>269</sup> In order to sort out these various positions and to

262. Professor Seymore has offered a slightly different burden-shifting methodology for use in the USPTO. See Seymore, Heightened Enablement, supra note 3, at 156–57. His proposal and this framework could complement each other, with mine focused on the litigation context and his the prosecution context. The PTO does currently use a variant of burden shifting when assessing the sufficiency of a patent application, although the initial burden lies on the examiner, not the applicant, to demonstrate a prima facie case of lack of written description or enablement. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Professor Seymore would shift this burden if the applicant has failed to provide a working example.

263. 35 U.S.C. § 282 (2006).

264. Of course, the Patent Office is not well-situated to evaluate the scope of disclosures, particularly enablement, as it has no ability to experiment or "try out" the invention. *See* Fromer, *Patent Disclosure*, *supra* note 3, at 579–80; Seymore, *Patently Impossible*, *supra* note 141, at 18–19 (both discussing the limits on the PTO's ability to assess disclosure). The disclosure in the patent application is presumed sufficient, and it is incumbent on the examiner to provide a basis to challenge the application's sufficiency. *See In re* Doyle, 482 F.2d 1385, 1392 (C.C.P.A. 1973); *see generally* Lichtman & Lemley, *supra* note 230, at 53–56 (noting difficulties examiners have in adequately reviewing patent applications).

- 265. See Apotex USA, Inc. v. Merck & Co., 254 F.3d 1031, 1037–38 (Fed. Cir. 2001).
- 266. 35 U.S.C. § 102(g)(2) (2006).
- 267. See Lutzker v. Plet, 843 F.2d 1364, 1366 (Fed. Cir. 1988).
- 268. See, e.g., Apotex, 254 F.3d at 1035–36.

269. See, e.g., id. at 1036 (arguing that Apotex's patent is not invalid because, although Merck was the first-to-invent, it suppressed the invention); cf. Young v. Dworkin, 489 F.2d 1277, 1281–82 (C.C.P.A. 1974) (awarding patent to the second-to-invent because the first-to-invent suppressed the invention).

account for the presumption of validity that attends an issued patent, the Federal Circuit articulated the following presumption-based framework:

[O]nce a challenger of a patent has proven by clear and convincing evidence that "the invention was made in this country by another inventor," 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. However, in accordance with the statutory presumption in 35 U.S.C. § 282, the ultimate burden of persuasion remains with the party challenging the validity of the patent. Once the patentee has satisfied its burden of production, the party alleging invalidity under § 102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary.<sup>270</sup>

In the context of assessing the sufficiency of the patent's disclosure, a presumption approach could work similarly. If the court considers the specification to be inadequate, then the burden of coming forward would shift to the patentee to produce evidence to create a genuine issue regarding the sufficiency of the patent's disclosure. The ultimate burden of proving the patent claim invalid for lack of written description or enablement would remain with the accused infringer. On the other hand, if the court views the specification as adequate, then the accused infringer would be presented with the daunting task of demonstrating that the extrinsic evidence shows the inadequacy of the disclosure. In this scenario, the presumption would buttress the presumption of validity, making demonstration of invalidity rather difficult. The patentee would have no obligation to come forward with any additional evidence. It would be a rare case where the party challenging the patent's validity would be successful if the patent document alone is viewed as sufficient.

The presumption expresses the norm in favor of disclosures and the public record but allows supplementation of evidence of the PHOSITA. This approach seems particularly appropriate given the hindsight advantage that subsequent readers of a patent might have. Patentees would not be entirely handcuffed by disclosures made years before, particularly if the PHOSITA at the time would have had such knowledge within her grasp.

With respect to the written description requirement, for a broad generic claim, the failure to disclose multiple species or other functional considerations that would teach that one could extrapolate readily from a narrower disclosure would create a presumption that the disclosure has not placed the public in possession of the invention. At that point, the court would consider evidence of the knowledge of the PHOSITA to determine if the representations made in the specification are accurate as a technological matter.

A similar analysis would apply in the enablement context. Indeed, the Federal Circuit in *Liebel-Flarsheim*<sup>271</sup> came close to adopting this approach. There, the specification taught away from a particular embodiment (which of course was the

<sup>270.</sup> Apotex, 254 F.3d at 1037-38 (citations omitted).

<sup>271. 481</sup> F.3d 1371 (Fed. Cir. 2007).

accused device). <sup>272</sup> The court then also considered extrinsic evidence to determine whether the claims were enabled. <sup>273</sup> In essence, the court was using a presumption-like framework: the specification contained a teaching away from a given embodiment, creating a presumption that the full scope of the claim was not enabled. Consultation of extrinsic evidence confirmed that the claim was not fully enabled. <sup>274</sup> Although the court did not use the language of presumptions, the methodology used in *Liebel-Flarsheim* demonstrates how such a presumption could work. Instead, however, the Federal Circuit's law evolved into the written description-like approaches of *Automotive Technologies*, *Sitrick*, and *ALZA*, which inappropriately discount extrinsic evidence.

### D. Possible Disadvantages of the Presumption-Based Approach

The proposed presumption-based methodology affords a way of balancing the interest in certainty and notice provided by giving primacy to the patent document, while providing a safety valve through the necessary admission of extrinsic evidence to ensure that the patent is given its appropriate, technological import. This approach depends, of course, on the courts actually respecting the method.

One potential outcome is that the courts would articulate such presumptions yet never find the extrinsic evidence compelling enough to rebut the clear teachings of the patent. Given the tendency for people to rely on heuristics when engaging technological information, such an intuition may flow naturally. Moreover, to the extent that the Federal Circuit would seek to retain control over doctrine, it may be reticent to relinquish some of its power of review on appeal.<sup>275</sup>

Nevertheless, the presumption-based approach would require the courts to readily consider the technological evidence in lieu of simply precluding it. The process of analyzing the evidence hopefully would add greater transparency to the judicial process and force the courts to engage with the relevant technological facts.

### CONCLUSION

The public notice function of patents is undeniably important. The Federal Circuit's preoccupation with this function, therefore, is entirely understandable. Unfortunately, the methodology that they have used in the context of claim construction, written description, and enablement, is flawed because it fails to adequately account for the technical aspect of the patent document and how that knowledge can impact the meaning of the terms contained therein. The use of presumptions, as advocated in this Article, provides a reasonable manner to balance the interest in certainty afforded by the intrinsic evidence with considerations of the technical. Those in the "real world," and not in litigation, would avail themselves of this information, which the Federal Circuit's current approach generally ignores,

<sup>272.</sup> Id. at 1380.

<sup>273.</sup> Id.

<sup>274.</sup> Id. at 1382.

<sup>275.</sup> Seemingly much of the admitted extrinsic evidence would be factual in nature, requiring deference on appeal, whereas the intrinsic evidence would be reviewed de novo.

to the detriment of the patent system.<sup>276</sup> In this way, the technical aspect of the patent is preserved and recognized, while giving an appropriate level of deference to the publicly available information.