# **Patent Disclosures and Time**

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#### INTRODUCTION

Patents by their very nature are pregnant with considerations of time. The exclusive rights they afford only last for a finite period generally from issuance until twenty years from the filing date of the application. Moreover, since patents necessarily engage with the evolution of technology, patents reflect various "snap shots" in time that reflect the state of the art at a particular moment. Patent law must constantly wrestle with time.

Many of these topics have been explored extensively in both judicial decisions and the literature. The most obvious example of considering the temporal aspect of patent law is . . . obviousness. The courts have discussed at length concerns about hindsight. Because obviousness is assessed at the present time based on the state of the art in the past,<sup>1</sup> the problem may arise that, with the patent in hand, one may inappropriately conclude that the invention is obvious. The literature has explored the hindsight problem both theoretically and experimentally.<sup>2</sup>

The Court of Appeals . . . drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. . . . Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007) (internal citations omitted).

<sup>1.</sup> W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983) (noting "the insidious attraction of the siren hindsight" in assessing obviousness); *see also* Eurand, Inc. v. Mylan Pharm., Inc. (*In re* Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.), 676 F.3d 1063, 1070–71 (Fed. Cir. 2012) (stating that "courts should reject 'hindsight claims of obviousness'" where prior art provides little guidance); Mobile Med. Int'l Corp. v. Advanced Mobile Hosp. Sys., No. 2:07-cv-231, 2015 U.S. Dist. LEXIS 146577, at \*18–19 (D. Vt. Oct. 29, 2015). The Supreme Court, while recognizing the potential for hindsight bias, has also noted that the Federal Circuit has gone too far:

<sup>2.</sup> See, e.g., Glynn S. Lunney, Jr. & Christian T. Johnson, Not So Obvious After All: Patent Law's Nonobviousness Requirement, KSR, and the Fear of Hindsight Bias, 47 GA. L. REV. 41 (2012); 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 (2008); Gregory N. Mandel, Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational, 67 OHIO ST. L.J. 1391 (2006); Gregory Mandel, Patently

In contrast, the relationship between time and patent disclosures is surprisingly underdeveloped.<sup>3</sup> Little literature has explored rigorously, for example, the hindsight bias that also arises in the context of patent disclosure requirements, which are assessed at the time of the filing date.<sup>4</sup> This Article explores how the nature of patent disclosures varies significantly based on the particular temporal context for which the disclosure is being considered. Section II of this Article explores five moments that implicate a form of disclosure. The scope of the disclosure at the first moment—the date that a disclosure is viewed as prior art<sup>5</sup>—is relatively unimportant.

The second—the moment of assessing novelty and nonobviousness—provides some interesting and underappreciated aspects of the nature of such prior art disclosures. This Article suggests that the importance of hindsight bias is present in ways for anticipation (the converse of novelty) that has only been addressed thoroughly in the obviousness context. It also suggests that current doctrine undervalues the importance of the knowledge of one of ordinary skill in the art, then offers ways to properly account for this knowledge, drawing on past practice that has fallen by the wayside in the modern era.

The third moment—that of the date of the relevant patent application—also creates interesting temporal dynamics regarding the

5. I am cheating here a little bit, as prior art disclosures may be in a patent, but they may also be found through other printed publications, sales activity, public uses, or other forms. *See* 35 U.S.C. § 102(a) (2012) (AIA).

Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR v. Teleflex, 9 YALE J.L. & TECH. 1 (2007); cf. Sean B. Seymore, Foresight Bias in Patent Law, 90 NOTRE DAME L. REV. 1105 (2015) (discussing hindsight bias and identifying foresight bias, a different problematic bias at assessing the future).

<sup>3.</sup> Mark Lemley has offered an overview of the relationship between time and patent disclosures, though his focus was on claim construction. *See* Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101 (2005).

<sup>4</sup> See Dan L. Burk & Mark A. Lemley, Is Patent Law Technology-Specific?, 17 BERKELEY TECH. L.J. 1155, 1199 (2002) ("[H]indsight bias risks infecting the PHOSITA analysis in enablement and claim scope as well. Hindsight bias will normally lead factfinders to overestimate the level of skill in the art, since subsequent advances will suggest that the invention could not have been that difficult to do."); R. Polk Wagner, Reconsidering Estoppel: Patent Administration and the Failure of Festo, 151 U. PA. L. REV. 159, 205 (2002) ("Again, consider enablement, which is measured through the lens of the knowledge of the relevant field as of the filing date of the patent application. As the filing date becomes distant, the potential for cognitive biases, such as a hindsight bias, increases."); Timothy Chen Saulsbury, Note, Pioneers Versus Improvers: Enabling Optimal Patent Claim Scope, 16 MICH. TELECOMM. & TECH. L. REV. 439, 443-44 (2010) ("This shortcut leads to outdated views of the PHOSITA and hindsight bias, which contaminate courts' enablement analysis."). For an argument that hindsight bias should be embraced in assessing patent disclosures, see Allen K. Yu, The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?, 33 CARDOZO L. REV. 895, 964 (2012) ("The more direct way to enable contribution to the art to be assessed in hindsight is to relax the requirement that enablement be evaluated solely at the time of filing.").

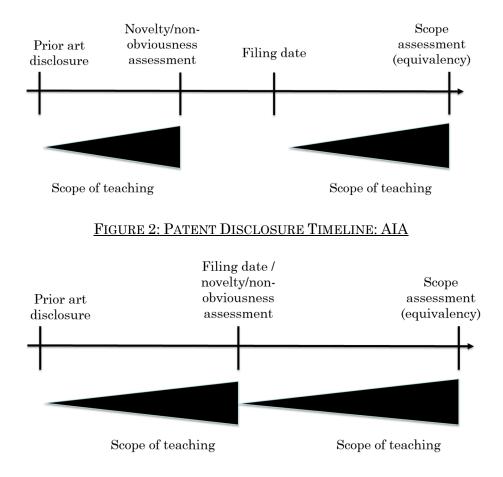
requisite proof that a particular patent application adequately discloses the patented invention. This moment in time involves the classic patent disclosure: that of 35 U.S.C. § 112(a). In this context, the disclosure is viewed as static. Satisfaction of the disclosure obligations is measured solely against the state of the art as of the filing date. Given this demanding focus on the filing date, Section IV addresses a problem that has vexed the law for some time: What type of post-filing evidence can be used to demonstrate whether the disclosure is sufficient, particularly with respect to utility and enablement? In particular, when, if ever, is it appropriate to consider scientific evidence that was created after the filing date to determine whether the disclosure is sufficient? This Article offers a variety of ways to deal with this evidentiary issue. It offers four possible alternative approaches. Ultimately, this Article recommends a bright-line rule against the introduction of post-filing generated evidence

Finally, the Article explores the fourth and fifth moments in time, both related to patent scope. The fourth moment is the point in time at which the court construes the claims of the patent, known as claim construction. The fifth moment is that of an act of infringement, which takes place after the patent issues. Considering these two moments in time, the Article posits that courts have not adequately consulted the specification of the patent at issue to properly assess the scope of the patent, particularly for purposes of the doctrine of equivalents. Here, again, we see a somewhat odd dynamic. For purposes of claim construction and literal infringement, the disclosure is in theory (though perhaps not in practice) frozen in time, limited to the state of the art as of the filing date. But, with respect to the doctrine of equivalents, the disclosure is permitted to grow to ensnare new technologies. In this way, the teachings of the patent grow over time and allow the patent to ensnare later-developed technologies. The Article then concludes.

#### I. PATENT DISCLOSURES AND TIME

Thinking about the temporal dynamic of patent disclosures, one can identify five dates for assessing the nature of that disclosure: the effective date as a prior art reference; the date that novelty or nonobviousness is assessed; the filing date of a particular patent against which novelty and non-obviousness is being determined; the date for construing the claims of the patent to determine their literal scope; and the date for assessing infringement under the doctrine of equivalents. Of course, these five points may in fact overlap: the proper time for assessing novelty could coincide with the exact date that a reference qualifies as prior art. Nevertheless, considering them as distinct points in time gives us insights about how time impacts patent disclosures at these distinct moments. The impact of time on patent (and other) disclosures depends importantly on which context the disclosure is being evaluated.

These dates are represented graphically below, one for the 1952 Patent Act and one for the America Invents Act ("AIA"). As the charts show, by shifting the United States from a "first inventor" to a "firstinventor-to-file" system, the AIA has effectively collapsed two of the dates—the date of assessment of novelty and non-obviousness—with the filing date.



#### FIGURE 1: PATENT DISCLOSURE TIMELINE: 1952 PATENT ACT

Consideration of these moments in time, and the attendant doctrines at issue, reveals different implications. The Article will first discuss the impact of time on prior art disclosures and the novelty and non-obvious analyses. In the next Section, it will discuss the role of time vis-à-vis a patent applicant's obligation to disclose her invention's utility and how to make and use that invention. The final Section will address the impact of time in assessing patent scope after the patent issues in terms of claim construction and the doctrine of equivalents.

## II. PRIOR ART DISCLOSURES AND TIME'S IMPACT ON NOVELTY AND NON-OBVIOUSNESS

#### A. The First Date: The Effective Date as Prior Art

The first date where a disclosure becomes relevant in the patent system is the date it can be treated as prior art. Prior art is the set of materials that a factfinder can use to determine whether an invention is novel<sup>6</sup> and potentially non-obvious. Section 102 of both the 1952 Patent Act and the AIA control whether something qualifies as "prior art." Section 102 of the 1952 Patent Act had two types of provisions first-to-invent provisions and statutory bars.<sup>7</sup>

The first-to-invent provisions required the prior art be generally available before the date of invention.<sup>8</sup> For example, § 102(a) of the 1952 Patent Act defined prior art as when the invention was known or used by others or was disclosed in a patent or printed publication prior to the invention date of the patent applicant.<sup>9</sup> Section 102(e) defined patent applications filed before another's invention date as prior art, so long as the United States Patent and Trademark Office ("USPTO") eventually published the application or issued the patent.<sup>10</sup> Under § 102(f), one could not obtain a patent if she had obtained the invention from

<sup>6.</sup> An invention must be "new" or "novel" to be eligible for patent protection. 35 U.S.C. \$\$ 101–102 (AIA).

<sup>7.</sup> See generally Timothy R. Holbrook, Possession in Patent Law, 59 SMU L. REV. 123, 151 (2006):

Section 102 of the Patent Act defines what constitutes a prior art reference.... The various provisions in § 102 differ in the timing of events that trigger the date when a publication or activity serves as a prior art reference. Some activities are prior art if they occur before the date that the inventor created the invention.... Other acts or publications qualify as prior art if they occur at a date one year prior to the inventor filing her application, regardless of when she created her invention.

<sup>8.</sup> See 35 U.S.C. §§ 102(a), (e)–(g) (2006) (1952 Act).

<sup>9.</sup> Id. § 102(a). Technically, only knowledge and use of the invention within the United States qualified, but those geographic limitations are not germane to the discussion.

<sup>10.</sup> Id. § 102(e).

someone else.<sup>11</sup> Finally, § 102(g) generally noted that a party could not get a patent if someone else invented the innovation first, so long as that other person had not abandoned, suppressed, or concealed the invention.<sup>12</sup>

Generally, the litmus test for whether these pre-invention dates qualify as prior art is whether these inventive acts have become publicly accessible.<sup>13</sup> Section 102(e) represents a slight exception to this rule, though the patent application must subsequently be accessible to the public through publication or issuance. Similarly, § 102(f) may not require general public accessibility, but it does require communication between the true first inventor and the person who took the idea, thus creating some aspect of awareness. Nevertheless, disclosures under these provisions have a particular date that they will be deemed prior art, such as the publication date or the filing date.

In contrast to these "first-to-invent" provisions, the statutory bars of the 1952 Patent Act are tied to the filing date, not the invention date. Specifically, particular activity qualifies as prior art if it occurred more than one year prior to the filing date of the patent at issue, known as the critical date. These provisions, therefore, bar the applicant from obtaining a patent even if she was the first to invent. The date of invention, thus, is irrelevant. Under § 102(b) of the 1952 Patent Act, a patent, printed publication, public use, or offer to sell the invention before the critical date qualifies as prior art and acts as a statutory bar.<sup>14</sup> These acts could be by the applicant herself or by third parties.

14. 35 U.S.C. § 102(b) (1952 Act). Some authors treat the statutory bars as distinct from prior art and novelty. See, e.g., CRAIG ALLEN NARD, THE LAW OF PATENTS 245–328, 425–90 (4th ed. 2016) (treating novelty and statutory bars distinctly in separate chapters). I reject that distinction. See Timothy R. Holbrook, Liability for the "Threat of a Sale": Assessing Patent

<sup>11.</sup> Id. § 102(f).

<sup>12.</sup> Id. § 102(g)(2). Section 102(g)(1) dealt with interference proceedings, administrative hearings at the USPTO to determine who among competing patent applicants was the first to invent. See *id.* § 102(g)(1).

<sup>13</sup> See, e.g., In re Cronyn, 890 F.2d 1158, 1160 (Fed. Cir. 1989) ("[T]he reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination of whether a prior art references was 'published.'" (quoting Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1568 (Fed. Cir. 1988))); In re Hall, 781 F.2d 897, 899 (Fed. Cir. 1986) (" '[P]ublic accessibility' has been called the touchstone in determining whether a reference constitutes a 'printed publication.'"); Carella v. Starlight Archery & Pro Line Co., 804 F.2d 135, 139 (Fed. Cir. 1985) ("The statutory language, 'known or used by others in this country,' means knowledge or use which is accessible to the public." (citation omitted) (quoting 35 U.S.C. § 102(a) (1952 Act)), amended on reh'g sub nom. Carella v. Starlight Archery, No. 86-728, 1986 WL 1154370 (Fed. Cir. Dec. 16, 1986); see also Mark A. Lemley, Does "Public Use" Mean the Same Thing It Did Last Year?, 93 TEX. L. REV. 1119, 1120 (2015) ("[P]atent law has traditionally required that most categories of prior art be 'accessible to the public."). For an exploration of the relationship between possession theory, prior art, and public accessibility, see Timothy R. Holbrook, Possession and Patent Prior Art (unpublished manuscript) (on file with author).

Moreover, any of these disclosures that arise after the critical date would not qualify as prior art, also regardless of whether the disclosure was by the applicant or a third party. Nevertheless, there is generally a certain date when something qualifies as a prior art reference. To qualify as prior art under the 1952 Patent Act, the reference must precede the invention date for first-to-invent provisions<sup>15</sup> or the critical date for statutory bars.<sup>16</sup>

Because the AIA generally creates a "first-to-file" regime for the United States, the key date for its prior art provisions is the applicant's filing date. As a result, the prior art provisions of the AIA work similarly to the statutory bars of the 1952 Patent Act. The AIA's analytical structure, however, differs from that of the 1952 Patent Act. Instead of offering distinct definitions of what qualifies as prior art, the AIA initially defines a broad class of prior art under 35 U.S.C. § 102(a). Specifically, under § 102(a)(1), a patent is unavailable if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."<sup>17</sup> This provision tracks the statutory bars of § 102(b) of the 1952 Patent Act, with the addition of the last, catchall provision "otherwise available to the public."<sup>18</sup>

On its face, this provision acts as an absolute bar to patentability for any of these acts by anyone, anywhere<sup>19</sup> that occur prior to the filing date. There is no generally applicable trigger of one year prior to the filing date, as was the case with the 1952 Patent Act. Section 102(b)(1) of the AIA, however, creates exceptions as to what qualifies as prior art, which effectively creates a one-year grace period similar to that of the 1952 Patent Act, but only as to acts that have their genesis in the

- 15. 35 U.S.C. § 102(a), (e)–(g) (1952 Act).
- 16. Id. § 102(b), (d).
- 17. 35 U.S.C. § 102(a) (2012) (AIA).

18. *Id.*; *see also* Lemley, *supra* note 13, at 1125 ("The terms 'patented,' 'described in a printed publication,' 'public use,' and 'on sale' are taken directly from § 102(b) of the 1952 Act. . . . The only new piece of § 102(a)(1), then, is the word 'otherwise' before 'available to the public,' which seems to create a catchall new category of prior art.").

19. The 1952 Patent Act previously limited the on-sale and public use bars to acts within the United States. See 35 U.S.C. § 102(b) (1952 Act). See generally Margo A. Bagley, Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World, 87 MINN. L. REV. 679 (2003). The AIA eliminated these geographic restrictions. See 35 U.S.C. § 102(a) (AIA). So, for example, an offer to sell the invention in Hungary would now bar a patent in the United States.

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, 780 (2003) ("The 'on-sale bar' is a prior art provision that defines what information is considered to be in the public domain with respect to assessing whether an invention is novel or nonobvious."); 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, 963–64 (2000) [hereinafter Holbrook, *More Things Change*].

applicant. Specifically, any disclosure by an applicant within one year of the filing date does not qualify as prior art.<sup>20</sup> Additionally, any disclosure made by someone who "obtained the subject matter disclosed directly or indirectly from the inventor" does not qualify as prior art if the disclosure was made less than a year prior to the filing date.<sup>21</sup> Unlike the 1952 Patent Act, there is no grace period for independent third party disclosures. For those disclosures, § 102(a) acts as an absolute bar.

Finally, in a somewhat odd provision, an applicant can effectively eliminate a prior disclosure by a third party if she can show that she publicly disclosed the invention prior to that third party disclosure, eliminating the third party disclosure as prior art.<sup>22</sup> This provision has led some to call the AIA a "first-to-file-or-disclose" regime.<sup>23</sup>

The first-to-file provisions work similarly to the general prior art rules of § 102(a)(1). Section 102(a)(2) sets out the first-to-file rule, and then § 102(b)(2) delineates exceptions to the rule, including a disclosure by a subsequent applicant that antedates an earlier applicant. These rules operate akin to § 102(e) under the 1952 Patent Act in treating earlier filed applications as prior art even though they are not publicly accessible as of the applicant's filing date. The applications only subsequently become public through issuance or publication of the application, which is a necessary condition for them to count as prior art.

For each of these forms of prior art, there is a particular date where they are considered to be prior art: the date of publication, the date of the patent application, or the date of the public use or offer to sell.<sup>24</sup> These dates must be before the relevant trigger under § 102 of

24. See, e.g., In re Morsa, 713 F.3d 104, 109 (Fed. Cir. 2013) (determining that prior art's date of publication preceded the inventor's date of patent application). There may be some uncertainty as to the precise date, but all that truly matters is whether the publication date was prior to the relevant date (i.e., invention, critical, or filing date). For example, in *In re Hall*, the evidence showed that the relevant PhD thesis had been cataloged prior to the critical date, even though no particular date could be identified. 781 F.2d 897, 899 (Fed. Cir. 1986). Instead, due to "general library procedure as to indexing, cataloging, and shelving of theses," the court found it sufficient that the dissertation "most probably was available for general use toward the beginning of the month of December, 1977." *Id.* (quoting the affidavit of a library administrator). Because the critical date was February 27, 1978, the court viewed this evidence as sufficient to show that the reference was sufficiently available to the public prior to the critical date. *Id.* 

<sup>20. 35</sup> U.S.C. § 102(b)(1)(A) (AIA).

<sup>21.</sup> Id.

<sup>22.</sup> Id. § 102(b)(1)(B).

<sup>23.</sup> See Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 42 (2012) ("The cornerstone of the AIA is a shift from a first-to-invent system of awarding patent rights to a first-to-file-or-disclose system.").

either statute: the invention date, the critical date, or the filing date. But what is the importance of the disclosure at that particular moment in time? The answer is not much. For a prior art patent, the owner of that patent would hope that it is sufficiently disclosed to satisfy that owner's obligations under 35 U.S.C. § 112. Indeed, such prior art patents are presumed enabled.<sup>25</sup> In terms of the impact of these disclosures as prior art on that date, the sufficiency of what they disclose *at this time* is irrelevant. Even though anticipation requires both that all of the limitations of the claim be found in a single reference and that the reference enable a person having ordinary skill in the art ("PHOSITA") to make the claimed invention, that assessment is irrelevant at this time.

Why? Because novelty and non-obviousness are not assessed as of the effective prior art date but instead generally at some later date. The publication or other date is relevant only for determining whether a disclosure qualifies as prior art. At that point, our relevant point in time shifts. Because enablement is based not only on the prior art disclosure but also on the knowledge of the PHOSITA, the teaching of a prior art reference is an ever-moving target, as the PHOSITA's knowledge grows over time. Indeed, it is conceivable that a prior art reference that was not enabled as of its effective prior art date *could become* enabled over time as the knowledge of the PHOSITA expands. The growth of the knowledge of the PHOSITA is essentially akin to the hindsight bias addressed in the obviousness context: one looking back at the prior art at a later time may be able to read more out of the reference's teachings.<sup>26</sup> The next Section elaborates this dynamic and discusses some of its implications.

## B. The Second Date: Assessment of a Claimed Invention's Novelty and Non-obviousness

In order to obtain a patent, the claimed invention must be both novel and non-obvious relative to the prior art.<sup>27</sup> Novelty is a term of art in patent law, and when an invention lacks novelty, it is said to have

<sup>25.</sup> Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003) ("We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff.").

<sup>26.</sup> It differs from the classic hindsight bias issue in obviousness in that the knowledge of the PHOSITA is not necessarily guided by the patent document itself.

<sup>27. 35</sup> U.S.C. §§ 101–103 (AIA); 35 U.S.C. §§ 101–103 (2006) (1952 Act).

been anticipated by the prior art.<sup>28</sup> Anticipation requires that a single prior art reference disclose each and every limitation of the relevant claim either expressly or inherently, and that the prior art reference enable one of skill in the art to make the claimed invention.<sup>29</sup> Unlike the enablement requirement of § 112(a), the prior art need only enable one embodiment of the claimed invention and not the entire scope of the claim whose validity is at issue.<sup>30</sup>

The non-obviousness requirement is not as rigidly defined. The obviousness inquiry essentially asks whether, even if the invention is technically new, it nevertheless is merely a trivial advance in the state of the art, unworthy of patent protection.<sup>31</sup> Unlike anticipation, the USPTO or a court can consider a variety of prior art references in combination when determining whether the claimed invention is obvious.<sup>32</sup> The assessment of whether an invention is obvious depends on a variety of factors. The Supreme Court has delineated four important considerations: the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the art, and any relevant objective indicia of non-obviousness, such as the failure of others, a long-felt but unsolved need,

30. In re Morsa, 803 F.3d 1374, 1377 (Fed. Cir. 2015) ("For a prior-art reference to be enabling, it need not enable the claim in its entirety, but instead the reference need only enable a single embodiment of the claim."); Am. Calcar., 651 F.3d at 1341–42; cf. MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012) ("[Enablement under § 112(a)] prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage."). For a discussion of a split in Federal Circuit law on whether § 112(a) requires enablement of the full scope of the claim or merely a particular embodiment, see Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 Nw. J. TECH. & INTELL. PROP. 278 (2008).

31. See John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 6 (2007) ("[W]orld patent law has now reached a consensus that the type of invention required for patentability must include some step that is not technically trivial, where triviality is measured by the capabilities of a person skilled in the relevant technical field.").

32. See Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim. A prior art disclosure that 'almost' meets that standard may render the claim invalid under § 103; it does not 'anticipate.'" (citation omitted)).

<sup>28.</sup> 1-3 DONALD CHISUM, CHISUM ON PATENTS § 3.02 (2015) ("The standard for lack of novelty, that is, for 'anticipation,' is one of strict identity.").

<sup>29.</sup> Am. Calcar, Inc. v. Am. Honda Motor Co., 651 F.3d 1318, 1341 (Fed. Cir. 2011) ("To be anticipatory, a reference must describe, either expressly or inherently, each and every claim limitation and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation."). The Federal Circuit has also suggested that the prior art reference must disclose the limitations as arranged in the claim. *See, e.g.*, Finisar Corp. v. DirecTV Grp., 523 F.3d 1323, 1334–35 (Fed. Cir. 2008). For an argument that neither the case law nor policy supports this additional requirement, see Timothy R. Holbrook, *Patent Anticipation and Obviousness as Possession*, 65 EMORY L.J. 987, 1012–19 (2016).

and the commercial success of the innovation.<sup>33</sup> The Court has noted other considerations may also be relevant, such as whether the prior art suggests combining the prior art in a way to yield the claimed invention; whether the prior art teaches away from making the combination; and whether design or market pressure would make the invention obvious to try.<sup>34</sup>

Both the novelty and non-obviousness assessments are generally made at a particular moment in time. That time is necessarily after the prior art reference has been published or is otherwise sufficiently publicly accessible. By definition, the prior art must exist prior to the relevant assessment date, which means that there generally is a gap in time between the prior art's disclosure and the validity assessment. Thus, in analyzing patent disclosures and time, the second relevant point is that of the novelty and non-obviousness assessment. Because the assessments of novelty and non-obviousness both take into account the state of the art, that gap in time means that the technology may have evolved. As a result, the baseline knowledge of the hypothetical PHOSITA, patent law's "reasonable person," may change as well.<sup>35</sup> Over time, we would expect the level of ordinary skill to grow, capturing new knowledge. In other words, we expect the PHOSITA to get smarter over time. Such new knowledge can impact these assessments in important ways. The time gap between a prior art disclosure and the validity assessment means that the knowledge of the PHOSITA has an opportunity to grow.<sup>36</sup>

<sup>33.</sup> Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17–18 (1966). The courts have identified other secondary considerations as well. *See, e.g.*, Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1350–53 (Fed. Cir. 2012) (discussing industry praise, unexpected results, copying, industry skepticism, and licensing as secondary considerations of non-obviousness).

<sup>34.</sup> KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418-22 (2007).

<sup>35.</sup> See Rebecca S. Eisenberg, Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA, 19 BERKELEY TECH. L.J. 885, 888 (2004) ("The risk posed by evaluating obviousness at a later date rather than 'at the time the invention was made' is that the bar will be set too high."); Timothy R. Holbrook, Patents, Presumptions, and Public Notice, 86 IND. L.J. 779, 781 (2011) (describing the PHOSITA as "an analog to tort law's 'reasonable person'"); John O. Tresansky, PHOSITA—the Ubiquitous and Enigmatic Person in Patent Law, 73 J. PAT. & TRADEMARK OFF. SOC'Y 37, 37–38 (1991) (discussing patent law's "use of the skill level in an art"); Jonathan J. Darrow, Note, The Neglected Dimension of Patent Law's PHOSITA Standard, 23 HARV. J.L. & TECH. 227, 228–29 (2009) (arguing that patent law has moved away from a "conception of the PHOSITA as practicing a stable art"); Joseph P. Meara, Comment, Just Who Is the Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage, 77 WASH. L. REV. 267, 267 (2002) (noting that the PHOSITA "has been likened to the reasonable person of tort law").

<sup>36.</sup> *See* Holbrook, *supra* note 29, at 1026–27 ("[T]he knowledge of the PHOSITA is necessarily a moving target because, as technology advances, so will the background knowledge of those in the field.").

Our "snap shot" in time for determining novelty and nonobviousness, however, recently changed. Under the 1952 Patent Act, novelty was generally determined as of the invention date: the invention must be viewed as new and non-obvious as of the date of the invention.<sup>37</sup> Inventors were not required by the USPTO to declare or prove a particular invention date, so the filing date became the default invention date.<sup>38</sup> If, however, an examiner at the USPTO or a litigant in the district court presented prior art from before the filing date, the inventor could antedate the reference by demonstrating an earlier date of invention.<sup>39</sup>

The 1952 Patent Act contained a variety of statutory bars to patentability that depended entirely on the filing date, not the invention date.<sup>40</sup> In this context, the novelty determination was made not as of the invention date but instead as of the critical date. The combination of the first-to-invent provisions and the statutory bars meant that novelty was assessed at some point between the filing date and the critical date. The invention date only became relevant if it was during the one-year grace period. If the date of invention was prior to the critical date, then the statutory bars would kick in, making the critical date the important date.

The AIA simplifies this dynamic. Novelty under the AIA is assessed as of the filing date. Some prior art that exists prior to the filing date may not qualify, such as inventor-generated disclosures made less than a year before the inventor files her application.<sup>41</sup> But those exclusions do not impact the timing of the analysis; they only

- 40. See supra notes 14–16 and accompanying text.
- 41. 35 U.S.C. § 102(b)(1) (2012) (AIA).

<sup>37. 35</sup> U.S.C. § 102(a), (e), (g) (2006) (1952 Act).

<sup>38.</sup> Spectralytics, Inc. v. Cordis Corp., 576 F. Supp. 2d 1030, 1042 (D. Minn. 2008) ("Under the default rule, the date on which the patentee made his invention is deemed to be the same as the date on which the patentee filed his patent application."), *aff* d, 649 F.3d 1336 (Fed. Cir. 2011).

<sup>39.</sup> See 35 U.S.C. § 102(g) (1952 Act); Spectralytics, 576 F. Supp. 2d at 1042:

But a patentee can attempt to avoid the default rule and establish an earlier invention date in two ways. First, if the patentee can establish that he in fact reduced his invention to practice as of a particular date, then that date (and not the patent-application date) will be treated as the invention date. Second, if the patentee can establish that he *conceived* his invention as of a particular date, then that date (and not the patent-application date) will be treated as the invention date, then that date (and not the patent-application date) will be treated as the invention date, but only if the patentee can also establish that, after conceiving his invention, he worked diligently to reduce it to practice.

To antedate a prior art reference, the inventor would need to show, prior to the reference's effective date, either a reduction to practice or conception followed by a diligent reduction to practice. *Id.* In the latter context, the filing of the patent application can serve as a constructive reduction to practice. Frazer v. Schlegel, 498 F.3d 1283, 1287 (Fed. Cir. 2007) ("[A] filed application serves as a constructive reduction to practice of its content.").

impact the disclosures that may be considered in the novelty assessment.

Obviousness under the 1952 Patent Act was timed similarly to novelty. The statute specifically noted that obviousness was to be determined "at the time the invention was made."<sup>42</sup> This language tracks well with the first-to-invent nature of the 1952 Patent Act. The statutory bars, however, created a bit of a wrinkle. The bars made the timing for some aspects of novelty at the critical date, not the invention date. The question arose, therefore, whether the statutory bars applied in the obviousness context notwithstanding the clear statutory language in  $\S$  103. In other words, one could argue that the statutory bars were limited to anticipation; an applicant could patent obvious variants of what may have been patented, in a printed publication, in public use, or on-sale.<sup>43</sup> Such an approach, of course, could lead to arbitrage, allowing applicants to begin to commercialize the invention yet still obtain patent protection on obvious variants. The Court of Customs and Patent Appeals ("CCPA"), a predecessor to the United States Court of Appeals for the Federal Circuit, clarified that the statutory bars could also be used in an obviousness determination.<sup>44</sup> Consequently, obviousness under the 1952 Patent Act, like anticipation, was effectively assessed as of the critical date, and not the invention date, unless the date of invention fell between the critical date and the filing date.

The AIA again simplifies this timing dynamic. Obviousness, like novelty, is now assessed as of the filing date. This shift in time should help mitigate potential hindsight bias during the prosecution process. Because obviousness is assessed as of the filing date, an examiner in the initial review of the patent application is closer in time to the relevant date. Hopefully this mitigates some concerns with the advancing state of the art. There remains, however, the hindsight bias issue of having the application in hand, which could serve as a roadmap through the prior art to make the inventor's contribution potentially seem less impressive.

Under the 1952 Patent Act, there was a gap in time for both novelty and non-obviousness. The snap shot in time for making these determinations was either the invention date or, if the invention date was more than a year before filing, effectively the critical date. Of

<sup>42. 35</sup> U.S.C. § 103(a) (1952 Act).

<sup>43.</sup> See id. § 102(b).

<sup>44.</sup> See In re Foster, 343 F.2d 980, 989 (C.C.P.A. 1965) (stating that the statutory bars may apply to obviousness inquiries). For a discussion of *Foster*, see Holbrook, *More Things Change*, supra note 14, at 988–90.

course, the filing date acted as the default invention date. In situations where the inventor could not show an earlier date of invention, the invention date became the filing date. But generally, and at least theoretically, there was a temporal gap between the date of assessment and the filing date. The gap created some complexity for hindsight concerns. Not only was the assessment of novelty and obviousness being made at an earlier date in time, any reconstruction of the state of the art as of the critical date or date of invention could not ensnare subsequent developments, which may be reflected in the application itself.

These temporal dynamics do not arise under the AIA. Both novelty and non-obviousness are assessed as of the filing date.<sup>45</sup> Third party public disclosures qualify for prior art for both novelty and nonobviousness so long as they are publicly accessible prior to the filing date.<sup>46</sup> Disclosures from the inventor made less than a year before the filing date do not count as prior art.<sup>47</sup> Inventors are thus given a oneyear grace period similar to the statutory bars under the 1952 Patent Act.<sup>48</sup> The grace period only impacts what materials may be considered in making the validity assessment. The law is clear that our snap shot in time is the filing date. As such, unlike the 1952 Patent Act, there is no gap in time between the date at which validity is assessed and the filing date. The system is much simpler.

The assessment of novelty and non-obviousness, however, both require consideration of the knowledge of the PHOSITA at a particular moment in time. The PHOSITA's knowledge is more formally part of the obviousness inquiry given the third factor articulated in *Graham v*. *John Deere*—the level of ordinary skill in the art.<sup>49</sup> Of course, the knowledge of the PHOSITA for obviousness purposes continues to evolve, potentially after the publication date of the prior art references used in the obviousness determination. This knowledge may not be reflected in the actual prior art considered as a result. Given the complex analysis entailed in assessing obviousness, this temporal dynamic is not as apparent.

But the PHOSITA's knowledge is also relevant in anticipation, often in underappreciated ways. Anticipation requires that each of the claim limitations be present expressly or inherently in a single prior art reference and that the reference enable the PHOSITA to make the

49. 383 U.S. 1, 17 (1966).

<sup>45. 35</sup> U.S.C. §§ 102–103 (AIA).

<sup>46.</sup> *Id.* § 102(a).

<sup>47.</sup> Id. § 102(b).

<sup>48.</sup> Id. Importantly, third party disclosures are no longer afforded such a grace period.

claimed invention.<sup>50</sup> At times, the knowledge of the PHOSITA is relevant in assessing whether a particular claim limitation is inherently present in the reference.<sup>51</sup> The Federal Circuit has noted, somewhat inconsistently, that contemporaneous appreciation of the inherent property by the PHOSITA is not required.<sup>52</sup> The enablement requirement, however, also involves the knowledge of the PHOSITA, as the reference must teach her how to make the claimed invention, permitting her knowledge to inform the inquiry into the sufficiency of the disclosure. As such, assessing enablement of a prior art reference entails combining the teachings of the reference with the knowledge of the PHOSITA.

The knowledge of the PHOSITA is a moving target. Between the effective date of a prior art reference and the subsequent assessment of novelty or non-obviousness, that knowledge likely will grow. The extent of such growth would be impossible to characterize across all technologies, but the diagrams in Section I use the lower triangles to demonstrate this dynamic. The implications, though, are significant. Someone reading a patent a few years after it issues may be able to glean far more from the disclosure than someone could back at the time of the original disclosure.<sup>53</sup> It is conceivable, therefore, that a disclosure that was not enabled at its effective prior art date could actually become

<sup>50.</sup> See, e.g., Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1336–37 (Fed. Cir. 2010) ("For a prior art reference to anticipate a patent, it must disclose each and every limitation of the claimed invention."); see also Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 931–36 (2011) (defining anticipation and discussing its requirements). The prior art need not enable how to use the claimed invention, with the exception of claims directed to methods of use or treatment. Recent cases have suggested there is also a requirement that the prior art disclose the limitations as arranged in the claim. See, e.g., Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008) ("Because the hallmark of anticipation is prior invention, the prior art reference . . . must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" (quoting Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983))). For a discussion explaining the bizarre and inapt development of this requirement, see Holbrook, supra note 29, at 1012–19.

<sup>51.</sup> See, e.g., Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) (noting that the inherent presence of a limitation must be "recognized by persons of ordinary skill"); see also Holbrook, supra note 29, at 1020–21 ("The PHOSITA, when reading such prior art, would recognize aspects of the invention as present even if not expressly stated.").

<sup>52.</sup> Toro Co. v. Deere & Co., 355 F.3d 1313, 1321 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art."). *But see* Holbrook, *supra* note 29, at 1023–25 (disagreeing with this rule and advocating a distinction between public uses and written prior art).

<sup>53.</sup> Cf. Timothy R. Holbrook, Equivalency and Patent Law's Possession Paradox, 23 HARV. J.L. & TECH. 1, 40–45 (2009) (arguing for an enablement-based approach to the doctrine of equivalents that ensnares later knowledge of the PHOSITA).

enabled later in time because the PHOSITA's knowledge has expanded to fill any such gap in knowledge.  $^{54}$ 

For the most part, modern case law fails to account for the fact that, because the knowledge of the PHOSITA expands over time, the nature of the prior art teaching also changes. This is particularly the case in the anticipation context. The cases focus almost exclusively on what the single prior art reference discloses without considering the broader implications of the state of the art.

Of course, taking greater account of the knowledge of the PHOSITA complicates the anticipation inquiry. First, consideration of the PHOSITA necessarily entails hindsight bias because the validity of the claim is being assessed later, during litigation or prosecution. Given the enablement aspect of anticipation, there is also a hindsight bias problem present in the anticipation inquiry—making sure we are not using a modern-day PHOSITA when assessing the enablement component of anticipation. Thus, there is a bias problem here, just as there is in the obviousness inquiry. Second, the analysis would require consideration of the growth of the knowledge of the PHOSITA between the effective prior art date and the date at which validity is assessed. Merely considering the disclosure of the prior art is technically insufficient for the analysis; a court should also assess subsequent knowledge that could supplement, or even complement, the prior art disclosure.

This dynamic is even more striking under the AIA. Under the 1952 Patent Act, the knowledge of the PHOSITA stops, at either the critical date or the invention date. Under the AIA, however, that knowledge continues to grow all the way to the filing date. Because that base level of knowledge is ever-expanding, the PHOSITA should be able to understand and to extrapolate more readily from the prior art. As a result, all things being equal, more things should be anticipated or obvious under the AIA than the 1952 Patent Act. While many have appreciated that a "first-inventor-to-file" system creates more pressure to file applications earlier, the literature has not recognized this additional, temporal pressure generated by the different timing of the obviousness and anticipation inquiry. The longer an inventor waits to file, not only is there the risk of more prior art references or another applicant filing first, but also the knowledge of the PHOSITA will

<sup>54.</sup> In re Donohue, 766 F.2d 531 (Fed. Cir. 1985). But cf. In re Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974):

If a disclosure is insufficient as of the time it is filed, can it be made sufficient, while the application is still pending, by later publications which add to the knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention? We think it cannot.

continue to expand, making it more likely the invention is anticipated or obvious regardless of the presence of new pieces of prior art.

The more recent law of anticipation has failed to account for the need for this additional information regarding the knowledge of the PHOSITA. Such knowledge would not be generated at the time of the prior art reference; instead, the relevant date would be that of the anticipation inquiry: either the invention date, the critical date, or the filing date. The Federal Circuit, however, has taken a fairly rigid approach to the "single reference" rule, relying solely on the information contained in the prior art reference and little else. Such limitations keep the inquiry rather straightforward and clear, as all the analysis focuses on the single prior art reference. But such myopic analysis also ignores the broader context of the analysis, particularly that of the PHOSITA and the state of the art.<sup>55</sup> It is possible that such knowledge is not reflected in a disclosure that qualifies as prior art. Nevertheless, it should be relevant to the inquiry as part of the assessment of the baseline knowledge of the PHOSITA.

There have been exceptions to the single-reference rule in the anticipation context. For example, the courts have made clear that a prior art reference can incorporate another by reference.<sup>56</sup> If the reference does so, then the court can consider that second reference as if it were a part of the first, thus not technically violating the single reference rule. As the Federal Circuit has explained:

[I]ncorporation by reference provides a method for integrating material from various documents into a host document—a patent or printed publication in an anticipation determination—by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.<sup>57</sup>

Incorporation by reference is, therefore, a particularly narrow exception to the single reference rule because, in effect, the second reference is a part of the single reference. Nevertheless, it does expand the information available to assess anticipation. Such knowledge, though, necessarily predates the primary reference, which means that it will

(quoting In re LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962)).

56. Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document.").

<sup>55.</sup> In re Sasse, 629 F.2d 675, 681 (C.C.P.A. 1980):

<sup>[</sup>T]he proper test of a description in a publication as a bar to a patent as the clause is used in section 102(b) requires a determination of whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought.

<sup>57.</sup> Id.

not reflect subsequent information of which the PHOSITA would be aware.

Inherency provides a second exception to the single reference rule. In order to prove that the missing subject matter is necessarily present in the prior art reference, courts can consider other evidence extrinsic to the prior art reference.<sup>58</sup> Of course, more recent cases have stepped away from the requirement that the PHOSITA appreciate the undisclosed information contemporaneously with the patent application.<sup>59</sup> Regardless, the party challenging the patent will need to provide evidence that the missing subject matter is necessarily present in the patent's disclosure, likely requiring the use of extrinsic evidence.<sup>60</sup>

There is, however, a third exception to the single-reference rule: proof of the knowledge of the PHOSITA. Importantly, this evidence need not qualify as prior art, such as being generally publicly available before the date of invention, critical date, or filing date (depending on under which regime a patent is prosecuted). Non-prior art references can be useful to inform the background state of the PHOSITA's knowledge.<sup>61</sup> Indeed, these references may arise *after* the prior art reference, so long as they are prior to or contemporaneous with the appropriate date for assessing novelty (or obviousness).<sup>62</sup> Such laterdated references are important to ensnare the ways in which the knowledge of the skill in the art may have evolved between the publication date of the prior art reference and the relevant date for assessing anticipation.

This important temporal dynamic can be seen in a variety of cases, where the courts made clear that references need not be published before the relevant piece of anticipatory prior art. For example, in *In re Samour*, the CCPA<sup>63</sup> dealt with the use of a second

<sup>58.</sup> Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence.").

<sup>59.</sup> Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art.").

<sup>60.</sup> See, e.g., Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1348 (Fed. Cir. 1999).

<sup>61.</sup> Seemingly this would also be relevant in the obviousness inquiry as well.

<sup>62.</sup> See Holbrook, supra note 29, at 1026–27 (stating that the USPTO and Federal Circuit relied on references that were filed after the prior art reference at issue).

<sup>63.</sup> The precedent of the CCPA is binding on the Federal Circuit unless overruled en banc or by the Supreme Court. *See* S. Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc) (holding that the holdings of the United States Court of Customs and Patent Appeals are binding as precedent on the Federal Circuit).

reference in the anticipation context.<sup>64</sup> The court recognized the appropriateness of using this reference to demonstrate that the anticipatory reference enabled the claimed invention, even though the enabling reference came after the anticipatory one:

[W]e do not believe that a reference showing that a method of preparing the claimed subject matter would have been known by, or would have been obvious to, one of ordinary skill in the pertinent art, must antedate the primary reference. The critical issue under 35 U.S.C. § 102(b) is whether the claimed subject matter was in possession of the public more than one year prior to applicant's filing date—not whether the evidence showing such possession came before or after the date of the primary reference.<sup>65</sup>

By using a reference that postdates the anticipatory reference, the CCPA implicitly endorsed the temporal dynamic discussed here. The later reference represented advances in the state of the art after the primary, anticipatory reference. Such growth in the knowledge of the PHOSITA is acceptable in this context.

In re Donohue demonstrates a similar temporal dynamic and also shows how later references, even those that do not count as prior art, can inform the anticipation inquiry.<sup>66</sup> The Federal Circuit relied on other references to assess whether the single prior art reference enabled the claimed invention.<sup>67</sup> As the court put it, "The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclosed in Nomura, was in the public's possession,"68 language used in earlier cases to describe the enablement aspect of anticipation. These other references included a patent that was filed three years after the prior art reference at issue and that issued five years after that reference. Like in *Samour*, the court's use of a more recent reference to demonstrate enablement would be inappropriate if the knowledge of the PHOSITA were not expanding over time. The combination of the earlier disclosure of all of the claim elements with a subsequent demonstration of enablement confirms that the knowledge of the PHOSITA expands over time. Such subsequent knowledge transforms the earlier reference into an enabled one, even if it was not enabled as of its publication date.

A more recent case confirms this temporal dynamic. In *In re Morsa*, the patent applicant challenged the anticipation conclusion of the USPTO on the ground that the reference was not enabled. The

<sup>64.</sup> In re Samour, 571 F.2d 559, 563 (C.C.P.A. 1978).

 $<sup>65. \</sup>quad Id.$ 

<sup>66. 766</sup> F.2d 531, 534 (Fed. Cir. 1985).

<sup>67.</sup> *Id.*; see also In re Donohue, 632 F.2d 123, 126 (C.C.P.A. 1980) ("Accordingly, the PTO's use of the Lincoln and Wagner references to show that a method of making Nomura's dicarboxylic acid TMBP and dimethyl ester TMBP was in possession of the public was proper.").

<sup>68.</sup> See Holbrook, supra note 29, at 1026 (citing In re Donohue, 766 F.2d at 534).

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Federal Circuit concluded that the reference was enabled, using the patent applicant's own disclosure as evidence. The applicant's disclosure, by definition, was subsequent to the prior art reference. Nevertheless, as the court noted, it demonstrated the knowledge of the PHOSITA as of the filing date:

[W]e do not use portions of the patent specification as prior art, but instead affirm the Board's use of one section in the specification solely as it relates to the knowledge of a person of ordinary skill in the art. There is a crucial difference between using the patent's specification for filling in gaps in the prior art, and using it to determine the knowledge of a person of ordinary skill in the art. Here, the Board did only the latter.<sup>69</sup>

Other cases have also permitted the use of such extrinsic evidence to demonstrate the knowledge of the PHOSITA, particularly to assess whether the anticipatory reference was enabling.<sup>70</sup> This is not to say that such evidence does not create complications, which may explain why the use of such evidence is rather rare in the present. Use of such evidence does create a quandary. As one judge noted:

[T]he difference between prior art and extrinsic evidence pertaining to common knowledge in a field is not always clear. Prior art and common knowledge seem to reside on the same spectrum, and the line between them blurs at a point. Common knowledge must often times be nothing more than that which is disclosed by prior art references that have been known for a substantial amount of time or extensively used.<sup>71</sup>

Technically, the jury should not rely on the teachings of such secondary references in assessing whether the reference discloses all of the claim limitations.<sup>72</sup> Moreover, as these other references need not be prior art under § 102, a court must be careful to keep those references distinct, particularly if the jury is also considering the issue of nonobviousness. Such pragmatic concerns, however, do not justify the exclusion of such information from the hands of the jury. Indeed, such references, which would be contemporaneous with the prior art (at the appropriate date), would seem no worse than the hindsight-biased assertions Such offers of experts. evidence an objective. contemporaneous source of evidence for the PHOSITA knowledge aspect of anticipation's enablement requirement.

<sup>69.</sup> In re Morsa, 803 F.3d 1374, 1378 (Fed. Cir. 2015).

<sup>70.</sup> In re '639 Patent Litig., 154 F. Supp. 2d 157, 174 (D. Mass. 2001), affd sub nom. SmithKline Beecham Corp. v. Copley Pharm., Inc., 45 F. App'x 915 (Fed. Cir. 2002).

<sup>71.</sup> Fenton Golf Tr. v. Cobra Golf, Inc., No. 97 C 247, 1998 WL 292997, at \*4 (N.D. Ill. May 28, 1998).

<sup>72.</sup> Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc., 726 F.2d 724, 727 (Fed. Cir. 1984): Dart relies on the Hall and Nash articles for a very specific teaching, not for any light they shed on what Fischer would have meant to those skilled in the art in his day. What Dart asked the trial court to do, and what it would have us do on appeal, is to combine the teachings of the references to build an anticipation. That would be contrary to settled law, and the trial court was correct in refusing to do so.

#### III. THE THIRD DATE: ASSESSING THE SUFFICIENCY OF A PATENT DISCLOSURE AS OF THE FILING DATE

The most typical concern about a patent's disclosure and time is the assessment of whether the specification adequately discloses the invention under 35 U.S.C. § 112(a). Relatedly, an applicant must also disclose the utility of the invention, which is mandated by 35 U.S.C. § 101. The courts have made clear, however, that utility is also part of the enablement inquiry: one cannot enable the PHOSITA to use an invention that has no use.<sup>73</sup>

Here, at a superficial level, the law is clear: the adequacy of the disclosure is assessed as of the filing date of the application.<sup>74</sup> This makes sense for a number of reasons. First, it assures that the inventor had actually completed the act of invention as of the filing date. Second, and relatedly, this temporal snap shot assures that, in subsequent patent applications, the applicant cannot add new matter, developed after the filing date, to bolster her claims. Because the standard is rooted in the PHOSITA, however, it also means that the standard for assessing the adequacy of a patent's disclosure is always shifting, evolving as the state of the art changes.<sup>75</sup>

The temporal snap shot has some variability, particularly in the context of litigation. For example, the assessment of whether the written description or enablement requirements have been satisfied is often tied to claim construction.<sup>76</sup> Claim construction, however, can be impacted by what arises after the filing date, including the original prosecution as well as subsequent reissuance, reexamination, or other post-issuance proceedings.<sup>77</sup> Nevertheless, one of the crystal rules in

<sup>73.</sup> Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1322–23 (Fed. Cir. 2005); *In re* Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999).

<sup>74.</sup> In re Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974) ("Since it is squarely raised here by appellant's contentions, we now rule that application sufficiency under § 112, first paragraph, must be judged as of its filing date.").

<sup>75.</sup> See Holbrook, *supra* note 35, at 806 ("By the time the litigation reaches the Federal Circuit, the state of the art will have evolved, particularly in rapidly developing technologies.").

<sup>76.</sup> See, e.g., Liebel–Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007) (invalidating claim because not enabled in part due to broad claim construction); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480 (Fed. Cir. 1998) (invalidating claims under written description requirement after affording them broad construction). See generally Holbrook, supra note 35, at 801–03 (discussing catch-22 for disclosure and claim construction and highlighting court's inappropriate preference for invalidity over narrower claim construction).

<sup>77.</sup> See, e.g., Markman v. Westview Instruments, Inc., 52 F.3d 967, 982 (Fed. Cir. 1995) (en banc) ("[T]he prosecution history of the patent on reissue conflicts with Markman's argument . . . ."), aff'd, 517 U.S. 370 (1996); ITT Mfg. Enters., LLC v. Cellco P'ship, No. 1:09-cv-190-LPS, 2011 WL 7121453, at \*6 (D. Del. Dec. 29, 2011) ("[T]he reexamination prosecution history is part of the intrinsic evidence which the Court can consult in construing these claims."); see also Glass, 492 F.2d at 1232 n.6 ("[W]hile later issuing patents or publications may not be relied upon

patent law is that enablement and written description are assessed as of the filing date.

The assessment of the disclosure is necessarily retrospective in both the prosecution and litigation contexts. As the Federal Circuit has noted, "[A]n enablement determination is made retrospectively, i.e., by looking back to the filing date of the patent application and determining whether undue experimentation would have been required to make and use the claimed invention at that time."<sup>78</sup> As others have recognized, the enablement inquiry is therefore subject to potential hindsight biases.<sup>79</sup> Although this bias may be different than in the obviousness context, where one could use the patent document as a map through the prior art, the bias does arise because the state of the art is always evolving.

When utility or enablement is challenged in litigation, there is a very significant hindsight problem. In litigation, assuming there is infringement, the invention necessarily did work. An infringer had to do something that would infringe, such as making, using, or selling the claimed invention. It is highly unlikely that there would be infringement of an inoperable, useless item.<sup>80</sup> Thus, at some point after the filing date, the utility of the invention has been demonstrated.<sup>81</sup>

This issue can also arise when a party is trying to claim the benefit of an earlier filing date. To do so, the disclosure must of course be the same as the later application. Moreover, and importantly, the earlier application must be enabled as of its filing date. It can be the case, given the temporal dynamics at play, that the relevant disclosure

to establish that the specification is enabling under § 112, paragraph one, reference may be made to such publications to construe claim language and in particular to prove the definiteness of claim terminology.").

<sup>78.</sup> Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (emphasis omitted).

<sup>79.</sup> See Holbrook, supra note 35, at 824 (finding that subsequent readers have a hindsight advantage in the enablement context).

<sup>80.</sup> Raytheon Co. v. Roper Corp., 724 F.2d 951, 959 (Fed. Cir. 1983) ("If a party has made, sold, or used a properly claimed device, and has thus infringed, proof of that device's utility is thereby established. People rarely, if ever, appropriate useless inventions.").

<sup>81.</sup> See, e.g., Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 F. App'x 917, 919 (Fed. Cir. 2011) (challenging drug approved to treat ADHD on utility grounds); Janssen Pharmaceutica N.V. v. Teva Pharm. USA, Inc. (*In re* '318 Patent Infringement Litig.), 583 F.3d 1317, 1323 (Fed. Cir. 2009) (challenging utility challenge of FDA approved drug for treating Alzheimer's disease); Petito v. Puritan's Pride, Inc., 35 F. Supp. 3d 494, 496 (S.D.N.Y. 2014) (challenging utility of a nutritional composition); CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at \*1 (N.D. Cal. Dec. 18, 2013) (challenging utility of "dietary supplements, containing olive-derived phenolic compounds intended to promote health"), *aff'd*, 579 F. App'x 1003 (Fed. Cir. 2014). I recognize that the latter two cases could be ones where the product is being sold even if there is no actual utility at all as there is some debate as to whether such supplements truly have the efficacies alleged, particularly if they have not gone through FDA approval.

may *become* enabled at a date after the earlier filing date.<sup>82</sup> Courts and USPTO tribunals, therefore, must guard against this potent hindsight problem: the invention eventually *did* work, but the proof required is whether such use was demonstrated as of the filing date.

The retrospective nature of assessing the adequacy of a patent's disclosure, and the attendant hindsight bias, creates issues for what type of evidence should be used in these evaluations. While courts have recognized obliquely the fear of hindsight bias in assessing the written description requirement,<sup>83</sup> the issue of evidence is not as problematic because the courts have emphasized the four corners of the document itself, with less emphasis on extrinsic evidence.<sup>84</sup>

For enablement and utility, however, the issue is different. Those doctrines depend on highly fact-intensive inquiries that depend on the state of the art and the knowledge of the PHOSITA.<sup>85</sup> As such, the USPTO and courts may have to rely on evidence outside of the intrinsic record to assess whether the patent adequately discloses a utility for the invention or provides an enabling disclosure. Evidence

84. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (noting written description "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed"); *see also Novozymes A/S*, 723 F.3d at 1347–51 (relying solely on disclosure to find patent invalid for lack of adequate written description). The Federal Circuit on occasion has relied on extrinsic evidence in assessing the written description requirement. *See, e.g.*, Vasudevan Software, Inc. v. MicroStrategy, Inc., 782 F.3d 671, 683–85 (Fed. Cir. 2015) (reversing grant of summary judgment of invalidity for lack of written description because the court found "the testimony of Dr. Cárdenas to at least raise a genuine issue of material fact on whether the specification shows how to achieve the functionality of accessing disparate databases"); Scriptpro, LLC v. Innovation Assocs., Inc., 762 F.3d 1355, 1361 (Fed. Cir. 2014) (relying on expert testimony to reverse summary judgment of invalidity due to disputed factual issues regarding sufficiency of written description).

85. The Federal Circuit, however, has emphasized that reliance on the knowledge of the PHOSITA is a rule of supplementation, not replacement, creating a strong incentive for applicants to include information in the patent specification. ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 941 (Fed. Cir. 2010) ("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."); Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283 (Fed. Cir. 2007) ("[T]he 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.'" (quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997))).

<sup>82.</sup> See, e.g., Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1324 (Fed. Cir. 2005) (rejecting that earlier filed application was enabledbut "conclud[ing], however, that as of the filing date of the ninth application, June 2, 1995, a person of ordinary skill in the art would have believed that 5AR inhibition could play a role in treating prostate cancer . . . .").

<sup>83.</sup> Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1345–46 (Fed. Cir. 2013) ("DuPont accuses Novozymes and its experts of relying on hindsight to work backward from the claims of the '23 patent, filed in 2009, to show that, given knowledge of the claimed invention, each limitation could be retroactively derived from the disclosure of the 2000 application.").

generated prior to the filing date is highly relevant to this inquiry because it affords a contemporaneous account of the state of the art.<sup>86</sup>

But what about evidence that is generated *after* the filing date? Should such evidence be allowed? One might think this question would have been addressed long ago. Surprisingly, the law is rather inconsistent as it relates to evidence generated post-filing used to demonstrate that specification *does* enable the claimed invention and adequately discloses its utility.<sup>87</sup> The filing date is important because the patent should reflect the inventor's contribution to the state of the art. Post-filing information could reflect a state of the art beyond that of the filing date. Just as we saw in the anticipation context, a disclosure that was not enabling as of its filing date could become enabled with later development in the field. Post-filing generated evidence could reflect such advances to the state of the art. The same is true with demonstration of utility: an inventor may only demonstrate the invention works subsequent to the filing date with such post-filing evidence.

In exploring this dynamic, it is important to categorize the postfiling evidence into three basic categories:<sup>88</sup> (1) affidavits reflecting what occurred prior to the filing of the application; (2) post-filing generated technical evidence demonstrating that the claimed invention lacks utility or is not enabled; and (3) post-filing generated technical evidence that the invention does have utility or that the disclosure is enabling. I consider each in turn.

# A. Post-filing Generated Affidavits and Testimony Relating to State of the Art as of the Filing Date Is (and Should Be) Routinely Permitted

During prosecution, applicants often submit affidavits for a variety of reasons, such as to prove an earlier invention date under the 1952 Patent Act<sup>89</sup> or, now under the AIA, to demonstrate an earlier

<sup>86.</sup> See, e.g., Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1372 (Fed. Cir. 1999) (relying upon "the inventor's own failed attempts to control the expression of other genes in prokaryotes or eukaryotes using antisense technology").

<sup>87.</sup> See Jacob S. Sherkow, Patent Law's Reproducibility Paradox, 66 DUKE L.J. (forthcoming 2017) (manuscript at 18–23), http://ssrn.com/abstract=2735181 [https://perma.cc/Q5QU-3B7E].

<sup>88.</sup> Technically, there is a fourth category of post-filing evidence: proceedings at the USPTO and other patent offices. *See, e.g., Enzo Biochem, Inc.*, 188 F.3d at 1375 ("Lastly, Enzo contends that the court ignored post-filing evidence proving enablement, including PTO and EPO conclusions of enablement."). These proceedings are generally assessing the patent's disclosure as of the filing date, such that, while technically post-filing, they should reflect the state of the art as of the filing date, in a manner akin to affidavits.

<sup>89. 37</sup> C.F.R. § 1.131 (2016).

disclosure of the invention to antedate a prior art reference.<sup>90</sup> The same efforts to antedate prior art can arise in litigation as well, though the evidence may come through deposition or witness testimony.<sup>91</sup> Applicants and inventors also use affidavits to demonstrate that their invention has utility or that the specification adequately enables the invention. At the USPTO, inventors can file evidence and affidavits.<sup>92</sup>

This evidence is routinely admitted and is uncontroversial because it relates to what occurred and the state of the art prior to the filing date. We do not expect perfect memorialization of everything that transpired prior to the filing date to be in the patent document and record. Indeed, such an approach would dramatically increase the disclosures to the USPTO and likely the cost. There are, of course, risks of faulty memory and potential hindsight bias concerns. Those concerns can be balanced by the amount of weight to afford the evidence. Moreover, in litigation, a party can challenge the recollection of witnesses through cross-examination. Nevertheless, evidence that informs the state of affairs as of, or prior to, the filing date is relevant and admissible.

## B. Evidence Generated Post-filing that the Invention Lacks Utility or Is Not Enabled Should Routinely Be Permitted

Another form of post-filing evidence is technical evidence, generated after the application has been filed, that the invention lacks utility or is not enabled by the specification. Experts may opine that the claims have not been sufficiently enabled. A party challenging the patent could also, for example, use evidence that someone tried—and failed—to practice the full scope of the invention as claimed based on the disclosure.<sup>93</sup> The courts have made clear that this evidence is routinely used to demonstrate lack of utility. For example, the courts relied upon post-filing publications in esteemed journals as evidence of

<sup>90.</sup> Id. § 1.130.

<sup>91.</sup> See, e.g., Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1337–40 (Fed. Cir. 2013) (discussing expert witnesses for both patentee and accused infringer).

<sup>92. 37</sup> C.F.R. § 1.132; U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107 (9th ed.).

<sup>93.</sup> See, e.g., In re Marzocchi, 439 F.2d 220, 223–24 (C.C.P.A. 1971) (noting use of "additional factors, such as the teachings in pertinent references... to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof"). The CCPA also noted that these references may "[n]ot necessarily [be] prior art references ... since the question would be regarding the accuracy of a statement in the specification, not whether that statement had been made before." Id. at 223 n.4. This language shows that post-filing references challenging the asserted utility or the sufficiency of the disclosure can be made, although it is not clear that the case itself dealt with post-filing evidence.

a lack of enablement.<sup>94</sup> In one case, the court relied on a publication five years after the application date to support its conclusion that claims in the patent were not enabled.<sup>95</sup> The Federal Circuit has also noted that the inventor's post-filing failed efforts to enable the full scope of the claim is relevant.<sup>96</sup>

Post-filing evidence of a lack of utility or enablement does not generate concerns about technological developments subsequent to the filing of the application. If such evidence demonstrates the lack of utility or enablement at some later date, then it is highly probative of whether the application adequately disclosed the utility or an enabling teaching as of the filing date. Even if the evidence does ensnare later advances in the field, it would then be particularly probative of a lack of utility or enablement at the time of filing, when the applicant did not have the benefit of those advances. In other words, if the PHOSITA cannot make or use the invention at a later date, it is hard to believe that she could have done so at the earlier filing date. The hindsight issue here is actually advantageous: later-generated evidence should bring into doubt the asserted utility or the sufficiency of the disclosure.

While this evidence is highly probative, it may also be difficult to get. During prosecution, the patent examiner will have little access to post-filing evidence unless it has been memorialized in some sort of printed publication. The patent applicant would have little incentive to provide post-filing evidence of a lack of enablement. In litigation, because there is an infringing device, seemingly the accused infringer had managed to make and use the invention, assuming infringement. An accused infringer's enablement challenge could be based on the failure of the specification to enable the full scope of the claim, even if a

96. MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1382 (Fed. Cir. 2012): Dr. Murdock's aggressive view of the scope of this invention, however, runs counter to his own testimony that the first junction with this level of resistive change was not developed until 2006 or 2007. It also does not explain why it took some twelve years after the '922 patent application was filed to achieve these results.

<sup>94.</sup> Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1376 (Fed. Cir. 1999) ("We agree with Calgene that citation of these articles in the declaration is as much a suggestion of nonenablement as enablement.").

<sup>95.</sup> In re Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993):

The Matthews et al. article, published approximately 5 years after the effective filing date of Wright's application, adequately supports the Examiner's and the Board's position that, in February of 1983, the physiological activity of RNA viruses was sufficiently unpredictable that Wright's success in developing his specific avian recombinant virus vaccine would not have led one of ordinary skill in the art to believe reasonably that all living organisms could be immunized against infection by any pathogenic RNA virus by inoculating them with a live virus containing the antigenic code but not the pathogenic code of that RNA virus.

particular embodiment was enabled.<sup>97</sup> Evidence that a party followed the teachings of the patent post-issuance but still needed undue experimentation to practice the invention is also relevant.<sup>98</sup> It is quite possible, though, that later investigation actually does contradict the asserted utility in the patent.<sup>99</sup> Post-filing evidence of a lack of utility, though, would seem difficult to obtain unless there was a considerable change in the state of the art between the filing date and the dates of infringement.

Post-filing evidence that the claim is not enabled or lacks utility is uncontroversial: even if the state of the art had evolved since the application date, the PHOSITA remains unable to practice the full scope of the claimed invention at a later date. This post-filing dynamic turns the hindsight bias into a benefit: even with a more knowledgeable PHOSITA, the patent disclosure fails to enable the PHOSITA to make and use the claimed invention.

# C. Should Evidence Generated Post-filing Be Permitted to Support a Conclusion that the Specification Is Enabled or that the Invention Has Utility?

Evidence generated after the filing date used to demonstrate that the patent lacks utility or an enabling disclosure is uncontroversial. The same cannot be said for post-filing evidence in support of utility or enablement. Because the appropriate time for assessing utility and enablement is the filing date, this evidence may reflect advances in the state of the art since the application was filed. As was noted in the anticipation context, a disclosure that at one point in time was not enabled could become enabled with technological

<sup>97.</sup> See, e.g., ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 943 (Fed. Cir. 2010) (noting that, while osmotic form was enabled, claim covered both osmotic and non-osmotic, resulting in lack of enablement as to the latter); Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007) (recognizing that patent enabled mechanical sensors but that "the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do"); Liebel–Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007). See generally Seymore, supra note 30, at 286 (discussing full-scope versus single-embodiment enablement).

<sup>98.</sup> Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("A party who wishes to prove that the claims of a patent are not enabled by means of a failed attempt to make the disclosed invention must show that the patent's disclosure was followed."); Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1367 (Fed. Cir. 1997) ("This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing HGH via cleavable fusion expression was not then within the skill of the art.").

<sup>99.</sup> See, e.g., Sherkow, supra note 87 (manuscript at 31–33) (discussing how subsequent investigation disproved asserted utility of Prempro to reduce cardiovascular disease).

advances. The same dynamic plays out here: the post-filing evidence may incorporate advances that would make the disclosure enabling *now* even though it was not enabled as of the filing date.

This problem is also particularly acute for utility. An applicant may have listed a utility in the application without actually demonstrating the invention works for its intended purpose. For example, an applicant could hypothesize that a drug has a particular effectiveness in treating a disease as of the filing date but may not have demonstrated that utility when the application is filed. The utility may be demonstrated after the filing date, but that dynamic suggests that the applicant simply filed too early.<sup>100</sup> She should have waited until there was sufficient proof of the invention's utility. Allowing post-filing evidence to demonstrate utility would reward a premature filer and prevent another party, who actually may have demonstrated the invention's utility, from getting the patent.

Post-filing technical evidence to demonstrate enablement or utility could come in various forms. A later publication could confirm the invention's utility or that the disclosure is enabling. In the prosecution context, the inventor is likely still working on developing the invention towards commercialization, so there may be additional, post-filing evidence that she herself generates that could be used to support the enabling disclosure or utility. The same could arise in litigation as well, where a party runs experiments after the filing date to show the invention's utility or that the disclosure is enabling.

Given the importance of this evidence, one might think that the law was clear on this issue. But, particularly in recent years, the courts have created uncertainty as to the use of such evidence. Generally, courts have rejected the use of such evidence. In 1995, however, the Federal Circuit appeared to create what one district court has deemed a "narrow exception"<sup>101</sup> to this rule.<sup>102</sup> In more recent cases, the Federal Circuit has stepped away from this exception.<sup>103</sup> Nevertheless, there

<sup>100.</sup> *Cf.* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1215 ("Further, because operable utility of pharmaceuticals is often evidentiary, utility can act as a timing lever if tests showing therapeutic effectiveness are allowed after the patent application is filed.").

<sup>101.</sup> CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at \*19 (N.D. Cal. Dec. 18, 2013) ("The Federal Circuit has created a narrow exception to the rule that post-filing data cannot support utility."), *aff'd*, 579 F. App'x 1003 (Fed. Cir. 2014).

<sup>102.</sup> See In re Brana, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995) (allowing post-filing data "to substantiate any doubts as to the asserted utility since [it] pertains to the accuracy of a statement already in the specification").

<sup>103.</sup> Janssen Pharmaceutica N.V. v. Teva Pharm. USA, Inc. (In re '318 Patent Infringement Litig.), 583 F.3d 1317, 1325 n.8 (Fed. Cir. 2009) ("The applicants also submitted animal testing results for the claimed compounds to the PTO after the filing date, but our finding of enablement

appears to be some uncertainty in the law, which merits consideration of the appropriate rule for the use of post-filing generated evidence to support enablement and utility.

The Federal Circuit's predecessor court, the CCPA, heard appeals out of the USPTO dealing with patentability issues. It is unsurprising, therefore, that it issued a variety of decisions dealing with evidence regarding enablement and utility. The CCPA was careful always to note that utility and enablement must be assessed as of the filing date. Some CCPA cases, therefore, demonstrate that the court generally rejected post-filing generated evidence. For example, in *In re Glass*, the applicant submitted four patents that issued after his filing date.<sup>104</sup> The court agreed with the USPTO's decision to refuse to consider them in assessing whether the claims in the patent were sufficiently enabled:

Appellant's attempt to use the disclosures of the four patents which issued after his filing date raises a subsidiary question: If a disclosure is insufficient as of the time it is filed, can it be made sufficient, while the application is still pending, by later publications which add to the knowledge of the art so that the disclosure, supplemented by such publications, would suffice to enable the practice of the invention? We think it cannot.<sup>105</sup>

The court noted the key problem with relying on such post-filing evidence: the subsequent publications add to the knowledge of the PHOSITA. Just as a prior art reference that initially was not enabled could *become* enabled subsequently, the court recognized that an unenabled patent specification could become enabled with subsequent knowledge. As the court noted, the applicant has an "obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file."<sup>106</sup>

The CCPA did carve out some exceptions for the use of post-filing publications for demonstrating the state of the art as of the filing date.<sup>107</sup> The CCPA was quick to emphasize, however, that such post-

did not depend on these post-application test results. In *Brana*, moreover, unlike the present case, the testing was submitted to the PTO during prosecution.").

<sup>104. 492</sup> F.2d 1228, 1232 (C.C.P.A. 1974). Technically, these patents would have qualified as prior art under the then-in-force 35 U.S.C. § 102(e), which allowed the use of an issued U.S. patent as a piece of prior art *as of its filing date*. Even though these four patents qualified as prior art under § 102(e), the court nevertheless rejected their use in assessing enablement. *Id.* at 1231–32.

<sup>105.</sup> Id. at 1232.

<sup>106.</sup> *Id*.

<sup>107.</sup> See In re Hogan, 559 F.2d 595, 605 n.17 (C.C.P.A. 1977) (delineating exceptions to the rule).

filing publications could not be used to demonstrate that an application's specification satisfied the enablement requirement.<sup>108</sup>

The Federal Circuit generally has maintained this proscription of evidence generated after the filing date to demonstrate utility or enablement, although not without some missteps. One example of an overstatement of the law arose in *Raytheon Co. v. Roper Corp.*<sup>109</sup> There, the court rejected the defendant's utility challenge in light of the party's infringement:

A correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under § 101.... If a party has made, sold, or used a properly claimed device, and has thus infringed, proof of that device's utility is thereby established. People rarely, if ever, appropriate useless inventions.<sup>110</sup>

Such a rule, however, allows post-filing evidence and ignores the timing of the utility and enablement inquiry, which is assessed as of the filing date.

The Federal Circuit itself appears not to view the *Raytheon* rule as "post-filing evidence." Instead, it appears to think of the rule as some form of estoppel. In *United States Steel Corp. v. Phillips Petroleum Co.*, the court relied on the *Raytheon* rule at one point in its opinion.<sup>111</sup> Yet, earlier in the decision, the court had to address the adequacy of the patent's disclosure to determine whether the patent holder could claim priority to an earlier filed application.<sup>112</sup> The court refused to consider

<sup>108.</sup> As the court noted in *Hogan*:

That approval does not extend, however, to the use of a later (1967, Edwards) publication disclosing a later (1962) existing state of the art in testing an earlier (1953) application for compliance with s 112, first paragraph. The difference may be described as that between the permissible application of later knowledge about art-related facts existing on the filing date and the impermissible application of later knowledge about later art-related facts (here, amorphous polymers) which did not exist on the filing date.

*Id.* at 605. The CCPA similarly noted such a use in *In re Koller*, 613 F.2d 819, 824–25 (C.C.P.A. 1980):

<sup>[</sup>T]he circumstances here do not fit any exception to the general rule that language in a specification is to be understood for what it meant to one having ordinary skill in the art at the time the application was filed.... In *Hogan*, an analysis using later-filed references to determine the scope of enablement was found to be impermissible. Similarly, it cannot be allowed when, as here, the description requirement is an issue.

<sup>109.</sup> Raytheon Co. v. Roper Corp., 724 F.2d 951, 959 (Fed. Cir. 1983); *accord* ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 507 (D. Del. 2013) ("Utility is proven where there is evidence of the patent claim's commercial success."), *aff'd*, 594 F. App'x 686 (Fed. Cir. 2015) (Rule 36 summary affirmance); Technicon Instruments Corp. v. Alpkem Corp., 664 F. Supp. 1558, 1580 (D. Or. 1986) ("If a court finds infringement of otherwise valid claims then a finding of utility as a matter of law is mandated."), *aff'd in part, vacated in part, rev'd in part*, 837 F.2d 1097 (Fed. Cir. 1987).

<sup>110.</sup> Raytheon, 724 F.2d at 959.

<sup>111. 865</sup> F.2d 1247, 1252 (Fed. Cir. 1989) ("The court's section 101 finding must be affirmed because we affirm, infra, the court's infringement finding.").

<sup>112.</sup> See 35 U.S.C. § 120 (2006):

evidence generated after the earlier filing date.<sup>113</sup> Thus, within the same decision, the court maintained its rule against post-filing evidence while, in a slightly different context, using the *Raytheon* rule to support its holding that the invention did not lack utility. The seeming inconsistency could be explained by the fact that the court considered the *Raytheon* rule to be a form of estoppel, preventing those who benefited from the invention (the infringers) from somehow later arguing it does not work.<sup>114</sup> But, as noted, the timing difference between infringement and validity brings this rule into considerable doubt. Unsurprisingly, the Federal Circuit has not relied upon this rule in over twenty-five years, and courts<sup>115</sup> and commentators have suggested it is wrong.<sup>116</sup>

Otherwise, with one exception, the Federal Circuit has maintained the line against using post-filing evidence to demonstrate utility or enablement. Unlike the CCPA, the Federal Circuit has also considered this issue in the context of infringement litigation. Nevertheless, the Federal Circuit has generally refused to consider post-filing evidence. For example, in *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.*, the Federal Circuit refused to consider post-

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

<sup>113.</sup> *Phillips Petroleum Co.*, 865 F.2d at 1252 ("Thus the district court correctly held defendants' evidence immaterial to the section 112, first paragraph inquiry. The central flaw in defendants' evidence, as recognized by the district court, is that it was directed solely to a later state of the art.").

<sup>114.</sup> See 1-4 CHISUM, supra note 28, § 4.04 (characterizing Raytheon as an estoppel).

<sup>115.</sup> The Central District of California has questioned this reasoning:

While the Federal Circuit has not expressly overruled this portion of *Raytheon*, it may be that the predictability of the different technical fields at issue in *Raytheon* and *In re* '318 Patent Infringement Litigation resulted in post-filing infringement being relevant to the utility analysis in one but not the other.

Tawnsaura Grp., LLC v. Maximum Human Performance, LLC, No. CV 12-07189 SJO (AGRx), 2013 WL 11011698, at \*7 n.2 (C.D. Cal. Sept. 12, 2013); *cf. In re* Hyatt, No. 87-1597, 1988 WL 57813, at \*1 (Fed. Cir. June 9, 1988) ("There is no question that the claimed invention can be built today. The legal question, however, is whether the disclosure in appellant's application would have enabled a person of ordinary skill in the integrated circuit are [sic] to make appellant's invention around December 1970.").

<sup>116.</sup> See 1–4 CHISUM, supra note 28, § 4.04 (noting Raytheon rule is "unsound"); ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 238–39 (LexisNexis 6th ed. 2012) (noting that Raytheon rule is wrong due to timing problem).

filing evidence regarding the suitability of other computer language translators when assessing whether the patent was enabled.<sup>117</sup>

Similarly, in Enzo Biochem. Inc. v. Calgene. Inc., the patent holder presented post-filing evidence to demonstrate enablement.<sup>118</sup> The evidence included publications in prestigious journals noting the success of the patented technology; however, the Federal Circuit noted these publications "arguably support a conclusion that of nonenablement" because "if the successes set forth in these articles .... were mere routine experimentation based on the written descriptions in the patent specifications, it is unlikely that they would have been published in such prestigious journals."<sup>119</sup> The court concluded that "the district court did not err in giving the post-filing evidence little weight" because "the fact that persons skilled in the art are able to practice the invention by the exercise of substantial experimentation well beyond the broad concepts that appear in the specifications is not probative of enablement."<sup>120</sup> Other courts also refused to consider post-filing evidence to demonstrate utility or enablement.<sup>121</sup>

The language in *Enzo*, of course, is not as strong as the line drawn by the CCPA, demonstrating there has been some slippage as to the prohibition on such evidence. This slight erosion is not surprising because the Federal Circuit began to carve out an apparent exception to the *Glass* rule. In *Gould v. Quigg*, a dispute over who was the first to invent the laser, the Federal Circuit confronted an issue about enablement.<sup>122</sup> An expert in the case had relied upon a post-filing date

713 F.2d 788, 791 (Fed. Cir. 1983) (citations omitted). The enablement problem arose because the specification disclosed only SPLIT, which was a trade secret and not publicly available, meaning that one skilled in the art could not practice the claimed invention. *Id.* at 790.

118. 188 F.3d 1362, 1375 (Fed. Cir. 1999).

120. Id.

122. 822 F.2d 1074, 1077-79 (Fed. Cir. 1987).

<sup>117.</sup> The court reasoned:

It is immaterial that commercial use made, and publications issued, after the October 1968 filing date of the '653 patent may have established the suitability of other language translators (e.g., ACTION, ADAPT, APT, AUTOSPOT, COMPACT and UNIAPT). A sufficient disclosure must exist as of the application filing date. That the listed language translators were not specifically identified at that time as suitable substitutes for SPLIT renders futile their citation by White in this case.

<sup>119.</sup> Id. at 1376.

<sup>121.</sup> For example, one district court detailed the appropriate role for a given patent as follows: We note that, while the original text of the '614 patent is available for assessing obviousness under 35 U.S.C. § 103 as of its March 1983 effective filing date, it is not evidence of what was generally known in the art as of that date and may not be used as of that date to supplement what are otherwise inadequate disclosures or priority proofs of others.

Eli Lilly & Co. v. Sicor Pharm., Inc., 705 F. Supp. 2d 971, 996 n.30 (S.D. Ind. 2010) (citation omitted), *aff'd*, 426 F. App'x 892 (Fed. Cir. 2011).

reference in assessing whether the disclosure was sufficiently enabled.<sup>123</sup> Acknowledging the *Glass* rule that "a later dated publication cannot supplement an insufficient disclosure in a prior dated application to render it enabling," the court nevertheless relied on the post-filing evidence because it "was not offered as evidence for this purpose" but rather "as evidence of the level of ordinary skill in the art at the time of the application and as evidence that the disclosed device would have been operative."<sup>124</sup> The district court, in the Federal Circuit's view, did not err in accepting the expert's testimony.<sup>125</sup>

Operability, of course, *is* part of the enablement/utility analysis. So, perhaps the court simply believed that the post-filing evidence merely confirmed, without any addition to the state of the art, that the invention would work as of the filing date. Moreover, the court relied upon the CCPA's decision in *In re Hogan* to support its conclusion.<sup>126</sup> Hogan, however, is rather inapt precedent. The examples in Hogan all related to post-filing evidence suggesting that the disclosure did not enable the claimed invention; the evidence was not presented to confirm or demonstrate enablement.<sup>127</sup> The former type of evidence is readily allowed, but the latter is problematic. The CCPA in Hogan was quick to emphasize that "[w]hatever may have been said en route to decision in these cases, the fact situation in none of them established a precedent for permitting use of a later existing state of the art in determining enablement under 35 U.S.C. § 112."<sup>128</sup> Notwithstanding the use of such inapposite precedent, the Federal Circuit created a small hole in the rule regarding post-filing evidence.

The Federal Circuit continued to create an exception to the postfiling evidence prohibition, most importantly in *In re Brana*. In *Brana*, the Federal Circuit addressed the utility of claimed compounds that the specification asserted had antitumor properties.<sup>129</sup> The Federal Circuit permitted post-filing evidence to be considered to bolster the applicant's argument that the specification was enabled. The court made clear that such post-filing evidence was permissible because it was used "to

128. Id.

<sup>123.</sup> Id. at 1078.

<sup>124.</sup> Id.

<sup>125.</sup> Id.

<sup>126.</sup> *Id.* (citing *Hogan* for proposition that "use of later publications as evidence of the state of the art existing on the filing date of an application").

<sup>127.</sup> In re Hogan, 559 F.2d 595, 605 n.17 (C.C.P.A. 1977). The court's examples of relevant post-filing evidence included: evidence that "undue experimentation would have been required," "a parameter absent from the claims was or was not critical," "that a statement in the specification was inaccurate," "that the invention was inoperative or lacked utility," "that a claim was indefinite," "or that characteristics of prior art products were known." *Id.* (citations omitted).

<sup>129.</sup> In re Brana, 51 F.3d 1560, 1562 (Fed. Cir. 1995).

substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification."<sup>130</sup> The

the accuracy of a statement already in the specification."<sup>130</sup> The evidence demonstrated the utility of the invention as of its filing date.<sup>131</sup> Even though the evidence was post-filing, it merely substantiated and confirmed the utility disclosed in the specification.

*Brana* is an odd case with respect to the post-filing evidence issue. The court's discussion of the post-filing evidence is technically dicta. The Federal Circuit held that the UPSTO failed to satisfy its initial burden of challenging the presumptively correct utility because the antitumor property of the claimed invention was not an "inherently unbelievable undertaking."<sup>132</sup> That conclusion was enough to decide the case, so there was no reason to consider the post-filing evidence. The court continued, however, explaining that, even if the USPTO had satisfied this initial burden, the applicants proffered sufficient evidence to convince the PHOSITA of the invention's utility.<sup>133</sup>

It is not clear what it means to "substantiate any doubts as to the asserted utility." If there are doubts, and there is no disclosure in the specification or through pre-filing sources, then likely the applicant filed prematurely. One could argue that such doubts should be resolved in favor of denying the patent, which would encourage applicants to demonstrate actual possession of the claimed invention. The *Brana* rule creates a narrow but unclear exception to the rule against the use of post-filing evidence to demonstrate utility or enablement.

Given the tension and uncertainty created by *Brana*, it is not terribly surprising that courts have stepped away from *Brana*, interpreting it narrowly. The Federal Circuit has expressly limited the holding of *Brana*. In *In re '318 Patent Litigation*, the Federal Circuit again faced the issue of the use of post-filing evidence to support the conclusion that the specification of the patent at issue was enabled.<sup>134</sup> The patent claimed a method of treating Alzheimer's disease using the chemical galanthamine.<sup>135</sup> The '318 patent's specification was thin—a mere one page in length—with little support demonstrating the drug could treat Alzheimer's.<sup>136</sup> During the prosecution of the patent, the applicant represented that animal model studies were underway, but those studies were not completed until after the patent issued.<sup>137</sup> The

137. Id. at 1322.

<sup>130.</sup> Id. at 1567 n.19.

 $<sup>131. \</sup> Id.$ 

<sup>132.</sup> Id. at 1566.

<sup>133.</sup> Id. at 1566–67.

<sup>134. 583</sup> F.3d 1317, 1325 (Fed. Cir. 2009).

<sup>135.</sup> Id. at 1320.

<sup>136.</sup> Id. at 1321.

Federal Circuit concluded that the district court was correct to reject those post-filing studies: "The results from the '318 patent's proposed animal tests of galantamine for treating symptoms of Alzheimer's disease were not available at the time of the application, and the district court properly held that they could not be used to establish enablement."<sup>138</sup>

In rejecting the use of these post-filing studies, the court distinguished *Brana*, effectively limiting it to its facts. The court noted that "[t]he applicants [in *Brana*] also submitted animal testing results for the claimed compounds to the PTO after the filing date, but our finding of enablement did not depend on these post-application test results,"<sup>139</sup> The court thus recognized that the language in Brana regarding post-filing evidence was dicta because it was not necessary to the holding in the case that the specification was enabled. The court also noted that the applicant in Brana submitted the testing data during the prosecution of the application.<sup>140</sup> In contrast, in the case before it, the patentee never submitted the evidence to the USPTO during prosecution; instead, it was used only in litigation.<sup>141</sup> The Federal Circuit did not elaborate on the importance of this prosecution versus litigation distinction. A possible explanation is that the studies in *Brana* ultimately became a part of the prosecution history and thus part of the public record. In In re '318 Patent Litigation, the evidence was private to the patent holder, only coming to light during litigation. Regardless, the Federal Circuit in In re '318 Patent Litigation limited the holding of Brana.

District courts have interpreted *Brana* and similarly have viewed it as somewhat aberrational. One district court, in *CreAgri, Inc.* v. *Pinnaclife, Inc.*, addressed the utility of compounds alleged to have anti-inflammatory qualities in the patent.<sup>142</sup> The court recognized the danger if *Brana*'s "narrow exception" was given too much reach: "Read too broadly, however, the *Brana* exception would swallow the rule that '[e]nablement, or utility, is determined as of the application filing date.' "<sup>143</sup> The court attempted to explain the contours of the *Brana* rule by reasoning that "[w]here actual results, garnered post-filing, mirror or otherwise substantiate predicted results, it is plain that those results will pertain to the accuracy of a statement in the specification within

<sup>138.</sup> Id. at 1325.

<sup>139.</sup> Id. at 1325 n.8.

 $<sup>140. \</sup> Id.$ 

<sup>141.</sup> Id. at 1322, 1325 n.8.

<sup>142.</sup> CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at \*17–21 (N.D. Cal. Dec. 18, 2013),  $af\!\!fd$ , 579 F. App'x 1003 (Fed. Cir. 2014).

<sup>143.</sup> Id. at \*19 (quoting In re Brana, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995)).

the meaning of *Brana*."<sup>144</sup> The district court, however, ultimately rejected the proffered post-filing evidence in *CreAgri*, noting, "[T]he [patent at issue] makes no assertions whatsoever regarding the outcomes of the proposed studies, so the study designs provided in the specification are not sufficiently prophetic such that later-achieved results can support the utility of the claimed invention."<sup>145</sup>

The Federal Circuit, however, has relied on the Brana rule subsequent to its decision in In re '318 Patent Litigation, albeit in a nonprecedential decision. In Eli Lilly & Co. v. Actavis Elizabeth LLC, the claimed method of treating patent at issue a attentiondeficit/hyperactivity disorder ("ADHD") with the drug atomoxetine.<sup>146</sup> This drug had previously been studied as an antidepressant, and while its safety in humans had been demonstrated, it failed to provide the sought-after medical benefits.<sup>147</sup> At the filing date, the inventors were not certain that the drug would be successful in treating ADHD.<sup>148</sup> They received FDA approval for clinical tests to evaluate the drug's efficacy for treating ADHD, and the applicant filed its application eight days later.<sup>149</sup> The data from the investigation, however, were not obtained until after the applicant filed.<sup>150</sup> During prosecution, the examiner at the USPTO never requested additional evidence of utility.<sup>151</sup>

The district court invalidated the patent for lack of utility, but the Federal Circuit reversed.<sup>152</sup> In addressing whether the post-filing clinical study results could be used, the court relied upon the *Brana* exception to permit such use.<sup>153</sup> The court noted that "[w]hen priority is not at issue, generally the applicant may provide data obtained either before or after the patent application was filed."<sup>154</sup> Here, like in *Brana*,

147. Eli Lilly, 435 F. App'x at 919-20.

148. *Id.* at 923 (noting inventor testimony stating the treatment was "a hypothesis" and that he "wasn't sure at all that it would work").

149. Id. at 920.

150. Id.

154. Id.

<sup>144.</sup> Id.

<sup>145.</sup> Id. (citations omitted).

<sup>146. 435</sup> F. App'x 917, 919 (Fed. Cir. 2011). In the interest of full disclosure, this case is at issue in an international arbitration between Eli Lilly & Co. and the government of Canada. I served as an expert for the government of Canada. *See* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Case Details (2016), https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&tab=DOC [https://perma.cc/SX7Q-7B8Q] (including Expert Report of Timothy R. Holbrook).

<sup>151.</sup> *Id.* at 924 ("During examination of the '590 application, the patent examiner did not require the submission of data showing treatment of ADHD with atomoxetine, although it is not disputed that such data were obtained shortly after the patent application was filed.").

<sup>152.</sup> Id. at 919.

<sup>153.</sup> Id. at 925.

the court reasoned that the post-filing experimental data only confirmed the speculated utility disclosed in the specification.<sup>155</sup>

The reasoning of this decision, beyond the post-filing issue, is thin and, at times, factually inaccurate. In particular, it is in considerable tension—if not utterly inconsistent—with the court's earlier decision in *In re '318 Patent Litigation*, particularly with respect to the post-filing rule.<sup>156</sup> The court never addressed the fact that the *In re '318 Patent Litigation* panel limited the holding of *Brana* in a binding, precedential decision.<sup>157</sup>

Much of the court's reasoning is troubling. The district court discussed the Federal Circuit's decision in *Rasmusson v. SmithKline Beecham Corp.*<sup>158</sup> extensively.<sup>159</sup> *Rasmusson* did not deal with the issue of post-filing generated evidence of utility. Instead, the issue in the case was whether one of the competing inventors in an interference was entitled to use an earlier filing date to demonstrate priority.<sup>160</sup> The invention was a method of treating prostate cancer using the chemical finasteride.<sup>161</sup> To claim that earlier filing date, the party needed to demonstrate that, at the time of that application, enablement and utility had to be demonstrated as of that filing date.<sup>162</sup> The Federal Circuit held that, as of the earlier filing date, the utility would not have been believed by the PHOSITA, meaning the application failed both the utility and enablement requirements.<sup>163</sup> Importantly, this is true *even though* this utility was subsequently proven.<sup>164</sup> The Federal Circuit reasoned:

If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor"

- 162. Id. at 1322–23.
- 163. Id. at 1324-25.
- 164. Id. at 1324:

<sup>155.</sup> Id. at 926.

<sup>156.</sup> See Sherkow, supra note 87 (manuscript at 20) ("Reconciling these two cases—and developing a working standard for when enablement can be demonstrated with post-application evidence—remains difficult.").

<sup>157. 583</sup> F.3d 1317, 1325 n.8 (Fed. Cir. 2009).

<sup>158.</sup> Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318 (Fed. Cir. 2005).

<sup>159.</sup> Eli Lilly & Co. v. Actavis Elizabeth LLC, 731 F. Supp. 2d 348, 382-84 (D.N.J. 2010).

<sup>160.</sup> *Rasmusson*, 413 F.3d at 1322 ("Rasmusson therefore sought priority on the basis of his first, second, and third applications . . . .").

<sup>161.</sup> Id. at 1320.

The Board concluded, however, that as of the filing date of the ninth application, June 2, 1995, a person of ordinary skill in the art would have believed that 5AR inhibition could play a role in treating prostate cancer in light of a presentation made by Dr. Ruben Gittes at the American Urological Association in August 1994, in which he reported successful results from treating prostate cancer with finasteride.

would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis. $^{165}$ 

The *Eli Lilly* panel dismissed the district court's reliance on *Rasmusson* off-hand and inaccurately by noting, "[T]he district court relied on patent 'interference' cases, as in [*Rasmusson*], where evidence of actual reduction to practice was required to establish a priority date earlier than that of an adverse claimant."<sup>166</sup> This statement is factually wrong on two levels. First, the district court did not rely on "plural" patent interference cases: it relied on one (extensively), *Rasmusson*. The district court otherwise only cited decisions from infringement cases or ex parte appeals from the USPTO. Far more importantly, however, is the erroneous statement that the issue was "evidence of actual reduction to practice." *Rasmusson* had nothing to do with actual reduction to practice. Instead, the entire decision was whether one party's earlier application was enabled as of its filing date.<sup>167</sup> So, the court was simply wrong about the nature of the case.

The court, without discussing the reasoning of *Rasmusson* at all, distinguished the case solely on the basis that it was an interference case without offering any reason as to why that distinction matters. Based on that distinction, and without a discussion of the language in In re '318 Patent Litigation, the court concluded that post-filing evidence could be used.<sup>168</sup> There are, of course, some distinctions between patent infringement litigation and interference proceedings that could be relevant—such as the fact that the burden of proof differs in litigation from that of an interference. But the court never addressed that issue and, of course, that distinction also applies to exparte appeals from the USPTO, like *Brana*, upon which the court relied upon extensively. Moreover, the court ignored that the In re '318 Patent Litigation panel also relied on Rasmusson, so seemingly the earlier panel did not view the case as inapposite to an infringement case.<sup>169</sup> Such inaccuracies could lead one to question the overall reasoning of the case.

The court in *Eli Lilly* also failed to consider the language in *Rasmusson* and *In re '318 Patent Litigation*, suggesting that more than a mere hypothesis would be needed to demonstrate utility. As noted

<sup>165.</sup> Id. at 1325.

<sup>166.</sup> Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 F. App'x 917, 925 (Fed. Cir. 2011).

<sup>167.</sup> Rasmusson, 413 F.3d at 1322–23.

<sup>168.</sup> *Eli Lilly*, 435 F. App'x at 925 ("When priority is not at issue, generally the applicant may provide data obtained either before or after the patent application was filed.").

<sup>169.</sup> Janssen Pharmaceutica N.V. v. Teva Pharm. USA, Inc. (*In re* '318 Patent Infringement Litig.), 583 F.3d 1317, 1327 (Fed. Cir. 2009).

above, *Rasmusson* rejected "mere plausibility" as the test for utility and enablement.<sup>170</sup> The court in *In re '318 Patent Litigation* similarly reasoned that a specification that does no more than "state a hypothesis and propose testing to determine the accuracy of that hypothesis" is insufficient,<sup>171</sup> which is, according to the inventors in *Eli Lilly*, the state of their invention as of the filing date.

Of course, *Eli Lilly* is a non-precedential decision and does not establish any law. Its broad statement regarding the use of post-filing evidence cannot be relied upon by future parties or panels as a correct statement of the law. Moreover, the decision was by a two-judge panel, and we do not know what the views of the original third judge may have been.<sup>172</sup> The most favorable reading of the *Eli Lilly* decision is that the court merely viewed the case as falling somewhere between *Brana* and *In re '318 Patent Litigation*, with the court concluding that, on the facts before it, the case was closer to *Brana*.<sup>173</sup> Such reasoning would support the non-precedential status of the decision.

Even if that is the case, the panel's failure to engage with either the legal standards or the reasoning of *In re '318 Patent Litigation* and *Rasmusson* renders its reasoning suspect. And, just like *Brana*, the ultimate holding of the case is that the specification was sufficient without consideration of the post-filing evidence, meaning that the discussion of this evidence was not necessary to the outcome. Ultimately, I am agnostic as to the outcome of the case; the decision on validity may be correct. Nevertheless, the reasoning is flawed. The decision, however, is non-precedential, so its holding has no reach beyond the parties to the litigation.

This discussion then leads to the question about what should be the appropriate treatment of post-filing generated evidence supporting utility or enablement. This Section explores a variety of options.

173. The court distinguished *In re '318 Patent Litigation*, using its alternative name *Janssen Pharmaceutica N.V. v. Teva Pharmaceuticals USA, Inc.*, as follows: "In the case of atomoxetine, however, the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimental verification had been obtained before the patent was granted, and the examiner had not requested additional information." *Eli Lilly*, 435 F. App'x at 926; *cf.* CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at \*20 n.19 (N.D. Cal. Dec. 18, 2013) (distinguishing case before it from *Eli Lilly* based on its facts), *aff'd*, 579 F. App'x 1003 (Fed. Cir. 2014).

<sup>170.</sup> Rasmusson, 413 F.3d at 1325.

<sup>171.</sup> In re '318 Patent Litigation, 583 F.3d at 1327.

<sup>172.</sup> The third judge, Judge Friedman, passed away after oral argument; the court decided the case with two judges pursuant to its internal rules. *Eli Lilly*, 435 F. App'x at 919 n.\*; *see also* FED. CIR. R. 47.11 ("If a judge of a panel that has heard oral argument or taken under submission any appeal . . . is unable to continue with consideration of the matter because of death . . . the remaining judges will determine the matter if they are in agreement and no remaining judge requests the designation of another judge.").

#### 1. Maintain the Current Brana Exception

One approach to the issue would be to retain the *Brana* exception. The courts or the USPTO would have to carefully police the *Brana* line to ensure that any post-filing evidence is tied to the specification language and reflects the state of the art as of the filing date. As one court has noted, "Where actual results, garnered post-filing, mirror or otherwise substantiate predicted results, it is plain that those results will pertain to the accuracy of a statement in the specification within the meaning of *Brana*."<sup>174</sup>

Of course, the *Brana* rule presents a variety of complications. It is not clear how to police that line. As that same court noted, the exception could swallow the filing date rule if read too broadly.<sup>175</sup> As demonstrated by its efforts to limit the holding in *Brana*, the Federal Circuit itself appears to recognize the problems with the *Brana* exception.<sup>176</sup> The line drawn in *Brana* would be difficult to monitor to ensure that any post-filing generated evidence does not ensure subsequent technical developments and advances in the relevant technology. A broad *Brana* rule would also permit an applicant to speculate as to the utility in a patent application and then subsequently confirm it. That would allow premature patent filing and award patents to parties who had not actually completed the invention. The confusion surrounding what qualifies under this rule renders it a problematic approach to the issue.

# 2. Take In All Relevant Evidence and Weigh for Its Probative Value

One option is to evaluate the evidence and determine what weight to afford it, per a traditional evidentiary approach. If evidence comes in that does not incorporate later advances in the art or additional investigation, then it could be used appropriately to evaluate the disclosure. For example, if someone has simply practiced the teachings of the patent without bringing to bear any additional knowledge or skill, then such evidence could be relied upon. This approach would be an expansion of the *Brana* exception because there would be no need to inquire whether the evidence is tied to particular statements of utility in the patent specification. Instead, the evidence would simply be evaluated for its probative value; statements in the specification would be relevant in the overall assessment, but no direct tie to that language would be needed.

<sup>174.</sup> CreAgri, 2013 WL 6673676, at \*19.

<sup>175.</sup> Id.

<sup>176.</sup> See In re '318 Patent Litigation, 583 F.3d at 1325 n.8.

Of course, this approach becomes very much a muddy standard. Courts and the USPTO would have to make case-by-case assessments of whether the evidence reflects advances in the state of the art. This approach could also present challenges for the factfinder, particularly if the evidence goes to the jury. Indeed, it presents the same linedrawing issue of *Brana*: When is evidence merely confirming something in the specification versus reflecting inappropriate supplementation?

This approach also reduces incentives for applicants to generate data prior to filing and to disclose such data to the USPTO. Applicants could file arguably before they know their invention has utility and hold off on obtaining data until a later date only if and when the USPTO or someone in litigation challenges the patent. Encouraging timely disclosure of such information could enhance the public record on the invention if it is included contemporaneously with the patent application.

# 3. Sliding Scale Based on Gap Between Filing and Experiment

Another approach would be to vary the weight provided to postfiling evidence by the length of time between the filing date and the date of the studies. For example, if, as in *Eli Lilly*, the study was approved prior to the filing date and the data developed shortly thereafter, then the evidence would be given greater weight. In contrast, evidence, such as in *In re '318 Patent Litigation*, which was not available until after the patent issued, would be given little, if any, weight. The sliding scale would thus act as a proxy for the state of the art: the closer to the filing date, the less likely the evidence would reflect an advance in the state of the art. It would be similar to the traditional evidentiary approach in that the evidence would not be per se rejected. Instead of doing a traditional analysis of weight, time would be used as a proxy for advances in the state of the art. This approach would create an incentive for applicants to generate data supporting enablement or utility as close to the filing date as possible.

The problem with this approach involves how to properly give differential weight to the evidence. Of course, utility and enablement are fact-intensive inquiries, so adding the sliding scale to the mix may not complicate the analysis too much. But it is not clear how a factfinder, particularly a jury, could perform this duty. Moreover, using time as a proxy may not be a good fit. Some fields advance more rapidly than others. Thus, a one-year gap in one field may result in little change in the state of the art or the knowledge of the PHOSITA, whereas a year in another field could ensnare a considerable amount of technological advance. While the traditional evidentiary approach could in theory capture this dynamic, the temporal sliding scale would not. As such, the use of time as a proxy may not be appropriate to police the timing concerns of such post-filing evidence.

## 4. Permit Post-filing Generated Evidence Only During Prosecution

Another approach to post-filing evidence would be to allow such evidence during the initial prosecution of the patent but to preclude it in litigation. This dichotomy was suggested by the Federal Circuit in In re '318 Patent Litigation.<sup>177</sup> The distinction also acts somewhat akin to the temporal sliding scale approach. By nature, evidence submitted during prosecution will be more contemporaneous with the state of the art at the filing date. Evidence during litigation could be generated much later. This method would create a relatively bright-line rule that would be easy to follow. Examiners at the USPTO would be able to readily accept post-filing generated evidence to support enablement or utility, but a patent holder could not use such evidence in litigation. This rule has the advantage of encouraging the generation and disclosure of such evidence during the prosecution process. Because such evidence becomes part of the prosecution history, it also becomes part of the public record. Allowing such evidence into the public record could enhance the understanding of both the patent itself and potentially the invention more broadly.

There are a number of problems with this approach. Of course, prosecution may take a considerable amount of time, even years. So, this rule could risk evidence being used during prosecution that actually ensnares later developments in the art. Moreover, this approach could ultimately be rather unfair to patent applicants. The asserted utility and disclosure are presumed to be accurate, so the burden is on the USPTO examiner to provide evidence challenging the utility or enablement.<sup>178</sup> Until the examiner does so, applicants are not required to submit any evidence in support of utility or enablement. An applicant may not be asked to submit evidence to support enablement

For an argument to modify the presumption of patentability at the USPTO, see Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 1023 (2013).

<sup>177.</sup> Id. ("[U]nlike the present case, the testing was submitted to the PTO during prosecution.").

<sup>178.</sup> In re Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971):

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

or utility during the prosecution process.<sup>179</sup> Under this rule, such evidence would be barred from litigation. Thus, due to no fault of the patent holder, the evidence would simply never be considered by either the USPTO or courts.<sup>180</sup>

As a result, the prosecution/litigation dichotomy creates a somewhat arbitrary line that could work unfairness to patent holders. This rule also would create an asymmetry: accused infringers could rely upon post-filing evidence that the patent is not enabled or lacks utility, but the patent holder would be somewhat handcuffed in rebutting such evidence. Of course, the patent holder could challenge the accused infringer's evidence on some other basis, such as demonstrating that the infringer's expert failed to follow the teaching of the patent. But it could make rebutting such evidence more difficult for patent holders.<sup>181</sup>

5. Complete Prohibition on All Post-filing Evidence

A final possibility for addressing post-filing generated evidence to support the demonstrated utility or enablement of a patent is to simply prohibit its use. As discussed above, the case law generally favors this approach, particularly after *Glass*.<sup>182</sup> The Federal Circuit, after its detour in *Brana*, appears to be moving back in this direction. The reasoning for this rule would be as the court in *CreAgri* explained in limiting the *Brana* exception: "Read too broadly, however, the *Brana* exception would swallow the rule that '[e]nablement, or utility, is determined as of the application filing date.' "<sup>183</sup>

This rule has the benefit of being crystal clear: no post-filing generated evidence supporting utility or enablement would be permitted. As such, it would be easy to administer and would preclude any risk of such evidence reflecting subsequent technological developments. Additionally, this rule would level the playing field during the prosecution of an application. The USPTO presently faces difficulty in raising utility and enablement challenges because it is not

<sup>179.</sup> *See, e.g.*, Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 F. App'x 917, 924 (Fed. Cir. 2011) ("During examination of the '590 application, the patent examiner did not require the submission of data showing treatment of ADHD with atomoxetine, although it is not disputed that such data were obtained shortly after the patent application was filed.").

<sup>180.</sup> It likely would be relevant to approval at the Food and Drug Administration, however.

 $<sup>181. \</sup>$  Of course, if the patentee had generated pre-filing data or evidence, then there is no issue at all.

<sup>182.</sup> See supra notes 104–128 and accompanying text (discussing the use of post-filing evidence).

<sup>183.</sup> CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at \*19 (N.D. Cal. Dec. 18, 2013) (quoting *In re* Brana, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995)), *aff'd*, 579 F. App'x 1003 (Fed. Cir. 2014).

in an easy position to generate evidence to challenge a patent applicant's assertions of utility and enablement. Any representations in the application are viewed as presumptively correct; it is incumbent on the patent examiner to proffer evidence to challenge these assertions.<sup>184</sup> As Professor Sean Seymore has elaborated:

[T]he fact still remains that an examiner who questions enablement still bears the burdens of both building a prima facie case of nonenablement and carrying the ultimate burden of persuasion on the issue. These burdens tip the scales toward patent issuance not only because of the examiner's time pressures and incentives . . . but also because "[i]t is actually very difficult to offer rigorous proof that something cannot be done . . . ." Thus, it is easy to see how dubiously enabled patents (and thus, patents of dubious quality) can slip through the cracks.  $^{185}$ 

Given the difficulty the USPTO faces in challenging even dubious assertions of utility and enablement, it would seem even more troubling to permit an applicant to rely on post-filing generated evidence. Prohibiting such evidence would serve to level the playing field slightly for the USPTO.

The prohibition on such evidence also provides a strong incentive for potential applicants to prepare such evidence in advance of filing.<sup>186</sup> This incentive should facilitate more robust patent applications and disclosures. Commentators have bemoaned the fact that applicants are currently rushing to the USPTO prematurely, a problem compounded under the AIA's first-inventor-to-file regime. Some commentators have gone as far as arguing that there should be a requirement for an actual reduction to practice or the presence of more working examples prior to filing an application.<sup>187</sup> A rule barring supportive post-filing generated evidence is a softer variant of this approach, as it would encourage applicants to complete testing prior to filing or risk losing the ability to use such evidence to support the patent's disclosure. In other words, this rule would create some drag on

<sup>184.</sup> In re Brana, 51 F.3d at 1566; In re Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971).

<sup>185.</sup> Seymore, supra note 178, at 1020–21 (quoting Arthur Kantrowitz, Proposal for an Institution for Scientific Judgment, 156 SCIENCE 763, 764 (1967)).

<sup>186.</sup> *See* Risch, *supra* note 100, at 1212 (noting "timing is critically important to utility's role as a policy lever").

<sup>187.</sup> See, e.g., Christopher A. Cotropia, The Folly of Early Filing in Patent Law, 61 HASTINGS L.J. 65, 120 (2009):

Patent rules need to increase the amount of invention information and certainty as to invention value available to an inventor prior to patenting. Doing away with constructive reduction to practice and, in turn, requiring all applicants to actually reduce their invention to practice . . . before receiving a patent is the specific front-end response explored below;

*cf.* Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 156 (2008) ("I propose that an application which lacks working examples or is supported by prophetic examples is prima facie nonenabled because it raises an inference that undue experimentation is required in order to practice the invention.").

the race to file and create an incentive for greater pre-filing development of the invention.

This rule would be similar to the rule that prohibits new matter from entering into a patent application. While applicants can amend their claims, they cannot add new subject matter into patent applications.<sup>188</sup> The only way an applicant can get new matter into a patent application is to file a continuation-in-part application,<sup>189</sup> but she will forfeit her earlier filing date for that new matter.<sup>190</sup> The rule is a clear one. A ban on post-filing generated evidence of utility or enablement would operate similarly, ensuring that the patent application is properly assessed as of its filing date.

Indeed, ensuring that the research backing the asserted claim and enabling disclosure can help to avoid some potential social costs. Professor Jacob Sherkow has identified this problem in the pharmaceutical context and has suggested that, even with some regulatory self-correction mechanisms, patents with dubious disclosures generate social costs.<sup>191</sup> He argues that the race to file earlier patents skews innovation incentives, particularly in favor of maximizing life spans of patients as opposed to preventative or earlystage technologies.<sup>192</sup> Other harms include an incentive not to share clinical data and disruptions in the innovation incentives for potential competitors, who may not pursue a line of research in light of a patent on an unproven utility.<sup>193</sup> These patents could be "weaponized" to prevent competition even when the utility is dubious.<sup>194</sup> By requiring only pre-filing evidence, there is a much stronger incentive for applicants to demonstrate the utility and enabling disclosures more robustly, mitigating some of these concerns.

190. Waldemar Link, GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994): A CIP application can be entitled to different priority dates for different claims. Claims containing any matter introduced in the CIP are accorded the filing date of the CIP application. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application.

- 193. Id. (manuscript at 41-42).
- 194. Id. (manuscript at 43).

 $<sup>188.\ 35</sup>$  U.S.C. § 132 (2012) (AIA) ("No amendment shall introduce new matter into the disclosure of the invention.").

<sup>189.</sup> PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1304 n.3 (Fed. Cir. 2008) ("While the PTO has noted that the expressions 'continuation,' 'divisional,' and 'continuation-in-part' are merely terms used for administrative convenience... the quintessential difference between a continuation and a continuation-in-part is the addition of new matter.").

<sup>191.</sup> See Sherkow, supra note 87 (manuscript at 40).

<sup>192.</sup> Id. (manuscript at 41).

With any bright-line rule, there may be a cost in terms of fairness to the applicant.<sup>195</sup> It is quite possible that some post-filing generated evidence does not reflect any advances in the state of the art. The mere march of time does not guarantee that such advances will be reflected in the evidence. Given that some fields may evolve slowly, the later-developed evidence could truly be indicative of the state of the art as of the filing date. Moreover, evidence that someone successfully followed the precise teachings of the application after the filing date would be rejected, regardless of any changes in the state of the art. Indeed, the line is very sharp. A publication or test performed one day prior to the filing date would be permissible, but the same evidence filed the day after would not.

Overall, notwithstanding the potential for such unfairness, the complete ban on post-filing evidence seems the most appropriate. It is a clear rule that is easy to administer, unlike the other options. Moreover, the potential unfairness to patent applicants does not seem terribly harsh. The patent applicants, in essence, are the lowest cost avoiders here: all the information about their invention is in their possession. They control when experiments are performed and when the application is filed. They are thus in the best position to control this information. This rule could create potential delays for a given applicant, of course, which could result in a particular applicant losing the patent race.

Such delays could also, on the margins, result in more wasteful duplicative research for a particular invention.<sup>196</sup> One advantage of earlier patent filing is that other researchers opt not to expend resources on the same pursuit, knowing they cannot obtain the patent.<sup>197</sup> Such mitigation can be facilitated by earlier disclosure of the invention through the published patent application or other peripheral disclosures.<sup>198</sup> It is not clear to me, however, that such delays will

<sup>195.</sup> See Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 1 (2003) ("The use of bright-line rules, however, is often at the cost of fairness.").

<sup>196.</sup> See John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 444 (2004) ("Firms competing for the patent reward are likely, in at least some circumstances, to duplicate each other's research.").

<sup>197.</sup> *Id.* at 472 ("By allowing a patent to occur before firms commit the bulk of the expenditures necessary to develop the invention, the prospect system reduces wasteful expenditures on duplication and thus makes the process of investing in innovation more efficient.").

<sup>198.</sup> See Rantanen, *supra* note 23, at 16–17 (discussing publications about the invention that an inventor could not make absent the patent system); *see also* Holbrook, *supra* note 7, at 146 ("An inventor who anticipates obtaining a patent on an invention will be more willing to publish a scientific article or other sort of disclosure to the public, because she knows her invention will eventually be protected by a patent and not by a trade secret.").

necessarily be significant. Many of the post-filing evidence cases dealt with evidence generated very shortly after the filing date, so it is not clear that such duplication will suddenly become overly robust. Delays in filing the application may not be dramatic. Moreover, parallel research already occurs extensively in the patent system. Most patent infringers are independent inventors, so it appears that competing innovators do not simply give up their pursuits if they fail to get the patent on a certain technology.<sup>199</sup> As such, I would support adoption of a complete ban on evidence generated after the application's filing date used to support the utility of the invention or the sufficiency of the disclosure.<sup>200</sup>

### IV. PATENT DISCLOSURES AND PATENT SCOPE

After a patent issues, its disclosure becomes important for assessing the scope of the patent's exclusive rights. The patent claims delineate that scope,<sup>201</sup> but those claims must be interpreted through the process of claim construction in order to assess their scope. Claim construction is generally assessed as of the filing date, though that rule is not as tight as one might think. Moreover, a patent holder gets more than the literal scope of her patent claims: the patent also covers all equivalents to the claimed invention. The doctrine of equivalents operates when the device accused of infringing is "close enough" to the claimed invention to justify affording protection to the patent owner. This assessment of equivalency, which impacts patents scope, is assessed at the time of infringement. This Section considers the temporal dynamics that attend these assessments of patent scope.

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<sup>199.</sup> See Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. REV. 1421, 1457 (2009) ("But the fact that all these diverse methodologies produce largely consistent results (as summarized in Table 4) gives us substantial confidence that copying is indeed rare in patent litigation." (emphasis omitted)).

<sup>200.</sup> This approach would also bring enablement in line with written description, which appears not to permit post-filing evidence. *See* Principal Brief for Defendant-Appellant Eli Lilly & Co. on Rehearing En Banc at 52, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. Nov. 9, 2009) (No. 2008-1248), 2009 WL 4248775 ("[W]ritten description examines whether the inventor had possession of the claimed invention as of the filing date judged by the description in the specification. As such, it is essentially irrelevant what others have published about the invention years after the applicable filing date." (emphasis omitted)).

<sup>201.</sup> Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) (describing the patent claims as "the portion of the patent document that defines the scope of the patentee's rights").

### A. The Fourth Date: Claim Construction and Literal Infringement Assessed as of the Filing Date . . . Sort of

Claim construction is perhaps the single most important act performed in patent litigation. Determining the scope of a patent's claims is important for both assessing validity and determining infringement. One might think, therefore, that the cases would be clear as to the timing of this inquiry. Well, that person may be a little disappointed. There is quite a bit of ambiguity as to the relationship between claim construction and time.<sup>202</sup>

Instinctively, one would think that claim construction would be assessed as of the filing date. This seems appropriate, as it would correlate with the timing of the § 112 disclosure obligations: we are taking a snap shot of the state of the art at the time the applicant files her application.<sup>203</sup> Claims must be interpreted exactly the same for purposes of both validity and infringement; it is legal error to offer different, contextual claim constructions.<sup>204</sup> So the appropriate snap shot in time would seem to be the filing date.

Surprisingly, there is some ambiguity as to this issue.<sup>205</sup> For the most part, the courts have suggested that the appropriate time for assessing the meaning of claim terms is at the date of invention.<sup>206</sup>

206. See, e.g., Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) ("[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."). The court has also addressed this temporal dynamic in the context of equivalents under 35 U.S.C. § 112, ¶ 6 and the doctrine of equivalents:

A proposed equivalent must have arisen at a definite period in time, i.e., either before or after patent issuance. If before, a § 112,  $\P$  6 structural equivalents analysis applies and any analysis for equivalent structure under the doctrine of equivalents collapses

<sup>202.</sup> See, e.g., Lemley, supra note 3.

<sup>203.</sup> See Christopher A. Cotropia, "After-Arising" Technologies and Tailoring Patent Scope, 61 N.Y.U. ANN. SURV. AM. L. 151, 165 (2005) ("The teachings of the whole patent are frozen as of the filing date of the patent. The specification is interpreted as it is understood at the time of filing."). For a discussion of the "temporal paradox" between enablement and patent scope, see Robert P. Merges, *Rent Control in the Patent District: Observations on the Grady-Alexander Thesis*, 78 VA. L. REV. 359, 379–80 n.73 (1992).

<sup>204.</sup> Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("[T]he claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses.").

<sup>205.</sup> See Lemley, supra note 3, at 116–19 (discussing four possible dates for claim construction: date of invention, date of filing, date of issuance, and date of infringement); see also Kevin Emerson Collins, The Reach of Literal Claim Scope into After-Arising Technology: On Thing Construction and the Meaning of Meaning, 41 CONN. L. REV. 493, 496–99 (2008) (discussing "fixation" theory, where claim is fixed as of filing date, "growth" theory, where literal scope evolves over time, and the "fixation-growth paradox"); Robin Feldman, Rethinking Rights in Biospace, 79 S. CAL. L. REV. 1, 3 (2005) ("Modern case law reflects confusion over whether the footprint of an invention includes things unknown at the time of the invention.").

Generally, the date of the invention should not be the appropriate date under the 1952 Patent Act, and certainly it is not the right date under the AIA. Under the first-to-invent system of the 1952 Act, courts and the USPTO did assess novelty and non-obviousness as of the date of invention, so there was some sense to making the date of claim construction that of the invention date. If we are assessing the novelty and obviousness of the invention as claimed at that date, then the terms should be interpreted as of the invention date. Such an approach, however, creates a considerable disconnect with the disclosure obligations of § 112.<sup>207</sup>

Use of the invention date under the AIA would not make sense. Under the AIA, novelty, non-obviousness, and the sufficiency of the disclosure are all assessed as of the filing date. The removal, for the most part, of concerns regarding the date of invention makes it clear that the appropriate date under the AIA is the filing date.

Even establishing the date in such a manner, however, does not eliminate the complications that arise with respect to claim construction, literal patent scope, and time. For example, in construing claims, the courts are free to use the intrinsic evidence regarding the patent: the claims, the specification, and the prosecution history.<sup>208</sup> The Federal Circuit has recognized that the prosecution record is an "ongoing negotiation between the PTO and the applicant," meaning that "it often lacks the clarity of the specification and thus is less useful for claim construction purposes."<sup>209</sup> In addition, and not as well appreciated by the courts, is the temporal gap involved: because the prosecution history necessarily arises after the applicant filed, then a considerable amount of time may pass between the application date and the filing date.<sup>210</sup>

This temporal dynamic can be further exacerbated through the use of various continuation applications, which will increase the gap in

into the § 112,  $\P$  6 analysis. If after, a non-textual infringement analysis proceeds under the doctrine of equivalents.

Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320 n.2 (Fed. Cir. 1999).

<sup>207.</sup> Such dynamics lead Professor Mark Lemley to propose that the appropriate date under the 1952 Patent Act is the filing date. Lemley, *supra* note 3, at 120–22. Professor Collins views these competing dynamics as reconcilable and "provides a theory that explains the fixation-growth paradox." Collins, *supra* note 205, at 499. In rejecting this dichotomy, he embraces the manner in which claims involve both "thing construction" and "meaning construction." *Id.* at 514–53.

<sup>208.</sup> Phillips, 415 F.3d at 1312–17; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582–83 (Fed. Cir. 1996).

<sup>209.</sup> Phillips, 415 F.3d at 1317.

<sup>210.</sup> Cf. Lemley, supra note 3, at 119 (discussing impact of continuation-in-part applications and amendments).

time between filing and the generation of the prosecution history.<sup>211</sup> Indeed, one applicant kept a patent application alive at the USPTO for over thirty-five years, although he was operating under the regime that afforded a patent term of seventeen years from the date of issuance.<sup>212</sup> Issued patents are also subject to post-issuance proceedings at the USPTO, and the records, as part of the prosecution history, also can be used for claim construction, notwithstanding that they are generated well after the filing date.<sup>213</sup>

These complications go further than simply the evidence used to construe the claims. As Professor Mark Lemley has explored, claim construction can at times capture technologies that did not exist as of the filing date.<sup>214</sup> Professor Kevin Collins also has extensively explored how literal claim scope—again supposedly assessed as of the filing date—can capture after-arising technologies.<sup>215</sup> This may seem unfair to subsequent inventors, who by definition created something that did not exist as of the filing date of the relevant patent. Nevertheless, they are deemed to fall within the literal scope of the patent and thus infringe. In theory, patent law has a safety valve for that situation. The reverse doctrine of equivalents precludes literal infringement if the accused device, while falling within the literal scope of the claims, functions in a substantially different way.<sup>216</sup> If the device is truly

214. Lemley, *supra* note 3, at 119–21; *see also* Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1975 (2005) ("Patent prosecutors have access to a range of claim-drafting techniques that mitigate problems with language and later-developed technology.").

215. See generally Kevin Emerson Collins, Enabling After-Arising Technology, 34 J. CORP. L. 1083 (2009); Collins, supra note 205.

216. As the Supreme Court has explained:

<sup>211.</sup> *Id.* at 118–19 (discussing use of reissuance proceedings to amend claims). *See generally* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004).

<sup>212.</sup> Lemley & Moore, *supra* note 211, at 76–77.

<sup>213.</sup> Golden Bridge Tech., Inc. v. Apple Inc., 758 F.3d 1362, 1366 (Fed. Cir. 2014) (disclaimer triggered by reexamination); AstraZeneca UK Ltd. v. Watson Labs., Inc., 905 F. Supp. 2d 589, 594 (D. Del. 2012) (exploring though rejecting disclaimer from reissuance); Paradox Sec. Sys. Ltd. v. ADT Sec. Servs., Inc., 710 F. Supp. 2d 590, 602 (E.D. Tex. 2008) (disclaimer during reissuance proceeding). See generally Timothy R. Holbrook, *The Patent Trial and Appeal Board's Evolving Impact on Claim Construction*, TEX. INTELL. PROP. L.J. (forthcoming 2016), http://ssrn.com/abstract=2828962 [https://perma.cc/LHK4-M6LL].

The wholesome realism of this doctrine is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608–09 (1950); *see also* Holbrook, *supra* note 53, at 12–14 (discussing scope limiting rule of reverse doctrine of equivalents).

different than what was claimed, this doctrine should privilege these later innovators. This doctrine, however, has rarely been invoked, rendering its current viability in doubt.<sup>217</sup>

Some of this temporal dynamic arises due to the nature of claims themselves. They are generally open-ended so that a claim covers a device even if the device contains extra elements, elements that may not have existed at the time of the application. For example, a party may hold a patent on a particular method of making a chemical. After the application date, someone else discovers an important catalyst that can be used in a process that makes it dramatically more efficient. Likely, the party using the catalyst infringes the earlier patent even though, by definition, the earlier patent holder did not invent the process with the catalyst.<sup>218</sup> Similar dynamics can arise when, for example, a patent holder claims some device, and later someone else creates a new material that can also be used in the same device. For example, many metal parts can now be replaced with plastic ones.<sup>219</sup> Although the patent holder did not create the invention with that material, her patent may nevertheless cover it literally.<sup>220</sup> As Professor Jeffrey Lefstin has noted, technically almost every patent claim is of infinite scope, given peripheral claiming, allowing claims frequently to cover later arising technologies literally.<sup>221</sup>

This temporal aspect is to be expected. Patents last from issuance until they expire twenty years after the filing date. Patent drafters by definition are trying to foresee what will transpire with the

<sup>217.</sup> See Holbrook, supra note 7, at 145; Lemley, supra note 3, at 121. Compare Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002) ("Even were this court likely ever to affirm a defense to literal infringement based on the reverse doctrine of equivalents, the presence of one anachronistic exception, long mentioned but rarely applied, is hardly reason to create another."), with Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325–27 (Fed. Cir. 2003) (rejecting application of the reverse doctrine of equivalents without questioning its ongoing vitality). The reverse doctrine of equivalents has been mentioned in recent district court litigation. See, e.g., Advanced Fiber Techs. (AFT) Tr. v. J & L Fiber Servs., Inc., No. 1:07-cv-1191 (LEK/DEP), 2015 WL 1472015, at \*8 (N.D.N.Y. Mar. 31, 2015).

<sup>218.</sup> See Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1580 (Fed. Cir. 1984); see also Holbrook, supranote 53, at 12.

<sup>219.</sup> See Alfred Joyner et al., 3D Printing in Aerospace: How Plastic Parts are Replacing Metal, INT'L BUS. TIMES (Nov. 3, 2014), http://www.ibtimes.co.uk/3d-printing-aerospace-how-plasticparts-are-replacing-metal-12641 [https://perma.cc/C7NX-HCJR].

<sup>220.</sup> See Merges, *supra* note 203, at 379 n.73 (discussing a claim to "fuzzballs" where later innovations create a new material from which fuzzballs could be made); *see also* Feldman, *supra* note 205, at 2 ("Once the patent holder identifies the 'doorknob' invention by describing the structure of a doorknob, the patent holder controls all doorknobs. This is true regardless of whether the other doorknobs are made of wood, glass, or plastic.").

<sup>221.</sup> Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1168–71 (2008). This dynamic makes the "full scope" enablement requirement seemingly nonsensical. *Id.* at 1171–72.

technology over the life of the patent, and patent enforcers will attempt to shoehorn an extant patent into somewhat odd shapes to ensure the patent does not become obsolete. The result, though, can be some odd claim construction disputes, where the patent holder attempts to stretch the claim terms beyond their definition as of the filing date. The cases reflect this dynamic, and the results are mixed.<sup>222</sup> Some of these efforts have been successful,<sup>223</sup> whereas other efforts have failed.<sup>224</sup>

The courts need to be more consistent, therefore, in interpreting the claims as of the filing date. Greater consistency in this regard would bring more coherence to claim construction doctrine. The law has appropriate safety values to deal with the ever-changing nature of technology. In those circumstances where after-arising technology is ensnared inappropriately, the courts should more freely rely on the reverse doctrine of equivalents. The reverse doctrine has its origins in the patent specification, and greater use of the doctrine would therefore create temporal consistency with claim scope: significant post-filing innovations will be beyond the scope of the patent.<sup>225</sup> It is also a more tailored lever than enablement or written description because the doctrine results in a conclusion of non-infringement and not the invalidation of the claim.<sup>226</sup> A stronger reliance on the specification also could help limit efforts to construe claims in an overly broad fashion where the patentee is trying to inappropriately ensnare later-developed technologies. This dynamic is particularly important where particular claim limitations are directly implicated by the relevant technological advance.227

Patentees could still resort to the doctrine of equivalents to protect themselves against later-developed technology that is nevertheless merely a minor variation from the claimed invention.<sup>228</sup>

<sup>222.</sup> Lemley, supra note 3, at 104 n.12 and accompanying text.

<sup>223.</sup> *See, e.g.*, SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 881 (Fed. Cir. 2004) (construing term to cover analog, digital, or combination signal even though digital signals did not exist as of filing date).

<sup>224.</sup> See, e.g., Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC, 824 F.3d 999, 1004 (Fed. Cir. 2016) (limiting "communications path" to wired connections and excluding wireless); Kopykake Enters., Inc. v. Lucks Co., 264 F.3d 1377, 1383 (Fed. Cir. 2001) (limiting claims to printing methods "conventional at the time of the invention").

<sup>225.</sup> See Holbrook, supra note 53, at 12–14 (noting link between reverse doctrine of equivalents and patent's disclosure).

<sup>226.</sup> Id.

<sup>227.</sup> Holbrook, supra note 7, at 158–59.

<sup>228.</sup> Id. at 159–60. Some have suggested that the doctrine of equivalents is dead. See John R. Allison & Mark A. Lemley, The (Unnoticed) Demise of the Doctrine of Equivalents, 59 STAN. L. REV. 955, 976–79 (2007); David L. Schwartz, Explaining the Demise of the Doctrine of Equivalents, 26 BERKELEY TECH. L.J. 1157, 1158 (2011). My argument here would suggest a need for the Federal Circuit to revitalize the doctrine. Regardless, the court has appeared more receptive to the doctrine

The doctrine can provide an important safety valve against a patent's obsolescence, though carefully cabined by a host of limitations. The determination of equivalency brings us to the fifth point in time.

# B. The Fifth Date: Patent Scope and Equivalency as of the Date of Infringement

Unlike the lingering ambiguity surrounding claim construction and literal infringement, the law is clear that infringement under the doctrine of equivalents is assessed as of the date of infringement.<sup>229</sup> At one level, the doctrine protects patentees against linguistic formalism given the difficulty that can arise in crafting precise language to capture an invention.<sup>230</sup> But the doctrine goes beyond this function. It is also designed to allow patentees to capture later-developed technologies: "Due to technological advances, a variant of an invention may be developed after the patent is granted, and that variant may constitute so insubstantial a change from what is claimed in the patent that it should be held to be an infringement."<sup>231</sup> The doctrine therefore helps to prevent obsolescence of the patent.<sup>232</sup>

On a temporal level, patent scope is dichotomous. The literal scope is generally assessed as of the filing date, yet equivalency is

of equivalents in recent years. *See, e.g.*, Textron Innovations Inc. v. Am. Eurocopter Corp., 498 F. App'x 23, 31 (Fed. Cir. 2012) ("We agree with Textron that it has raised a genuine issue of material fact as to infringement under the doctrine of equivalents, and we therefore reverse the district court's ruling on that issue."); U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1380 (Fed. Cir. 2007) (vacating summary judgment of non-infringement under doctrine of equivalents and remanding); DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1018 (Fed. Cir. 2006):

It is important to note that when we have held that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation, it was not to hold that the doctrine is always foreclosed whenever a claim limitation does not literally read on an element of an accused device; such an interpretation of the "all elements" rule would swallow the doctrine of equivalents entirely.

<sup>229.</sup> Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997) ("Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency—and thus knowledge of interchangeability between elements—is at the time of infringement, not at the time the patent was issued.").

<sup>230.</sup> 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.

<sup>231.</sup> Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1310 (Fed. Cir. 1998).

<sup>232.</sup> Holbrook, *supra* note 53, at 39; *see also* Cotropia, *supra* note 203, at 174 ("Extending a patent's scope to include after-arising equivalents will maintain the patent's effective life in the face of such developments.").

assessed at the later date of infringement. Minimally, courts must be careful to monitor this temporal dichotomy to appropriately apply the various infringement doctrines. Indeed, somewhat paradoxically, the doctrine of equivalents generally will only afford protection to patentees for things not in their possession at the time of their filing date.<sup>233</sup>

Importantly, because assessment of equivalency is as of the date of infringement, necessarily the scope of the patent is always changing over time.<sup>234</sup> The equivalency inquiry is tied to the PHOSITA, and that skill level will necessarily change and grow over time.<sup>235</sup> The timing component to the doctrine of equivalents can create some difficulties. While the courts note that the time for assessing equivalents is at the time of infringement, they have failed to elaborate precisely what date that would be.

That date for assessing equivalency should not necessarily be the date that the infringer begins commercializing the invention, which is typically the most notorious date of infringement. Instead, the focus should be much earlier in time. The relevant date for assessing equivalency should be the first time the infringer manages to reduce the invention to practice, thereby demonstrating, actually or constructively, that the device will work even if it is not yet commercially viable.<sup>236</sup> The use of this earlier date is important because the infringer's first instantiation of the device may have actually been a technological breakthrough. Over time, as the state of the art develops, the accused device may *become* an equivalent. But, the

236. Cf. Scott v. Finney, 34 F.3d 1058, 1061 (Fed. Cir. 1994) ("Reduction to practice does not require 'that the invention, when tested, be in a commercially satisfactory stage of development.'" (quoting *In re* Dardick, 496 F.2d 1234, 1238 (C.C.P.A. 1974))). The reduction to practice could effectively be constructive, where the invention's proof of concept is through detailed, enabling diagrams. *See, e.g.*, Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 58 (1998) (inventor sold invention based on diagrams only). For an argument that infringement should be possible for selling or offering to sell the invention based on diagrams or digital representations alone, see Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. DAVIS L. REV. 1319, 1360 (2015) (positing that sales and offers to sell computer-aided design files should constitute infringement); Timothy R. Holbrook, *Territoriality and Tangibility After* Transocean, 61 EMORY L.J. 1087, 1106 (2012) ("[I]nfringement of a patent through sales or offers to sell as an appropriation of the economic value of the invention, as opposed to its physical incarnation.").

<sup>233.</sup> Holbrook, *supra* note 53, at 29–31. Most of the limitations on the doctrine of equivalents are assessed as of the filing date or, potentially, the date of an amendment to the patent during the prosecution process. *See id.* at 21–29. Thus, courts must be particularly careful in this area to maintain their focus on the state of the art at the relevant time period.

<sup>234.</sup> Id. at 45.

<sup>235.</sup> See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997) ("Much as the perspective of the hypothetical 'reasonable person' gives content to concepts such as 'negligent' behavior, the perspective of a skilled practitioner provides content to, and limits on, the concept of 'equivalence.'"); Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950) ("An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.").

appropriate snap shot in time for the assessment of equivalency would be the state of the art at that earliest instance of infringement, and the PHOSITA may have viewed the infringer's device as equivalent at that time.

Consider a comparison to anticipation. A piece of prior art may not be enabled when it issues and thus cannot be anticipatory as of that date. Over time, however, as the knowledge of the PHOSITA grows, that prior art reference may become enabled.<sup>237</sup> The assessment of equivalency operates in the same fashion. At an earlier point in time, the changes made to the claimed invention may be viewed as significant to one of skill in the art. Over time, however, the PHOSITA may come to view those changes as insignificant. Thus, an alteration to the claimed invention may not be equivalent at an earlier date but become equivalent later.

This temporal dynamic would be particularly important if the infringer independently developed the invention. One cannot say in that context that she was an "unscrupulous copier" or otherwise free rode on the patent holder's invention. While such consideration is technically irrelevant to the equivalency analysis, because equivalency does not depend on the intent of the infringer,238 it nevertheless demonstrates the concern that some infringers actually may have innovated in their own right. The moving target of equivalency risks ensnaring within the scope of an earlier patent a true innovation. To best police this dynamic, the courts need to ensure that they are assessing equivalency as of the earliest possible infringement date, which very well may not be the date that commercial infringement began. These latter acts of infringement are likely to be the key acts in litigation because the patent holder will want damages for those acts. They are also likely the acts that initially garnered the patent holder's attention. It could very well be the case, however, that those acts were not the first incidents of infringement, which is the date at which equivalency should be assessed.

This temporal dynamic is also consistent with the foreseeability aspect of prosecution history estoppel. Under prosecution history estoppel, if a patent applicant's amendment surrenders the asserted equivalent, she cannot use the doctrine of equivalents to recapture that subject matter.<sup>239</sup> A limit on prosecution history estoppel, however, is

<sup>237.</sup> See supra note 54 and accompanying text.

 $<sup>238.\</sup> Warner-Jenkinson$  Co., 520 U.S. at 36 (holding "intent plays no role in the application of the doctrine of equivalents").

<sup>239.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733–34 (2002) ("When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory

foreseeability: if the asserted equivalent was unforeseeable at the time of the amendment (or perhaps more appropriately at the time of the application), then the patentee can resort to the doctrine of equivalents.<sup>240</sup> To infringe, though, that once unforeseeable embodiment must become insubstantially different. The only way something can be unforeseeable at one point in time but then insubstantially different later, is due to the change in the state of the art over time.

One way to manage some temporal aspects of equivalency is to tie the analysis back to the patent's disclosure. In other words, the question would be whether the PHOSITA at time of infringement knew that one could extrapolate the teachings of the patent to determine that the change could be made. I have previously articulated this approach, and its value in wrestling with the temporal component of equivalency becomes even clearer.<sup>241</sup> Courts should assess what is the *earliest* potential date of infringement and freeze the equivalency analysis at that time. Courts could then ask whether, at that date, the patent specification would have enabled the PHOSITA to make and use the asserted equivalent. If so, then there would be infringement under the doctrine of equivalents. This approach affords a coherent methodology consistent with the role of the specification in moderating claim scope.

The issue of time, therefore, is important in the post-issuance context, where courts are assessing the appropriate scope to afford the patent. Literal scope should be assessed as of the filing date, with some appreciation that, given the open-ended nature of patent claims, it may be possible to cover after-arising technology literally. The reverse doctrine of equivalents, however, can help police that issue, with careful attention to the patent's specification to moderate whether the infringing item should be deemed outside of the patent claims. Similarly, the timing of equivalents is at the date of infringement,

comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.").

<sup>240.</sup> *Id.* at 738 ("There is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered."). We again see discrepancies in the timing issue. While the time of amendment makes intuitive sense, likely the timing of the inquiry should be as of the application's filing date. Any subject matter must be supported by the specification, so if the patentee could have claimed the subject matter it has given up, that would be measured as of the filing date.

<sup>241.</sup> Holbrook, *supra* note 53, at 40–45. I also offered an alternative approach that would limit the doctrine of equivalents to circumstances where the change in the invention was the result of technological advances outside of the inventor's field. *Id.* at 37–40. This approach is consistent with a fairness rationale for the doctrine of equivalents because inventors cannot be expected to monitor all technological developments outside of their field, though we may expect them to be aware of those within their field. *Id.* at 37.

which is meant to ensnare later-developed technologies. Courts should be sure to find the earliest date of infringement to make that assessment, as what was once not equivalent may become equivalent, working an unfairness to the infringer if she is the one who generated that innovation. Courts should tie the equivalency analysis more closely to the patent disclosure in a manner akin to the anticipation analysis, asking whether the patent at issue would enable the asserted equivalent as of the date of infringement.

#### CONCLUSION

Patents are intimately intertwined with time. Aside from being of limited duration, patents necessarily engage with ever-changing technological fields. Patent law has tools to deal with these temporal dynamics, but the courts at times have failed to truly appreciate the important nuances and issues that this temporal dynamic creates. These difficulties are particularly salient in the context of patent disclosures because of their interactions with the PHOSITA, an everchanging and evolving hypothetical person in the law. This Article has demonstrated how time impacts the patent throughout its lifetime: in assessing its validity vis-à-vis the prior art, its compliance with the disclosure obligations of § 112, and its appropriate scope. There are ample tools upon which courts can rely to combat these difficulties, as this Article has elaborated. Hopefully, courts will begin to use them more appropriately and robustly in the future.<sup>242</sup>