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# Patent Scope and Enablement in Rapidly Developing Arts

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## PATENT SCOPE AND ENABLEMENT IN RAPIDLY DEVELOPING ARTS\*

#### ALAN L. DURHAM<sup>\*\*</sup>

The claims of a patent and its enabling disclosure must be commensurate in scope. However, because of the open-ended nature of most patent claims, in fields of rapidly developing technology it is almost inevitable that, before the patent has expired, the claims will read on embodiments that the specification does not teach. The current law on scope enablement is the source of much confusion. Because enablement must be judged from a filing-date perspective, some cases dismiss later advancements (e.g., a newly discovered species within a claimed genus) as irrelevant. Other cases, in contrast, hold patent claims invalid because they exceed the scope of what could have been achieved when the application was filed. A clear and balanced rule of scope enablement is essential to a patent system designed to "promote the Progress of ... useful Arts." Claims that exceed the scope of the patent's teachings can stand in the way of technological progress; at the same time, claims to important advancements—the advancements most susceptible to elaboration and improvement—should not be so severely limited in scope that they are all but worthless. In this Article, I propose an analytical framework designed to reconcile some of the apparent contradictions and to reward patentees in a manner that promotes technological advancement in rapidly developing fields. I propose that courts address patent claims that include nonenabled embodiments from the perspective of a reasonable applicant. The claims should not be held invalid (1) if the nonenabled embodiments were unforeseeable; (2) if the nonenabled embodiments are "tangential" (i.e., the nonenabled aspects of those embodiments are unrelated to the patentee's contribution to the art); or (3) if for some other reason a reasonable applicant could not have been expected to draft claims that would have excluded the nonenabled embodiments. The model for this three-part test is the Supreme Court's rule on

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prosecution history estoppel, as outlined in Festo. Although enablement and prosecution history estoppel are very different areas of patent law, in both instances respect for the limitations of a reasonable applicant leads to outcomes consistent with sound patent policy.

INTR	ODU	CTION	1101
I.	BA	SIC ENABLEMENT	
II.	SCO	DPE ENABLEMENT	
	А.	Incomplete Enablement	1115
		1. Distinct Alternatives	1117
		2. Genus and Species	1122
		3. Unlimited Ranges	1124
	В.	Enablement by a Single Mode	1127
	С.	Enablement in the Context of Rapidly Developing	
		Technologies	1129
III.	ΑF	FRAMEWORK FOR ADDRESSING EMBODIMENTS OF	
	TH	E CLAIMED INVENTION THAT FILING-DATE	
	TE	CHNOLOGY DID NOT ENABLE	
	Α.	Unforeseeable Embodiments	
		1. Claims Broadened to Include a Nonenabled	
		Embodiment	
		2. References to the Nonenabled Embodiment in the	
		Specification	1143
		3. Failed Attempts to Practice the Nonenabled	
		Embodiment	
		4. Progress in the Art Toward the Nonenabled	
		Embodiment	
		5. Categorical Distinctions Between the Enabled and	
		Nonenabled Embodiments	
		6. Result-Oriented Claiming	
	В.	Tangential Embodiments	1149
	С.	Other Embodiments That Could Not Reasonably Have	
		Been Excluded from the Claim	
	D.	A Role for the Reverse Doctrine of Equivalents	
CONC	CLUS	SION	

2016]

## PATENT SCOPE & ENABLEMENT

1101

#### INTRODUCTION

One of the fundamental requirements of a valid patent is a disclosure that teaches persons skilled in the art how to make and use the invention without undue experimentation.<sup>1</sup> Because the rights of the patentee extend to all devices, methods, or compositions of matter that have the elements set forth in the patent claims—e.g., all mousetraps that combine features A, B, and C-courts also require that the teachings of the patent be commensurate in scope.<sup>2</sup> If some embodiments covered by the claims cannot be made or used without undue experimentation, the disclosure may be nonenabling.<sup>3</sup> The problem is that open-ended patent claims almost inevitably include some embodiments that cannot be made or used without technological advancements unknown when the patent application was filed and unachievable without extensive experimentation. If courts allow only narrow claims that exclude such embodiments, they risk limiting patent rights in rapidly developing fields so much that the incentive to secure a patent-an incentive necessary, in the constitutional phrase, to "promote the Progress of... [the] useful Arts"—is severely diminished.<sup>4</sup> On the other hand, progress in the useful arts is also dependent on subsequent innovations, which will be hindered if the rights of patentees extend far beyond their contributions to the field. These competing considerations demand an approach to enablement that considers both sides of the equation.

The current state of the law relating to scope enablement is frustratingly obscure. Some courts say that the disclosure of even *one* mode of making and using the invention is enough to satisfy the enablement requirement.<sup>5</sup> Others suggest that *every* embodiment

<sup>1.</sup> See, e.g., MagSil Corp. v. Hitachi Glob. Storage Techs. Inc., 687 F.3d 1377, 1380– 81 (Fed. Cir. 2012) ("To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997))).

<sup>2.</sup> See, e.g., id. at 1381 ("The scope of the claims must be less than or equal to the scope of the enablement...." (quoting Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008))).

<sup>3.</sup> *See, e.g., id.* ("Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.").

<sup>4.</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>5.</sup> See, e.g., Takeda Pharm. Co. v. Zydus Pharm. USA, Inc., 743 F.3d 1359, 1369 (Fed. Cir. 2014) ("It is well established that the 'enablement requirement is met if the description enables *any* mode of making and using the invention.'" (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998))).

within the scope of the claim must be enabled.<sup>6</sup> Some cases warn that developments subsequent to the filing date of the patent are irrelevant.<sup>7</sup> Others rely on such developments to demonstrate that the claims are too broad.<sup>8</sup> In this Article, I propose a framework for addressing scope enablement designed to reconcile some of these apparent contradictions and to reward patentees in a manner that promotes technological advancement in rapidly developing fields. This framework, in essence, requires that a patent disclosure teach persons skilled in the relevant art how to make and use all embodiments within the scope of the claims, except in cases where the nonenabled embodiments could not reasonably have been avoided by the prosecution of narrower claims. The exception would apply (1) if the nonenabled embodiments were unforeseeable when the claims were prosecuted; (2) if the aspects of the nonenabled embodiments that render them nonenabled are tangential to the patentee's contribution to the art (i.e., they are additions to, rather than substitutions for, the patentee's invention); or (3) if the lack of a suitable vocabulary, or some other reason, made it impossible for the patentee to supply a more narrowly tailored claim.

Part I provides a brief summary of the basic enablement requirement, which demands that a patent include enough information to allow persons skilled in the art to practice the invention without undue experimentation. Part II deals with matters of scope. Section II.A discusses claims that are not enabled because they include distinct alternatives to the embodiments taught in the specification or a range of embodiments inadequately represented by the disclosed species. Section II.B examines instances where, in contrast, a single mode of practicing the claimed invention was said to suffice. Section II.C addresses scope enablement within the context of rapidly developing technologies, where the law has seemed inconsistent; some cases consider post-filing-date advancements to be irrelevant, while others use such advancements to demonstrate the shortcomings of the patent disclosure. Part III proposes a framework for examining issues of scope enablement where rapid technological advancements lead to nonenabled embodiments within the scope of the claims. Section III.A discusses unforeseeable embodiments,

<sup>6.</sup> See MagSil, 687 F.3d at 1381 ("The scope of the claims must be less than or equal to the scope of the enablement ...." (quoting Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008))).

<sup>7.</sup> *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("[N]ew technology [is] by definition, outside the bounds of the enablement requirement.").

<sup>8.</sup> See MagSil, 687 F.3d at 1382.

Section III.B "tangential" embodiments, and Section III.C other embodiments that could not reasonably have been excluded by the patent claims. Section III.D considers a role for the reverse doctrine of equivalents in cases where over-broad claims could not reasonably have been avoided.

#### I. BASIC ENABLEMENT

The object of the United States patent system, as expressed in Article 1, Section 8 of the Constitution, is to "promote the Progress of ... [the] useful Arts."<sup>9</sup> Inventors who achieve technological advancements unattainable by those of "ordinary skill in the art"<sup>10</sup> are eligible to receive, through a patent, the exclusive right to make, use, or sell the invention.<sup>11</sup> By promising inventors appropriate financial rewards, the patent system encourages investments in technological progress that benefit society as a whole.<sup>12</sup> In addition, a patent applicant must provide a detailed disclosure of the invention.<sup>13</sup> When that disclosure is published as a part of the patent specification, the information it contains enriches the knowledge available to the public. A "full, clear, enabling description of the invention" has been called the "sine qua non of a valid patent."<sup>14</sup>

The enablement requirement demands that the patent specification teach persons of ordinary skill in the art how to make and use the claimed invention without "undue experimentation."<sup>15</sup> Although the distinction is not commonly discussed, enablement may be broken down into two requirements: "how to make" and "how to

<sup>9.</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>10.</sup> Minor advancements that would have been obvious to persons of ordinary skill in the art are barred from patenting under § 103 of the Patent Act. See 35 U.S.C. § 103 (2012) ("A patent for a claimed invention may not be obtained ... if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious... to a person having ordinary skill in the art ...."); Ritchie v. Vast Res., Inc., 563 F.3d 1334, 1337 (Fed. Cir. 2009) (obvious advancements include "those modest, routine, everyday, incremental improvements of an existing product or process that ... do not involve sufficient inventiveness to merit patent protection").

<sup>11. 35</sup> U.S.C 271(a) (2012). The exclusive rights of the patentee also include the right to offer the claimed invention for sale and the right to import it into the United States. *Id.* 

<sup>12.</sup> *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (exclusive rights permit inventors to recoup the costs of research and development).

<sup>13.</sup> See generally id. ("[T]he patent laws impose upon the inventor a requirement of disclosure.").

<sup>14.</sup> White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 790–91 (Fed. Cir. 1983) (citing *Kewanee*, 416 U.S. at 480).

<sup>15.</sup> MagSil Corp. v. Hitachi Glob. Storage Techs. Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012); ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010).

use."<sup>16</sup> An enabling disclosure is an essential element of the "bargain" between a patent applicant and the public at large.<sup>17</sup> Patentees receive exclusive rights in exchange for a concrete disclosure of how one may use the invention.<sup>18</sup> Thus the enablement requirement exists "in order to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts."<sup>19</sup>

The source of the enablement requirement is the first paragraph of § 112, which states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor...of carrying out the invention.<sup>20</sup>

Section 112 is also the source of the best mode and written description requirements.<sup>21</sup> The best mode requirement demands disclosure of what the applicant believed to be the best manner of practicing the invention at the time the application was filed.<sup>22</sup> Although the America Invents Act recently eliminated failure to disclose the best mode as a ground for challenging the validity of a patent,<sup>23</sup> the best mode language nevertheless remains in § 112, and it

21. Id.

<sup>16.</sup> In re Angstadt, 537 F.2d 498, 502 (C.C.P.A. 1976).

<sup>17.</sup> See Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1360 (Fed. Cir. 2011) (referring to patent rights as a "bargained-for-exchange" (quoting Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001))).

<sup>18.</sup> See Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997) ("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."). In the context of the utility requirement, which demands that a patented invention be "useful," the Supreme Court has observed that a patent is "not a hunting license." Brenner v. Manson, 383 U.S. 519, 536 (1966).

<sup>19.</sup> Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005).

<sup>20. 35</sup> U.S.C. § 112(a) (2012).

<sup>22.</sup> See High Concrete Structures, Inc. v. New Enter. Stone & Lime Co., 377 F.3d 1379, 1383 (Fed. Cir. 2004) (the best mode requirement bars inventors from "concealing from the public preferred embodiments of their inventions which they have in fact conceived" (quoting *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962))); Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306, 1314 (Fed. Cir. 2002) ("[T]he existence of a best mode is a purely subjective matter depending on what the inventor actually believed at the time the application was filed.").

<sup>23.</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, 15(a)(3)(A), 125 Stat. 284, 328 (2011) ("[T]he failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable....") (codified as amended at 35 U.S.C. 282(b)(3)(A) (2012)).

may shed some light on the distinct nature of the enablement requirement. The written description requirement demands that the patent specification demonstrate "possession" by the applicant of the invention claimed.<sup>24</sup> A principal function of the written description requirement is to ensure that patent claims, which may change during prosecution, do not stray from the invention disclosed in the application originally filed.<sup>25</sup> If, after amendment, the claims no longer match the invention described in the specification, one cannot rely on the filing date of the application to resolve important questions of priority.<sup>26</sup> In recent years, courts have also used the written description requirement to invalidate claims that are broader than the invention the applicant actually "possessed," even in cases where the claims did not change during prosecution.<sup>27</sup> Applied in this way, the written description requirement overlaps substantially with the enablement requirement.<sup>28</sup>

Patent disclosures are directed to persons of ordinary skill in the art,<sup>29</sup> and whether a disclosure is enabling must be judged from their

26. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255 (Fed. Cir. 2004) (if not for the written description requirement, applicants "could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention").

27. See Ariad, 598 F.3d at 1349.

28. See LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005) (when the issue is that of the breadth of the disclosure, the written description and enablement requirements "usually rise and fall together"). The written description and enablement requirements are, nevertheless, distinct. Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (referring to "two separate and independent requirements"); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991) ("[I]t is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention." (quoting *In re* DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971))). The enablement requirement is "more indulgent" than the written description requirement because omitted details can be supplied through the knowledge possessed by persons of ordinary skill. *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) ("[T]he [enablement] requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention ...").

29. Patent law often calls on the perspective of the hypothetical "person of ordinary skill in the art," just as tort law often calls on the perspective of the hypothetical "reasonable person." The "person of ordinary skill" does not possess the ingenuity of an inventor, but only the typical competence of workers in the field. *See* Standard Oil Co. v.

<sup>24.</sup> Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (to satisfy the description requirement, a patent specification must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date").

<sup>25.</sup> See In re Wright, 866 F.2d 422, 424 (Fed. Cir. 1989) ("When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a *different invention*...[one asks] whether the newly claimed subject matter was *described* in the patent application when filed....").

perspective.<sup>30</sup> The specification need not disclose, and preferably omits, information that would already be known to those of ordinary skill.<sup>31</sup> Although the phrase "undue experimentation" does not appear in the statute, courts have long held that the need for some experimentation before one can make or use the invention is not fatal.<sup>32</sup> Consequently, the enablement requirement looks to the information disclosed in the patent specification, the information already available in the art, and additional information that might be gleaned by those of ordinary skill through experimentation that is not "undue."<sup>33</sup> Minor details may be omitted from the disclosure,<sup>34</sup> in the expectation that persons skilled in the art, armed with the general knowledge available to such persons, may be able to fill gaps and

31. Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("[A] specification need not disclose what is well-known in the art."); *LizardTech*, 424 F.3d at 1345 ("[T]he patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before."); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art.").

32. Cephalon, 707 F.3d at 1336 ("[A] reasonable amount of routine experimentation...does not violate the enablement requirement."); ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention ...."); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (the qualifier of "undue experimentation" is "well established").

33. See Warner-Lambert Co. v. Teva Pharm. USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005) ("[T]he specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation."); Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) ("The scope of enablement... is that which is disclosed in the specification plus... what would be known to one of ordinary skill in the art without undue experimentation." (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999))).

34. Adang v. Fischhoff, 286 F.3d 1346, 1358 (Fed. Cir. 2002) ("It is well settled that 'omission of minor details does not cause a specification to fail to meet the enablement requirement.'" (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997))).

Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985) (the person of ordinary skill "thinks along the line of conventional wisdom"). The person of ordinary skill is, however, "a person of ordinary creativity, not an automaton." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420 (2007).

<sup>30.</sup> See Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) (the enablement requirement is satisfied if "at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation'"); Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1055 (Fed. Cir. 2003) (the enablement inquiry is "from the viewpoint of persons experienced in the field of the invention"); Singh v. Brake, 317 F.3d 1334, 1345 (Fed. Cir. 2003) ("[E]nablement . . . looks to the objective knowledge of one of ordinary skill in the art." (quoting Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1050 (Fed. Cir. 1995))).

extrapolate as necessary to practice the claimed invention.<sup>35</sup> On the other hand, a patent applicant cannot rely entirely on the knowledge possessed by those of ordinary skill to supply an enabling disclosure. It is a matter of supplementation only,<sup>36</sup> and the novel aspects of the invention, in particular, must be supported by the teachings of the specification.<sup>37</sup>

When enablement arises as a validity defense in litigation, or as a reason for rejecting a patent application, the dispute is typically over whether undue experimentation would be required in order to make and use the invention.<sup>38</sup> Because some experimentation is permitted, the "key word" in the inquiry is "undue."<sup>39</sup> The decision "is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations."<sup>40</sup> Those considerations concern the relationship between the claimed invention, the disclosures included in the patent specification, and the knowledge and abilities of persons of ordinary skill.<sup>41</sup> A well-established list of factors, known as the *Wands* factors, figures routinely in the enablement decisions of the Federal Circuit Court of Appeals. These factors are:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples,<sup>42</sup> (4) the nature of the invention, (5) the

38. See, e.g., ALZA, 603 F.3d at 940 (deciding whether the necessary experimentation is "undue"); Warner-Lambert, 418 F.3d at 1337 (same).

<sup>35.</sup> See AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("[T]he artisan's knowledge of the prior art and routine experimentation can often fill gaps ....").

<sup>36.</sup> Streck, 665 F.3d at 1288 (use of knowledge available in the art is "merely a rule of supplementation, not a substitute for a basic enabling disclosure" (quoting ALZA, 603 F.3d at 940–41)); ALZA, 603 F.3d at 941 (a patentee "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification").

<sup>37.</sup> Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283 (Fed. Cir. 2007) ("It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997))).

<sup>39.</sup> Warner-Lambert, 418 F.3d at 1337 (quoting In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

<sup>40.</sup> Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quoting *ALZA*, 603 F.3d at 940).

<sup>41.</sup> See Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999).

<sup>42. &</sup>quot;Working examples" are embodiments of the claimed invention that are disclosed in the specification and that have actually been reduced to practice by the patentee. *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1577 n.1 (Fed. Cir. 1984) (distinguishing working examples and prophetic or "paper" examples). "Prophetic examples" are embodiments described in the specification that have not been reduced to

state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.<sup>43</sup>

The *Wands* factors are "illustrative" rather than "mandatory,"<sup>44</sup> meaning that only relevant factors need be considered in any particular case.<sup>45</sup>

A factor of great significance is the kind of experimentation that would be required of a person skilled in the art, working from the patent disclosure, to produce a working embodiment of the invention. Whether experimentation is "undue" is a matter of degree,<sup>46</sup> and the standard is one of reasonableness.<sup>47</sup> The test is not solely quantitative;<sup>48</sup> a "considerable amount of experimentation" is permitted, so long as it would be "'merely routine,' or the specification provides 'a reasonable amount of guidance.' "<sup>49</sup> For example, in *In re Wands*,<sup>50</sup> the invention concerned laboratoryproduced antibodies capable of detecting the hepatitis B virus.<sup>51</sup> A person skilled in the art desiring to practice the invention would have to isolate and clone specialized hybridoma cells, culture them in separate chambers, test the antibodies they produced to determine

44. *Cephalon*, 707 F.3d at 1336; Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

45. See Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999) (not all of the *Wands* factors need be considered because "[w]hat is relevant depends on the facts" (quoting *Amgen*, 927 F.2d at 1213)).

46. Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385–86 (Fed. Cir. 2013); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004); PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996).

47. See Cephalon, 707 F.3d at 1336 ("[A] reasonable amount of routine experimentation...does not violate the enablement requirement."); *ALZA*, 603 F.3d at 940 ("[A] 'reasonable' amount of routine experimentation" is permissible.); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness...."); Ansul Co. v. Uniroyal, Inc., 448 F.2d 872, 878–79 (2d Cir. 1971) (finding that the disclosure "did not place an unreasonable burden upon one skilled in the art").

48. Cephalon, 707 F.3d at 1339; PPG, 75 F.3d at 1564; Wands, 858 F.2d at 737.

49. Wyeth, 720 F.3d at 1386 (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998)).

50. 858 F.2d 731 (Fed. Cir. 1988).

51. Id. at 733.

practice. *Id.* Prophetic examples are not forbidden. *Id.* A patentee can rely entirely on "constructive reduction to practice" through the filing of an application including an enabling disclosure. *See* Solvay S.A. v. Honeywell Int'l, Inc., 622 F.3d 1367, 1376 (Fed. Cir. 2010).

<sup>43.</sup> Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012) (quoting *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)); *see also Cephalon*, 707 F.3d at 1336; *ALZA*, 603 F.3d at 940.

which would bind to the hepatitis B antigen, and engage in further screening to identify those antibodies having the qualities required by the patent claims.<sup>52</sup> The court found that the required experimentation was not undue because, however time consuming and complex, it would be routine for persons skilled in the art.<sup>53</sup> The level of skill in the art was high, the specification provided extensive guidance, and the techniques required to produce and screen the antibodies were well known.<sup>54</sup> In short, "extensive experimentation" may not be "undue" where "the experiments involve repetition of known or commonly used techniques."<sup>55</sup>

On the other hand, some courts have used the term "unduly *extensive*" experimentation, rather than "undue" experimentation, to mark the limit of enablement,<sup>56</sup> or they have noted that the flexibility allowing for routine experimentation is "not without bounds."<sup>57</sup> Although quantitative limits are not the sole criterion, experiments that would require months or years may well be "unduly extensive."<sup>58</sup> In *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.*,<sup>59</sup> the patentee omitted from the specification the software code necessary to operate the patented machine tool.<sup>60</sup> It would have required "from 1½ to 2 man years of effort" for persons of ordinary skill to supply a substitute, which the court found to be "a clearly unreasonable requirement."<sup>61</sup>

The simplest form of enablement dispute arises where the parties debate whether the disclosures of the patent specification would allow a person of ordinary skill in the art to practice the claimed invention in *any* manner, without the need for undue experimentation. In

<sup>52.</sup> Id. at 737–38.

<sup>53.</sup> Id. at 740.

<sup>54.</sup> *Id.; see also* Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (referring to experimentation that "is either 'undue' or sufficiently routine that an ordinarily skilled artisan would reasonably be expected to carry it out"); Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("[R]outine experimentation does not constitute undue experimentation ....").

<sup>55.</sup> Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1338 (Fed. Cir. 2013).

<sup>56.</sup> See, e.g., Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004) (emphasis added) (quoting PPG Indus., Inc. v. Guardian Indus., Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996)); Nat'l Recovery Techs. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1197 (Fed. Cir. 1999) (emphasis added).

<sup>57.</sup> Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1386 (Fed. Cir. 2013) (quoting *Cephalon*, 707 F.3d at 1339).

<sup>58.</sup> See In re Ghiron, 442 F.2d 985, 992 (C.C.P.A. 1971) (a period of "many months or years... does not bespeak of a routine operation").

<sup>59. 713</sup> F.2d 788 (Fed. Cir. 1983).

<sup>60.</sup> *Id.* at 790.

<sup>61.</sup> Id. at 791.

National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.,<sup>62</sup> the invention was a system for separating recyclable containers that took advantage of the fact that different types of plastic absorb different amounts of electromagnetic radiation.<sup>63</sup> If the radiation passed through an irregularity in the container (through a fold, for example), this confused the results.<sup>64</sup> Consequently, the claims required that one using the invention "select[] for processing" only signals representative of radiation that did not pass through such irregularities.<sup>65</sup> The patent did not provide a method for identifying those signals, but suggested, as a "good proxy," treating the signals associated with the highest transmission rates as those that were not tainted by irregularities.<sup>66</sup> The court held that "enabling a proxy for the claimed invention is not the same as enabling the claimed invention itself."<sup>67</sup> The patent specification "[did] not at all purport to enable one of ordinary skill in the art to determine where irregularities exist in the containers."68 As a result, one could not practice the claimed invention in any manner without undue experimentation.<sup>69</sup>

Although, in any given case, conclusions may differ as to whether undue experimentation would be required before the invention could be practiced at all, the analytical framework, based on the *Wands* factors, is uncontroversial. However, as discussed in the next Part, things become more complicated when the dispute concerns the *scope* of the claim.

#### II. SCOPE ENABLEMENT

Patent claims define the boundaries of the patent owner's exclusive rights.<sup>70</sup> A hypothetical claim to a mousetrap might read: "A

69. Id. at 1197-98.

70. *In re* Warmerdam, 33 F.3d 1354, 1360 (Fed. Cir. 1994) ("It is the claims which define the metes and bounds of the invention entitled to the protection of the patent system.").

<sup>62. 166</sup> F.3d 1190 (Fed. Cir. 1999).

<sup>63.</sup> See id. at 1192.

<sup>64.</sup> Id.

<sup>65.</sup> *See id.* at 1193–94.

<sup>66.</sup> *See id.* at 1197.

<sup>67.</sup> Id.

<sup>68.</sup> *Id.* Curiously, the court calls this "a classic example of a claim that is broader than the enablement as taught in the specification." *Id.* at 1196. Unless the court is imagining the improbable case in which the containers have been presorted to eliminate irregularities, the case seems to have nothing to do with the breadth of the claim. On the contrary, the specification did not enable "at all" the system demanded by the claims. *Id.* at 1197.

mousetrap comprising: a spring, a trigger, a latch, and bait." *Any* mousetrap having a spring, a trigger, a latch, and bait would fall within the scope of the claim.<sup>71</sup> The claim does not embrace a particular mousetrap, but a *class* of mousetraps distinguished by the inclusion of a spring, a trigger, a latch, and bait.<sup>72</sup> The spring, the trigger, the latch, and the bait of an infringing mousetrap could take any number of forms—various materials or designs—so long as the variants still fell within the meaning of those terms. The patent specification would disclose, in detail, the patentee's own preferred embodiments—representative examples of the invention, including the patentee's "best mode." While those embodiments might be used to interpret the meaning of the claim (e.g., what qualifies as "bait"), the patentee's rights are not limited to those specific examples.<sup>73</sup>

Because it is the nature of patent claims to embrace classes of things rather than specific embodiments, courts have long been aware of the danger that a claim may encompass more than the patentee's contribution to the arts. *O'Reilly v. Morse*<sup>74</sup> provides a famous example. Morse, the inventor of the telegraph, included one claim in his patent that would have covered any use of electromagnetism for printing characters at a distance.<sup>75</sup> The Court held that claim unpatentable, observing that it would impinge on the discoveries of future inventors who did not employ any of the specific means disclosed in Morse's specification.<sup>76</sup> Morse would be allowed to patent his invention, but not every means of accomplishing the same thing. Since then, courts have rejected claims found to be broader than the patentee's invention on a number of grounds: under the subject matter provision of the Patent Act,<sup>77</sup> denying patents to "abstract

<sup>71.</sup> Because the claim includes the open-ended term "comprising," mousetraps that have elements in addition to those set forth in the claim (e.g., a bell that sounds when a mouse is captured) would also come within its scope. *See* Free Motion Fitness, Inc. v. Cybex Int'l, Inc., 423 F.3d 1343, 1353 (Fed. Cir. 2005) ("Basic patent law holds that a party may not avoid infringement of a patent claim using an open transitional phrase, such as comprising, by adding additional elements.").

<sup>72.</sup> See 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, 501 (2008) (claims "specify the necessary and sufficient criteria for the inclusion of a thing within the set of things" over which the patentee has exclusive rights).

<sup>73.</sup> Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

<sup>74. 56</sup> U.S. (15 How.) 62 (1854).

<sup>75.</sup> Id. at 112.

<sup>76.</sup> Id. at 113.

<sup>77. 35</sup> U.S.C. § 101 (2012).

ideas;"<sup>78</sup> under the written description requirement, which demands that the disclosures of the specification demonstrate "possession" of the claimed invention;<sup>79</sup> and under the enablement requirement.

The enablement requirement comes into play because courts require that the patent disclosure be "commensurate in scope" with the territory covered by the claim.<sup>80</sup> In other words, one must ask not only whether the disclosure allows the invention to be made and used (what one might call "basic enablement" or "general enablement"), one must also ask whether the teachings of the specification justify a claim of broader scope than the preferred embodiments.<sup>81</sup> An enabling disclosure that matches the scope of the claims is said to be an essential part of the "quid pro quo of the patent bargain."<sup>82</sup> A patentee who chooses broad claims, and who expects the far-reaching exclusive rights that accompany them, must provide teachings of comparable breadth.<sup>83</sup> This ensures that "the public knowledge is enriched" in a proportionate manner.<sup>84</sup>

80. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004) (quoting *In re* Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983)); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) ("[W]hat is necessary is that [the applicant] provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of [the] claims.").

<sup>78.</sup> See Gottschalk v. Benson, 409 U.S. 63, 64–68 (1972) (rejecting a claim to a computer algorithm that was not confined "to any particular art or technology, to any particular apparatus or machinery, or to any particular end use"); Dan L. Burke & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1642 (2003) ("The rule against patenting abstract ideas, while couched in terms of patentable subject matter, is really a judicial effort to restrict the permissible scope of patents and to channel patent protection towards finished products.").

<sup>79.</sup> See supra note 24 and accompanying text. For example, in *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004), the applicant claimed a dental floss made of PTFE (Teflon) with a friction-enhancing coating. *Id.* at 1352. Although the applicant disclosed only one coating—microcrystalline wax—he claimed the broad genus of all such coatings that would adhere to the Teflon. *Id.* at 1353. Given the difficulty of discovering materials that will stick to a Teflon surface, the court held that the applicant had not demonstrated possession of the broader genus. *Id.* 

<sup>81.</sup> See In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999) (distinguishing between "general enablement rejection[s]" where the specification "does not teach how to make or use the invention" and "scope of enablement rejection[s] where the written description enables something within the scope of the claims, but the claims are not limited to that scope").

<sup>&</sup>lt;sup>82.</sup> Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003)); LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344 (Fed. Cir. 2005).

<sup>83.</sup> *Sitrick*, 516 F.3d at 999 ("A patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

<sup>84.</sup> MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012) (quoting *Sitrick*, 516 F.3d at 999).

In some cases, addressing the scope of enablement is much the same as addressing basic enablement. Those are the cases where the patentee (or applicant) argues that the teachings of the patent do allow persons skilled in the art to make and use the invention as broadly as claimed, without undue experimentation. Although the claims embrace embodiments not specifically disclosed, those alternatives may (or may not) remain within reach through the combination of the patent's teachings, the knowledge available in the art, the predictability of the art, and the fruits of reasonable experimentation.

Streck, Inc. v. Research & Diagnostic Systems, Inc.<sup>85</sup> is a case where a claim broader in scope than the disclosed embodiments was nevertheless adequately enabled. The patent concerned blood "control" samples used to monitor the accuracy of laboratory equipment.<sup>86</sup> The claims required a control including both a white blood cell component and a reticulocyte component, the latter consisting of either true reticulocytes or reticulocyte analogs.<sup>87</sup> The defendant conceded that the disclosures enabled controls with reticulocyte analogs (the form of the invention in which the patentee had reduced it to practice), but argued that the patent did not enable true reticulocytes, as used in the accused product.<sup>88</sup> The court found that the specification enabled the "full scope of the claimed invention," including true reticulocytes, because persons skilled in the art, following the teachings of the patent, could have substituted true reticulocytes reticulocyte for analogs without undue experimentation.<sup>89</sup> True reticulocytes and reticulocyte analogs are "virtually indistinguishable" and "work in exactly the same way."90

A contrary example can be found in *Wyeth & Cordis Corp. v. Abbott Laboratories*,<sup>91</sup> where the invention concerned the use of rapamycin to prevent arterial blockages from returning after a balloon angioplasty procedure. The claims called for administering rapamycin, but the specification disclosed only sirolimus, one species of rapamycin.<sup>92</sup> Rapamycin is actually a broad genus of tens of

90. Id.

<sup>85. 665</sup> F.3d 1269 (Fed. Cir. 2012).

<sup>86.</sup> Id. at 1274.

<sup>87.</sup> *Id.* at 1276–77.

<sup>88.</sup> *Id.* at 1287.

<sup>89.</sup> *Id.* at 1288–89 (quoting ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010)).

<sup>91. 720</sup> F.3d 1380 (Fed. Cir. 2013).

<sup>92.</sup> Id. at 1382.

thousands of compounds.<sup>93</sup> Even small changes in the sirolimus molecule could alter its effect, and one skilled in the art would have to undertake laborious testing to determine which of the thousands of rapamycin compounds could prevent the return of an arterial blockage.<sup>94</sup> The court found no genuine dispute that practicing the full scope of the claims would require "excessive experimentation."<sup>95</sup>

Where the question is whether one could or could not practice undisclosed embodiments without undue experimentation, the *Wands* factors are precisely what is needed. The patent specification may point researchers in the right direction or, as in *Streck*, provide a working example close to the alternative embraced by the claim. Alternatively, it may do nothing more than "[t]oss[] out the mere germ of an idea,"<sup>96</sup> leaving it to those skilled in the art to work out the rest. The knowledge already available in the art may allow practitioners to "fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments ...."<sup>97</sup> If the level of skill in the art is high, more successful "interpolation" can be expected.<sup>98</sup>

Another important factor is the "predictability" of the art. Gaps in the disclosure are bridged more easily when results can be predicted in advance. Accordingly, courts have observed that the scope of enablement varies inversely with the unpredictability of the art.<sup>99</sup> In predictable arts, even "a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws."<sup>100</sup> In unpredictable arts, researchers may have little idea of what to expect until they have tested alternatives to the embodiments disclosed in the patent. In *Adang v. Fischhoff*,<sup>101</sup> the invention concerned plant cells genetically modified to confer resistance to insects. The claims covered the use of the technique with tomato and other plants, but the specification only

<sup>93.</sup> Id. at 1384–85.

<sup>94.</sup> Id. at 1385.

<sup>95.</sup> Id.

<sup>96.</sup> Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 (Fed. Cir. 1999) (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

<sup>97.</sup> Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004) (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).

<sup>98.</sup> See In re Wands, 858 F.2d 731, 740 (Fed. Cir. 1988) (referring to a high level of skill and well-known techniques).

<sup>99.</sup> In re Angstadt, 537 F.2d 498, 502 (C.C.P.A. 1976); In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

<sup>100.</sup> In re Fisher, 427 F.2d at 839.

<sup>101. 286</sup> F.3d 1346 (Fed. Cir. 2002).

demonstrated success with tobacco.<sup>102</sup> The court found the claims inadequately enabled, in large part because the art was so unpredictable that one could not expect success with one species to be transferred to another.<sup>103</sup>

Courts have sometimes suggested that a narrow disclosure possibly the disclosure of a single embodiment—can enable a broad claim in the "mechanical" arts, because outcomes in such arts are predictable based on the application of well-understood physical laws.<sup>104</sup> In contrast, patents in the chemical and biological arts require more extensive disclosure to support broad claims, because those arts are inherently unpredictable.<sup>105</sup> In other cases, courts have shied away from the mechanical/chemical distinction—perhaps because the principles of the latter arts have become better understood—in favor of a general distinction between technologies that are predictable or unpredictable.<sup>106</sup>

#### A. Incomplete Enablement

When the parties dispute whether gaps in the disclosure can be bridged without undue experimentation, resolving the issue may be difficult.<sup>107</sup> It is a fact-intensive inquiry with a strong theoretical component. Nevertheless, as when the parties dispute whether the patentee's disclosures allow the invention to be practiced at all, there are few controversies over the legal framework. The *Wands* factors are firmly established. The hard cases, from a legal/policy point of view, are those where the issue is not whether a particular

<sup>102.</sup> Id. at 1356.

<sup>103.</sup> See id. (relaying the Board of Patent Appeals and Interferences' finding that "the successful transformation of plant cells using vectors... is not necessarily predictable prior to attempting a desired transformation" (quoting Fischhoff v. Adang, No. 103,324 (B.P.A.I. Sept. 29, 2000) (unpublished slip opinion) (alteration in original)).

<sup>104.</sup> See Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) ("If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment ...."); *In re* Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944) ("[O]rdinarily in a mechanical case broad claims may be supported by a disclosure of a single form of the apparatus disclosed in an application.").

<sup>105.</sup> See In re Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) (referring to "the high level of predictability in mechanical or electrical environments and the lower level of predictability expected in chemical reactions and physiological activity").

<sup>106.</sup> See, e.g., In re Cook, 439 F.2d 730, 734 (C.C.P.A. 1971) ("This dichotomy... we would prefer to see denominated a dichotomy between predictable and unpredictable factors in any art rather than between 'mechanical cases' and 'chemical cases'....").

<sup>107.</sup> See In re Bowen, 492 F.2d 859, 861 (C.C.P.A. 1974) ("Whether, in a particular case, the requisite 'reasonable correlation' between the scope of claims and the scope of enablement provided by the specification exists is often a difficult question.").

embodiment of the claimed invention could be made or used, but whether it actually matters. In other words, can a claim be valid even if it embraces some embodiments that *cannot* be practiced without undue experimentation? Here the *Wands* factors are no longer relevant.

The simplest answer is that the specification must enable *every* embodiment within the scope of the claim to be made and used without undue experimentation. Courts frequently employ language that suggests that simple approach. It is said, for example, that the specification, to be enabling, must teach how to make and use the "full scope" of the claimed invention.<sup>108</sup> In a more mathematical vein, courts say that "[t]he scope of the claims must be less than or equal to the scope of the enablement ..... "<sup>109</sup> The problem is that a rigid application of that rule would invalidate nearly every patent claim. For example, unless the science of spring design has come to an end, inevitably a mousetrap claim calling for a "spring" will include some embodiments that the inventor did not specifically disclose and that persons skilled in the art could not make or use without extensive experimentation. New springs, for example, might be made from exotic metal alloys requiring years of development, yet be perfectly suited for use in a basic mousetrap. Only patentees who limited themselves to "picture claims"-claims so constricted that they track every detail of the preferred embodiments<sup>110</sup>—could hope to survive an enablement challenge.

<sup>108.</sup> See, e.g., MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012) ("[A] patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage."); Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("A patent's specification must 'teach those skilled in the art how to make and use the full scope of the claimed invention ....'" (quoting ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010))); Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008) ("The full scope of the claimed invention must be enabled."); Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1360 (Fed. Cir. 2007) ("[T]he specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention ...." (quoting *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993))). *MagSil* also uses the term "entire scope." *MagSil*, 687 F.3d at 1381.

<sup>109.</sup> *MagSil*, 687 F.3d at 1381 (quoting *Sitrick*, 516 F.3d at 999); *see also* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005) ("The scope of [patent] claims must be less than or equal to the scope of the enablement." (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999) (alteration in original))).

<sup>110.</sup> See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1342 (Fed. Cir. 2006) (a claim that "recites in detail nearly all of the features of the invention" is "often referred to as a 'picture claim'").

However, a rigid application of the "less than or equal to" rule may not be what courts have in mind. Often courts refer to a "reasonable correlation" between the scope of the claims and the scope of the enablement,<sup>111</sup> or "reasonable enablement" of the claims.<sup>112</sup> But what does "reasonable," in this context, mean? If it refers simply to a numerical percentage (e.g., ninety percent of the mousetraps within the scope of the claim can be practiced without undue experimentation), one wonders how such a percentage could ever be determined. One also wonders how often the number of enabled embodiments would be more than an infinitesimal proportion of all of the variations made possible by continuing innovation in the technological arts, including that of spring design. Aware of these pitfalls, courts have sometimes said that, because "[t]he law does not require the impossible," an applicant need not "describe in his specification every conceivable and possible future embodiment of his invention."113

In order to understand when embodiments of the claimed invention may *reasonably* be omitted from the scope of enablement, it may be illuminating to consider some of the cases in which the courts found omissions *un*reasonable. These can be roughly divided into three categories: cases involving a distinct alternative to an enabled embodiment, cases involving a broad genus including an enabled species, and cases involving a numerical range on which the claims place no limit.

## 1. Distinct Alternatives

In *AK Steel Corp. v. Sollac*,<sup>114</sup> the patents concerned a method of applying an aluminum coating to strips of stainless steel.<sup>115</sup> If the aluminum does not adhere well to the steel, it may flake off when the

<sup>111. &</sup>quot;The scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification to persons of ordinary skill in the art." *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970); *see also MagSil*, 687 F.3d at 1381; *Invitrogen*, 429 F.3d at 1071; Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991).

<sup>112.</sup> See Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007) (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed. Cir. 2007)); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("[W]hen a range is claimed, there must be reasonable enablement of the scope of the range.").

<sup>113.</sup> SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985); *see also* U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251–52 (Fed. Cir. 1989) (the state of the art at the time of filing is critical).

<sup>114. 344</sup> F.3d 1234 (Fed. Cir. 2003).

<sup>115.</sup> Id. at 1234.

strip is bent.<sup>116</sup> The inventors addressed the problem by keeping the steel strips in a hydrogen atmosphere until they were dipped into the aluminum-coating bath.<sup>117</sup> The inventors believed that the invention would only work with substantially pure "Type 2 aluminum,"<sup>118</sup> and the patent disclosures "clearly and strongly warn[ed]" that one should avoid "Type 1 aluminum," which includes a significant proportion of silicon.<sup>119</sup> However, the inventors eventually obtained broad claims requiring only the use of "aluminum or aluminum allovs" (a term that includes Type 1 aluminum) and alluding to the end result that the aluminum layer is "tightly adherent to the strip and resistant to... flaking during bending."<sup>120</sup> Because the specifications did not teach any manner of achieving that result except with Type 2 aluminum, the court found that the disclosures failed to enable the full scope of the claims.<sup>121</sup> In fact, teaching against the use of Type 1 aluminum was "[w]orse than being silent as to that aspect of the invention," because it discouraged experimentation.<sup>122</sup> The specifications "tell[] the public that higher amounts of silicon will not work."123

*Liebel-Flarsheim Co. v. Medrad, Inc.*<sup>124</sup> is a similar case. The patented invention involved a mechanism for injecting pressurized fluids, such as contrast media, into patients.<sup>125</sup> All of the disclosed embodiments included a "pressure jacket" to prevent the syringe from bursting.<sup>126</sup> The specification warned that syringes capable of operating without a pressure jacket would be expensive and impractical.<sup>127</sup> The inventors had explored the possibility of a jacketless injector but abandoned the effort as "too risky."<sup>128</sup> The patent claims, as originally filed, each included a pressure jacket limitation, but when the inventors became aware of the defendant's jacketless design they modified the claims to remove those limitations.<sup>129</sup> Although the broadened claims covered injectors with

116. Id. at 1236.
117. Id.
118. Id. at 1240.
119. Id. at 1244.
120. Id. at 1237.
121. Id. at 1244.
122. Id.
123. Id.
124. 481 F.3d 1371 (Fed. Cir. 2007).
125. Id. at 1373.
126. Id. at 1379.
127. Id.
128. Id.
129. Id. at 1374.

and without pressure jackets,<sup>130</sup> the court found the patent invalid because the disclosures did not enable the full scope of the claims.<sup>131</sup> The failure of the specification to suggest how a jacketless system could be made, its warning that such designs were "impractical," and the inventors' own failure to produce a jacketless design, all supported the conclusion that "undue experimentation" would be required before one could practice the invention as broadly as it was claimed.<sup>132</sup> The court ended by remarking: "[t]he motto, 'beware of what one asks for,' might be applicable here."<sup>133</sup>

Thus, in both *AK Steel* and *Liebel-Flarsheim*, the embodiment that the specification failed to enable (the use of Type 1 aluminum and the elimination of the pressure jacket) was not just one of a countless number of undisclosed alternatives. In each case, the patentee deliberately excluded the alternative from the claims as originally filed, warned against the alternative in the patent disclosures, and broadened the claims to include the alternative only after discovering that competitors had managed to adopt it. Yet there are cases reaching similar results where the patentee did not "teach away" from the nonenabled alternative, but tried from the beginning to embrace it.

One such case is *Automotive Technologies International, Inc. v. BMW of North America, Inc.*<sup>134</sup> The invention concerned a crash sensor to trigger an airbag in a side-impact collision.<sup>135</sup> Earlier side-impact sensors had been crush sensors triggered only when deformed by an impact. These were ineffective unless struck directly.<sup>136</sup> The "conventional wisdom" was that velocity sensors, triggered by sudden changes in velocity and used successfully with front-impact airbags, would not react fast enough to be effective in side-impact collisions.<sup>137</sup> However, the inventors discovered that velocity sensors could be effective in that application if properly designed.<sup>138</sup> The claims called for a side-impact crash sensor incorporating a mass, and a "means

<sup>130.</sup> See id. at 1374–75.

<sup>131.</sup> *Id.* at 1380 ("[T]he asserted claims read on, and the full scope of the claimed invention includes, an injector system with and without a pressure jacket. There must be 'reasonable enablement of the scope of the range' which, in this case, includes both injector systems with and without a pressure jacket." (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003))).

<sup>132.</sup> Id. at 1379.

<sup>133.</sup> Id. at 1380.

<sup>134. 501</sup> F.3d 1274 (Fed. Cir. 2007).

<sup>135.</sup> Id. at 1276–77.

<sup>136.</sup> Id. at 1277.

<sup>137.</sup> Id.

<sup>138.</sup> Id.

responsive to the motion of said mass... for initiating an occupant protection apparatus."<sup>139</sup> The specification taught that either a mechanical sensor or an electronic sensor could be used to detect the movement of the mass in situations calling for deployment of the airbag.<sup>140</sup> A detailed drawing of a mechanical sensor showed a flapper that would move in a crash, closing an electrical circuit and triggering the airbag.<sup>141</sup> In contrast, the drawing of an electronic sensor, described in the specification as a "conceptional view," depicted little more than rectangles representing the moving mass and its housing.<sup>142</sup> The specification stated that, in the electronic sensor, the motion of the mass "can be sensed by a variety of technologies using, for example, optics, resistance change, capacitance change or magnetic reluctance change."<sup>143</sup>

The court held that the claims covered both mechanical and electronic sensors, but the specification, by disclosing so few details about an electronic sensor, failed to enable the full scope of the claims.<sup>144</sup> The court relied heavily on the contrast between the detailed disclosure of the mechanical sensor and the cursory depiction of the electronic version.<sup>145</sup> The specification devoted two columns and five drawings to the mechanical sensor, but only one paragraph and a "very general view" to the electronic alternative.<sup>146</sup> The latter was merely a concept with no disclosure of how an electronic sensor would be built or operated.<sup>147</sup> Because side-impact sensors were "a new field"<sup>148</sup> and the specification provided nothing more than "a starting point, a direction for further research,"<sup>149</sup> one could not expect persons skilled in the art to implement electronic sensors without undue experimentation. In fact, the defendant's expert

<sup>139.</sup> Id.

<sup>140.</sup> See id. at 1278.

<sup>141.</sup> See id. at 1277–78.

<sup>142.</sup> See id. at 1278, 1282–83; U.S. Patent No. 5,231,253 fig.11 col. 10 ll. 3–14 (filed June 2, 1992).

<sup>143.</sup> Auto. Techs., 501 F.3d at 1278 (quoting '253 Patent col. 10 ll. 8–10).

<sup>144.</sup> *Id.* at 1285.

<sup>145.</sup> Id. at 1284 ("The inadequacy of the description of an electronic side impact sensor is highlighted by comparison with the extensive disclosure of how to make and use a mechanical side impact sensor... If such a disclosure is needed to enable making and using a mechanical side impact sensor, why is not a similar disclosure needed to enable making and using an electronic side impact sensor, which is an essential aspect of the invention?").

<sup>146.</sup> Id. at 1282.

<sup>147.</sup> Id. at 1283.

<sup>148.</sup> *Id.* at 1284.

<sup>149.</sup> Id. (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

testified that "a great deal of experimentation" would be required to sense the motion of the mass electronically and process the resulting data.<sup>150</sup> Consequently, the "[d]isclosure of only mechanical side impact sensors [did] not permit one skilled in the art to make and use the invention as broadly as it was claimed."<sup>151</sup>

The Federal Circuit came to a similar conclusion in Sitrick v. Dreamworks, LLC.<sup>152</sup> Here the patent concerned technology for inserting a user-generated visual image into a preexisting audiovisual work.<sup>153</sup> The claims covered the insertion of images into both video games and movies.<sup>154</sup> The specification discussed how, in a video game, address and control signals representing particular characters could be intercepted and data corresponding to the user-created image substituted.<sup>155</sup> The specification did not discuss how anything similar could be accomplished with a movie, which does not include separable character signals.<sup>156</sup> In some undisclosed manner, the characters would have to be "carved out" of the scene and the user's image substituted.<sup>157</sup> The court found that the specification did not enable the full scope of the claimed invention: "Because the asserted claims are broad enough to cover both movies and video games, the patents must enable both embodiments. Even if the claims are enabled with respect to video games ... the claims are not enabled if the patents do not also enable for movies."<sup>158</sup>

In *Automotive Technologies*, the patentee called attention to the problematic nature of the electronic sensor through its uniquely minimalist description.<sup>159</sup> That may be one reason for the court's conclusion that "[e]lectronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor."<sup>160</sup> In *Sitrick*, on the other hand, the specification was merely silent on the subject of movies.<sup>161</sup> Nevertheless, the fundamental technological differences between movies and video games made clear that the former were not "just another species" of a

161. See supra notes 153–56 and accompanying text.

<sup>150.</sup> Id.

<sup>151.</sup> Id. at 1285.

<sup>152. 516</sup> F.3d 993 (Fed. Cir. 2008).

<sup>153.</sup> Id. at 994-96.

<sup>154.</sup> Id. at 996.

<sup>155.</sup> Id. at 997.

<sup>156.</sup> Id. at 1000.

<sup>157.</sup> See id. at 998–99.

<sup>158.</sup> Id. at 1000 (citation omitted).

<sup>159.</sup> See supra notes 140-43 and accompanying text.

<sup>160.</sup> Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007).

common genus, but a "distinctly different" alternative. Expert testimony showed that "movies and video games are technically different," so that one skilled in the art could not "take the teachings regarding video games and apply them to movies."<sup>162</sup> In fact, the techniques disclosed for use with video games had "no relevance to movies."<sup>163</sup>

In one respect, it is difficult to argue with the result in these cases. Each time the patentee tried to secure exclusive rights to an alternative that could not be made or used based on the teachings of the patent, even with the benefit of knowledge available in the art and the potential for reasonable experimentation. Yet doubts arise when one considers other alternatives that the patentees did not teach. The patent in Automotive Technologies disclosed one mechanical sensor in detail, but it did not discuss every mechanical sensor that might be devised, some of which would demand considerable ingenuity. Would the patent claims have been too broad even if limited to mechanical sensors? If the claims in Liebel-Flarsheim had each included a pressure jacket limitation, they would still have covered injectors that could only be made after long experimentation and further technological advancements-perhaps injectors with pressure jackets made from improbable or yet-to-be-discovered materials. Would these variations of a variation have doomed the patent? It may be important that in each case something distinguished the undisclosed embodiment as a "distinctly different"<sup>164</sup> alternative—whether it was the treatment of the alternative in the specification (as a variant merely hinted at or positively discouraged), the omission of the alternative in the original claims, or simply an apples-and-oranges difference in technology between the disclosed and undisclosed embodiments.

## 2. Genus and Species

The preceding cases suggest two distinct roads, one not taken (or taught). Other cases, primarily in the chemical and biological arts, concern claims to broad genuses supported by the enabling disclosure of only a few species. One example, *Wyeth & Cordis Corp. v. Abbott Laboratories*, has already been discussed.<sup>165</sup> The claims called for the use of rapamycin to prevent arterial blockages but taught only one

<sup>162.</sup> *Sitrick*, 516 F.3d at 1000.

<sup>163.</sup> *Id.* 

<sup>164.</sup> Auto. Techs., 501 F.3d at 1285.

<sup>165.</sup> See supra notes 91–95 and accompanying text.

species of rapamycin, known as sirolimus.<sup>166</sup> Because this left thousands of other rapamycin compounds to be tested for effectiveness, a task that would require "excessive experimentation," the patentee had failed to enable "the full scope of the claims."<sup>167</sup>

A similar case is *Amgen, Inc. v. Chugai Pharmaceutical Co.*,<sup>168</sup> where the patentee claimed a technique of producing EPO (a protein that stimulates the production of red blood cells), or EPO analogs, through recombinant DNA technology.<sup>169</sup> The patentee did not enable DNA sequences corresponding to the thousands of possible EPO analogs, and did not, therefore, provide a disclosure commensurate in scope with its "all-encompassing claims."<sup>170</sup> Although "a patent applicant is entitled to claim his invention generically,"<sup>171</sup> the disclosure here fell short: "There may be many other genetic sequences that code for EPO-type products [but] Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them."<sup>172</sup> The court noted "the structural complexity of the EPO gene" and "the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs."<sup>173</sup>

Where a claimed genus encompasses thousands of species and the specification teaches only a few, one may conclude based on the numbers alone that there is no "reasonable correlation" between the scope of enablement and the scope of the claims, at least if the unpredictability of the art makes it difficult to apply the teachings of the patent to the undisclosed species. In some genus/species cases there is the additional factor that the claims ignore recognized taxonomic distinctions that demonstrate the limited scope of the patent disclosure. One such distinction, appearing in a number of cases, is that between flowering plants that produce one leaf in the early stages of their development (known as "monocots") and plants that produce two leaves (known as "dicots"). In *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*,<sup>174</sup> the patent claimed a

<sup>166.</sup> Wyeth & Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1382 (Fed. Cir. 2013).

<sup>167.</sup> Id. at 1386.

<sup>168. 927</sup> F.2d 1200 (Fed. Cir. 1991).

<sup>169.</sup> *Id.* at 1204.

<sup>170.</sup> Id. at 1213.

<sup>171.</sup> Id.

<sup>172.</sup> Id. at 1213–14.

<sup>173.</sup> *Id.* at 1214; *see also In re* Wright, 999 F.2d 1557, 1562–63 (Fed. Cir. 1993) (claims to vaccines for all pathogenic RNA viruses were not adequately enabled where the disclosures related to only one species of virus).

<sup>174. 315</sup> F.3d 1335 (Fed. Cir. 2003).

technique for making plants resistant to certain herbicides through genetic engineering.<sup>175</sup> All of the working examples were dicot plants, such as tobacco and tomato plants, whereas the accused product was a variety of corn, a monocot plant.<sup>176</sup> Because the ability to genetically engineer monocot plants arrived only after the filing date of the patent, the court found that the full scope of claims, covering both dicot and monocot plants, was not enabled.<sup>177</sup>

#### 3. Unlimited Ranges

Enablement shortfalls also arise in cases where the patent claims include an unlimited numerical range. A recent example is MagSil Corp. v. Hitachi Global Storage Technologies, Inc.<sup>178</sup> The patent involved read-write sensors for hard disk data storage devices that rely on changes in electrical resistance.<sup>179</sup> The inventors achieved changes in resistance of as much as 11.8%—considerably better than past efforts, which had effected a change of only 2.7%.<sup>180</sup> The claims, however, called for "a change in the resistance [of] at least 10% at room temperature,"<sup>181</sup> a range that extends from "at least 10% up to infinity."182 As the art progressed, other experimenters achieved changes in resistance of more than 600%—still within the scope of the claims but by no means enabled by the patent disclosure.<sup>183</sup> Having disclosed only "a marginal advancement," the patentee was not entitled to claims covering "the modern dimensions of this art."<sup>184</sup> The teachings of the specification did not enable the claims "across [the] full scope of coverage."<sup>185</sup>

<sup>175.</sup> Id. at 1337.

<sup>176.</sup> Id. at 1338.

<sup>177.</sup> *Id.* at 1340–42; *see also* Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1361–62 (Fed. Cir. 2007) ("broad functional language" covering genetic transformation of both dicot and monocot plant cells was not enabled before the transformation of monocot cells was possible); *In re* Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (a single example of manufacturing mammalian peptides in dicot plant cells did not enable claims including monocot cells). A similar taxonomic distinction has been observed between eukaryotic and prokaryotic cells. *See* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374 (Fed. Cir. 1999).

<sup>178. 687</sup> F.3d 1377 (Fed. Cir. 2012).

<sup>179.</sup> Id. at 1378-79.

<sup>180.</sup> Id. at 1379–80.

<sup>181.</sup> Id. at 1379 (quoting U.S. Patent No. 5,629,922 col. 8 ll. 52-54 (filed Mar. 21, 1995)).

<sup>182.</sup> Id. at 1382.

<sup>183.</sup> Id.

<sup>184.</sup> *Id.* 

<sup>185.</sup> Id. at 1381.

Similarly, the Court of Custom and Patent Appeals held in *In re* Fisher<sup>186</sup> that claims to therapeutic hormone compositions with potency recitations of "at least 1 International Unit of ACTH per milligram" were not adequately enabled by the disclosure of products having potencies of 1.11 to 2.30 International Units.<sup>187</sup> The "'openended' recitation" of potency had "a lower limit but no upper limit."<sup>188</sup> The court concluded that, in this case, the patentee should not be "allowed to dominate all such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill."189 The court observed that some claimed ranges have inherent limits. In the case of a "substantially pure" composition, the upper limit of purity is 100%.<sup>190</sup> If the composition disclosed in the specification is already so pure that "the possible range of further purification [is] either small or nonexistent," the range encompassed by the claim may be adequately enabled.<sup>191</sup> However, in *Fisher* it "appear[ed] theoretically possible to achieve potencies far greater than those obtained by [the applicant]."192

These principles are difficult to reconcile with another line of cases concerning improved manners of practicing the claimed invention. In *CFMT*, *Inc. v. YieldUp International Corp.*,<sup>193</sup> the invention concerned a method of cleaning semiconductor wafers. The system disclosed in the patent performed poorly at first; wafers cleaned by the disclosed system, when subjected to laser scanning, looked "filthy."<sup>194</sup> Only after six months of experimenting and the adoption of "hundreds of modifications"—improvements made the subject of a later patent—were the inventors able to achieve a commercially satisfactory system.<sup>195</sup> The court noted that one must

194. Id. at 1337 (quoting CFMT, Inc. v. YieldUp Int'l Corp., 144 F. Supp. 2d 305, 309 (D. Del. 2001)).

195. *Id.* at 1338 (quoting CFMT, Inc. v. YieldUp Int'l Corp., 144 F. Supp. 2d 305, 320 (D. Del. 2001)).

<sup>186. 427</sup> F.2d 833 (C.C.P.A. 1970).

<sup>187.</sup> Id. at 839.

<sup>188.</sup> Id.

<sup>189.</sup> Id.

<sup>190.</sup> Id.

<sup>191.</sup> *Id.* at 839–40; *see also* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1572 (Fed. Cir. 1991) ("Open ended claims are not inherently improper .... They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.").

<sup>192.</sup> In re Fisher, 427 F.2d at 840.

<sup>193. 349</sup> F.3d 1333 (Fed. Cir. 2003).

enable "the full scope of the claimed invention."<sup>196</sup> But the claims in this case recited "no standard of cleaning[;]" they only required "cleaning" in the sense of "removing contaminants from the wafer surface."<sup>197</sup> Such claims would be enabled if the disclosures allowed persons skilled in the art to "achieve any level of contaminant removal without undue experimentation."<sup>198</sup> Although the original system was in need of improvement, it did successfully remove grease marks from semiconductor wafers—an instance of "contaminant removal."<sup>199</sup> The court contrasted this patent, which claimed "a general system to improve the cleaning process[,]" with a hypothetical patent claiming a system to "achieve[] cleanliness up to a specified numerical particle-free range[.]"<sup>200</sup> In the latter case, enablement would require disclosures allowing persons skilled in the art to "achieve that range without undue experimentation."<sup>201</sup>

More recently, in *Alcon Research Ltd. v. Barr Laboratories*, *Inc.*,<sup>202</sup> the Federal Circuit considered patents on a method of enhancing the stability of prostaglandin compositions, including glaucoma medications, by adding polyethoxylated castor oil ("PECO").<sup>203</sup> The claims required the single step of adding a chemically stabilizing amount of PECO to the prostaglandin composition.<sup>204</sup> They required only "some increase in chemical stability," not "a particular level of stability or a particular magnitude of increase."<sup>205</sup> Although one might have to experiment to "*optimiz[e]*" the stability of a particular prostaglandin composition, the court did not treat such experimentation as relevant to the claimed invention.<sup>206</sup> The court found the claims adequately enabled even though the stabilization had no quantifiable boundary.<sup>207</sup>

What is troubling about these cases is that the claims seem to embrace *implicitly* open-ended ranges that the disclosures cannot

<sup>196.</sup> Id.

<sup>197.</sup> *Id.* 

<sup>198.</sup> *Id*.

<sup>199.</sup> *Id.* at 1338–39.

<sup>200.</sup> Id. at 1338.

<sup>201.</sup> Id.

<sup>202. 745</sup> F.3d 1180 (Fed. Cir. 2014).

<sup>203.</sup> Id. at 1184.

<sup>204.</sup> Id. at 1189.

<sup>205.</sup> Id.

<sup>206.</sup> *Id.*; *see also In re* Cortright, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (because claims calling for the use of a composition to "restor[e] hair growth" covered any increase in the hair grown on the scalp, the specification was not required to enable one to restore a "full head of hair").

<sup>207.</sup> In re Cortright, 165 F.3d at 1359.

fully enable. If the claims in *CFMT* cover any level of cleaning, then they might be expressed in terms of a range of cleaning extending from the removal of any contaminants to the removal of all contaminants. Similarly, the claims in *Alcon* might be said to cover changes in stability ranging from the most minor improvement to the ultimate in prostaglandin permanence. In neither case were the disclosures' working examples so close to an inherent limit as to leave little room for improvement. Unless there is some reason for distinguishing between explicit and implicit ranges, it is difficult to see why the claims in *CFMT* and *Alcon* are less objectionable, in terms of enablement, than the claims in *MagSil* or *Fisher*.

#### B. Enablement by a Single Mode

Although courts have often said that patent claims and patent disclosures must be commensurate in scope, a handful of decisions indicate that enablement of a single embodiment of the claimed invention is all that is required. As just discussed, *CFMT*, holding that a method of removing grease marks adequately enabled a claim covering any level of cleaning, suggests a single-mode standard. A more explicit instance is the Federal Circuit's opinion in *Spectra-Physics, Inc. v. Coherent, Inc.*<sup>208</sup> There the patents described the structure of a laser and a method of constructing it.<sup>209</sup> An important element of the laser was an array of copper cups firmly bonded to a ceramic tube.<sup>210</sup> The inventors disclosed brazing with TiCuSil (a copper/silver/titanium alloy) as the preferred method of attachment, but failed to disclose a six-stage braze cycle that they had perfected.<sup>211</sup> The inventors disclosed well-known moly-manganese and pulse-soldering processes as acceptable alternatives.<sup>212</sup>

The court held that failure to disclose the six-stage braze cycle amounted to concealment of the inventor's best mode.<sup>213</sup> The enablement requirement, on the other hand, had been satisfied by disclosure of the moly-manganese and pulse-soldering alternatives.<sup>214</sup> The court described the situation as "one in which the patent specifications disclose more than one means for making the claimed invention, but do not adequately disclose the best means actually

<sup>208. 827</sup> F.2d 1524 (Fed. Cir. 1987).

<sup>209.</sup> Id. at 1528–29.

<sup>210.</sup> Id.

<sup>211.</sup> Id. at 1530.

<sup>212.</sup> See id. at 1529-31.

<sup>213.</sup> See id. at 1535–37.

<sup>214.</sup> Id. at 1533.

known to the inventors."<sup>215</sup> Where "[e]nablement looks to placing the subject matter of the claims generally in the possession of the public[,]" the best mode requirement demands disclosure of "specific instrumentalities or techniques which are recognized [by the applicant] as the best way of carrying out the invention."<sup>216</sup> In contrast, "[n]onenablement," said the court, "is the failure to disclose *any* mode."<sup>217</sup> Here it was "sufficient... with respect to enablement that the patents disclose[d] at least one attachment means [that] would enable a person of ordinary skill in the art to make and use the claimed inventions."<sup>218</sup> The adequacy of one mode of enablement is, the court explained, "the logical implication of having a separate best mode requirement... which contemplates that the specification can enable one to make and use the invention and still not disclose a single preferred embodiment."<sup>219</sup>

The only reference the court made to enabling the full scope of the claimed invention was to distinguish between predictable and unpredictable arts: "If an invention pertains to an art where the results are predictable... a broad claim can be enabled by disclosure of a single embodiment, and is not invalid for lack of enablement simply because it reads on another embodiment of the invention which is inadequately disclosed...."<sup>220</sup> A simple explanation for *Spectra-Physics* is that it involved such a predictable art that a person of ordinary skill, armed with knowledge of the familiar molymanganese and pulse-soldering techniques, as well as the patents' disclosure of TiCuSil brazing in general, could have achieved the undisclosed six-stage braze cycle, or any other means of attaching the copper cups to the ceramic tube, without undue experimentation.<sup>221</sup>

<sup>215.</sup> Id. at 1532.

<sup>216.</sup> Id.

<sup>217.</sup> *Id.* at 1534; *see also* Takeda Pharm. Co. v. Zydus Pharm. USA, Inc., 743 F.3d 1359, 1369 (Fed. Cir. 2014) ("It is well established that the 'enablement requirement is met if the description enables *any* mode of making and using the invention.'" (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998))); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("[T]he law makes clear that the specification need teach only one mode of making and using a claimed composition." (quoting Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 160 (D. Mass. 2001))); Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991) ("The enablement requirement is met if the description enables any mode of making and using the claimed invention.").

<sup>218.</sup> Spectra-Physics, 827 F.2d at 1533.

<sup>219.</sup> Id. at 1533 n.5.

<sup>220.</sup> Id. at 1533 (citations omitted).

<sup>221.</sup> See In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) ("In cases involving predictable factors...a single embodiment provides broad enablement in the sense that, once

But this simple explanation is inconsistent with the court's general statements regarding enablement ("[n]onenablement is the failure to disclose *any* mode")<sup>222</sup> and the facts that were before it. In order to successfully employ the moly-manganese process, the defendant had been compelled to hire a brazing expert who experimented for nearly a year, and who ultimately developed techniques deserving of their own patents.<sup>223</sup> The field of the invention hardly seems to be one so uncomplicated that the disclosure of one mode of making and using the invention constitutes de facto enablement of every mode.

*Spectra-Physics* would be easier to dismiss as an aberration if it were not so emphatic (chiding the district court<sup>224</sup> for categorizing the failure to disclose an alternative mode as an enablement issue rather than as a best mode issue), if it had not been written by Judge Rich (a prominent figure in the development of the 1952 Patent Act),<sup>225</sup> and if its discussion of the rationale for a separate best mode requirement did not ring true. If enablement required disclosures providing access to every mode of making and using the claimed invention, why would the law separately require disclosure of the "best" mode?<sup>226</sup>

#### C. Enablement in the Context of Rapidly Developing Technologies

The most difficult issues concerning scope of enablement are in the context of rapidly developing technologies. Patents confer exclusive rights for a limited time—currently, in most cases, until twenty years from the filing date of the patent application.<sup>227</sup> In some fields of technology, a great deal can happen even in so short a span. As previously discussed, the goal of the patent system is to promote

imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.").

<sup>222.</sup> See Spectra-Physics, 827 F.2d at 1534.

<sup>223.</sup> See id. at 1531.

<sup>224.</sup> See id. at 1534.

<sup>225.</sup> See Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2243 (2011) (referring to Judge Rich as "a principal drafter of the 1952 Act").

<sup>226.</sup> It might be because the applicant benefits the public not only by disclosing the best mode but by identifying it explicitly *as* the best mode. *See* Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 592 (Fed. Cir. 1988) (Mayer, J., dissenting) (the best mode may be inadequately differentiated). Yet the statutory language—"shall set forth the best mode contemplated by the inventor of carrying out his invention"—seems to require that a particular mode be disclosed ("set forth"), not merely that it be identified as the best. *See* 35 U.S.C. § 112(a) (2012).

<sup>227.</sup> \$154(a)(2). Previously, the basic patent term was seventeen years from the issue date. See \$154(c) (the term for patents applied for prior to June 8, 1995 is the greater of the twenty-year term allowed by the current statute or the seventeen-year term provided by the former statute).

the progress of the useful arts.<sup>228</sup> Since *O'Reilly v. Morse*, courts have expressed concern that patentees who claim rights embracing future advancements will stand in the way of such progress:

For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.<sup>229</sup>

One tool that courts have used to prevent patentees from interfering with future progress has been the requirement that the specification enable the full scope of the claim.<sup>230</sup> On the other hand, if the field of the invention is changing so rapidly that significant advancements can be expected during the term of the patent, there is the risk that narrowly drafted claims will prove irrelevant and that broadly drafted claims will be invalidated for failure to enable the newly invented alternatives. The inventor caught in the middle could be left with a worthless patent—hardly an adequate incentive to promote the progress of the useful arts. As detailed below, courts discussing scope enablement have sometimes emphasized one side of the dilemma, and sometimes the other.

The first principle in dealing with fields of changing technologies is that enablement is measured from the perspective of the patent's filing date.<sup>231</sup> The issue is approached "retrospectively... by looking

<sup>228.</sup> See U.S. CONST. art. I, § 8, cl. 8.

<sup>229.</sup> O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853); see also Matheson v. Campbell, 78 F. 910, 915 (2d Cir. 1897) (describing a patentee who claimed a broad genus of chemicals after discovering, by experiment, that a few would achieve the desired results, as "propos[ing] to set himself in the pathway of future experimenters . . . and, as the result of each new experiment is disclosed, [firing] away at it, calculating to 'hit it if it is a deer, and miss if it is a cow' ").

<sup>230.</sup> See supra note 108 and accompanying text.

<sup>231. &</sup>quot;The enablement determination proceeds as of the effective filing date of the patent." MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012); *see also* Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) ("This requirement is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation."); ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("Enablement is determined as of the effective filing date of the patent's application."); Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("Whether the earlier applications enable the claims... is determined as of the filing date of each application.").

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>232</sup> One consequence is that inadequacies in the disclosure that existed at the time of filing cannot be remedied by subsequent additions to the knowledge available to those skilled in the art.<sup>233</sup> If it were otherwise, one could not rely on the filing date of the application as the date on which the applicant had a completed invention.<sup>234</sup> The filing-date perspective can also work to the patentee's advantage if later events render a once-enabling disclosure no longer adequate. This could happen, for example, if products described in the specification as necessary to practice the invention later became unavailable.<sup>235</sup>

Some cases suggest that the filing-date perspective on enablement protects a patentee from the impossible task of having to predict the future. *In re Hogan*<sup>236</sup> is one such case. The claims covered a genus of solid polymers, including high-molecular-weight amorphous polymers. Because the specification disclosed how to make only low-molecular-weight crystalline polymers, the Patent Office rejected the claims as not commensurate in scope with the enabling disclosure.<sup>237</sup> The Court of Custom and Patent Appeals reversed. The amorphous polymers referenced by the examiner were revealed in a publication subsequent to the filing date of the patent; at the time of filing, they did not exist.<sup>238</sup> If the application was enabling when filed, considering all of the evidence then available, "then the fact of that enablement was established for all time and a later change in the state of the art [could not] change it."<sup>239</sup> To require the

236. 559 F.2d 595 (C.C.P.A. 1977).

<sup>232.</sup> Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1056–57 (Fed. Cir. 2003) (quoting Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999)).

<sup>233.</sup> In re Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974).

<sup>234. &</sup>quot;It is an applicant's 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." *Id.* 

<sup>235.</sup> See In re Coleman, 472 F.2d 1062, 1064–65 (C.C.P.A. 1973) (the chance that specific materials required to practice the invention would be removed from the market was too small to support a rejection for nonenablement); In re Argoudelis, 434 F.2d 1390, 1393–94 (C.C.P.A. 1970) (dismissing as "speculative" the possibility that a disclosure might someday become nonenabling).

<sup>237.</sup> Id. at 602-04.

<sup>238.</sup> Id. at 604-05.

<sup>239.</sup> Id. at 605. One can use subsequent developments to shed light on the state of knowledge at the time the application was filed. See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1344 (Fed. Cir. 2003); In re Koller, 613 F.2d 819, 824

applicants to disclose in 1953 a polymer that did not exist until 1962 would "impose an impossible burden on inventors and thus on the patent system."<sup>240</sup>

The court linked its timing rule to broader considerations of policy. Rejections based on the scope of enablement raise, it said, "the more fundamental question: To what scope of protection is this applicant's particular contribution to the art entitled?"241 If the applicants in Hogan were "pioneers"-perhaps the first to introduce any form of solid polymer—then they "deserve[d] broad claims to the broad concept."242 "Basic inventions" should result in "basic patents" in order to provide the incentives necessary to foster progress in the useful arts.<sup>243</sup> If later discoveries could be used to invalidate claims, "the opportunity for obtaining a basic patent upon early disclosure of pioneer inventions would be abolished."<sup>244</sup> To require the applicants in this case to confine their polymer claims to the crystalline form, if they were in fact pioneers, would be "a poor way to stimulate invention, and particularly to encourage its early disclosure."245 Limiting inventors to such narrow claims, the court explained, would be "merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts."246

"Basic patents" may leave room for improvement, but such improvements, if nonobvious, should be rewarded with their own

241. Id. at 605–06.

242. Id. at 606.

<sup>(</sup>C.C.P.A. 1980); *In re Hogan*, 559 F.2d at 605. Documents published later might serve as evidence that the invention had been enabled as of the filing date. *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1336 (Fed. Cir. 2003) (enablement conclusion was "buttressed by numerous post-filing publications that demonstrated the extent of the enabling disclosure"). Alternatively, a long period of delay before success was achieved by persons skilled in the art might demonstrate that a disclosure was not enabling as of its filing date. *See* Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1367 (Fed. Cir. 1997).

<sup>240.</sup> In re Hogan, 559 F.2d at 606.

<sup>243.</sup> *Id.*; *see also In re* Anderson, 471 F.2d 1237, 1240 (C.C.P.A. 1973) (the principle requiring that claims be commensurate in scope with the invention "requires as much the granting of broad claims on broad inventions as it does the granting of more specific claims on more specific inventions" (quoting *In re* Sus, 306 F.2d 494, 497 (C.C.P.A. 1962))).

<sup>244.</sup> In re Hogan, 559 F.2d at 606.

<sup>245.</sup> *Id.; see also In re* Goffe, 542 F.2d 564, 567 (C.C.P.A. 1976) ("[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work . . . would not serve the constitutional purpose of promoting progress in the useful arts.").

<sup>246.</sup> In re Hogan, 559 F.2d at 606.

patents.<sup>247</sup> "It is quite another thing," warned the court in *Hogan*, "to utilize the patenting or publication of later... improvements to 'reach back' and preclude or invalidate a patent on the underlying invention."<sup>248</sup> Were such "reaching back" allowed, the validity of a claim would forever be unsettled.<sup>249</sup>

Hogan may represent the high-water mark of concern for "pioneer" inventors. Later cases adopt Hogan's filing-date rule, but without discussing the need to encourage pioneer inventors with broad patent claims. United States Steel Corp. v. Phillips Petroleum  $Co.^{250}$  is a case with similar facts. The claims covered polypropylene generally, including a high molecular weight crystalline version discovered long after the filing date of the application—a version that, at the time of filing, "no one thought ... possible."<sup>251</sup> The adequacy of the disclosure had to be judged in relation to the art as it existed when the application was filed.<sup>252</sup> Anything else, in the words of Hogan, would "impose an impossible burden on inventors and thus on the patent system."253 Later, in Chiron Corp. v. Genentech, Inc., 254 the Federal Circuit considered claims to monoclonal antibodies that bind to an antigen associated with breast cancer cells.<sup>255</sup> Initially, such antibodies were derived from mice.<sup>256</sup> "Chimeric" versions with human content have fewer side effects, but these were not developed until after the filing date on which the patentee relied.<sup>257</sup> A patent, the court observed, "cannot enable technology that arises after the date of the application."<sup>258</sup> One cannot "expect an applicant to disclose knowledge invented or developed after the filing date" because "[s]uch disclosure would be impossible."<sup>259</sup> Citing Hogan, the court held that chimeric antibodies, not revealed in the literature until after

248. Id.

<sup>247.</sup> Id.

<sup>249.</sup> See id. ("An examiner could never safely call a halt and pass an application to issue.").

<sup>250. 865</sup> F.2d 1247 (Fed. Cir. 1989).

<sup>251.</sup> Id. at 1251-52.

<sup>252.</sup> *Id.* at 1252.

<sup>253.</sup> Id. (quoting In re Hogan, 559 F.2d at 606).

<sup>254. 363</sup> F.3d 1247 (Fed. Cir. 2004).

<sup>255.</sup> Id. at 1250.

<sup>256.</sup> Id.

<sup>257.</sup> See id. at 1250–51.

<sup>258.</sup> Id. at 1254.

<sup>259.</sup> Id.

the applicant's filing date, were "new technology" that was "by definition, outside the bounds of the enablement requirement."<sup>260</sup>

While not abrogating the filing-date rule of *Hogan*, other cases treat later-developed technologies as highly relevant to the question of whether the scope of a claim is fully enabled. Indeed, it is generally in the context of later-arising technologies that the question of scope enablement arises at all. In MagSil, the court devoted much of its discussion to advances in technology that occurred after the patent's filing date. By 1995, the year the patent application was filed, the patentees had achieved changes in resistance of 11.8%.<sup>261</sup> Although the patentees predicted resistance changes of up to 100%, these levels were not achieved until 2006 or 2007, following experiments with electrode metals and insulator materials.<sup>262</sup> By 2008, researchers had achieved resistance changes of 604%-well beyond what the inventors had considered the theoretical limit at the time of filing.<sup>263</sup> The court found that the "field of art ha[d] advanced vastly after the filing of the claimed invention," yet the disclosures did not "present even a remote possibility that an ordinarily skilled artisan could have achieved the modern dimensions of this art."264 While these later developments shed light on what could be achieved (or, more accurately, could not be achieved) at the time of filing, it seems unlikely that the Hogan court would have found 2008 disk drive technology more relevant than the post-filing-date invention of amorphous polymers.

In *MagSil*, the court did not express concern that requiring inventors to anticipate later developments in the art would impose an "impossible burden," nor did the court discuss the need to encourage pioneer inventors with broad patent claims.<sup>265</sup> On the contrary, the court recited the benefits of *limited* patent claims:

<sup>260.</sup> *Id.* The court did, however, find a problem under the written description requirement. *See supra* note 26 and accompanying text. A patent that introduced the chimeric antibody technology as "new matter" could not rely on the filing date of an application filed when such technology did not exist. At the time of the original application, the patentees could not have demonstrated "possession" of a later-arising technology. *See Chiron*, 363 F.3d at 1255.

<sup>261.</sup> MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012).

<sup>262.</sup> *Id.* at 1382.

<sup>263.</sup> Id. at 1382-83.

<sup>264.</sup> Id. at 1382.

<sup>265.</sup> Had the court addressed the discussion of policy in *MagSil*, it might have dismissed it, as the Federal Circuit did on another occasion, as "extended dicta." Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1341 (Fed. Cir. 2003) (quoting *In re* Hogan, 559 F.2d 595, 610 (C.C.P.A. 1977) (Miller, J., concurring in part)).

The enablement doctrine's prevention of over broad claims ensures that the patent system preserves necessary incentives for follow-on or improvement inventions. In this case, for instance, many additional inventions and advances were necessary to take this technology from a 20% resistance change to the over 600% change in present data storage systems. Moreover this technology area will continue to profit from inventive contributions. Enablement operates to ensure fulsome protection and thus "enable" these upcoming advances.<sup>266</sup>

Although *MagSil* stands out for its reliance on post-filing-date advancements in the art, many other cases contrast the limited teachings of a challenged patent to after-arising technologies. In *Enzo Biochem, Inc. v. Calgene, Inc.*,<sup>267</sup> for example, the court found that claims to the use of "antisense" technology to block gene expression were not adequately enabled because it was only later that antisense techniques were successfully applied to eukaryotic organisms like the accused FLAVR SAVR tomato.<sup>268</sup> In *Monsanto Co. v. Syngenta Seeds, Inc.*,<sup>269</sup> claims involving the genetic transformation of plant cells were not fully enabled because they were "filed before transformation of monocot [plant] cells was possible."<sup>270</sup> In *Liebel-Flarsheim*, the practical jacketless injectors that rendered the claims nonenabled were invented only after the filing date of the patent.<sup>271</sup>

One distinction discussed by the Federal Circuit may explain why after-arising technologies are sometimes proper to compare to the disclosures of a patent and sometimes "out of bounds." In *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, the court confirmed that technologies "not known or in existence when the application was filed[,]" like the amorphous propylene at issue in *Hogan*, need not be enabled.<sup>272</sup> This forgiveness does not extend, however, to

1135

<sup>266.</sup> *MagSil*, 687 F.3d at 1384.

<sup>267. 188</sup> F.3d 1362 (Fed. Cir. 1999).

<sup>268.</sup> *See id.* at 1367–68. The disclosure was limited to the practice of the invention in prokaryotic E. coli cells; the patent offered no more than an "invitation' [to] those of skill in the art to experiment practicing antisense in eukaryotic cells." *Id.* at 1374.

<sup>269. 503</sup> F.3d 1352 (Fed. Cir. 2007).

<sup>270.</sup> Id. at 1361.

<sup>271.</sup> See Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1375 (Fed. Cir. 2007) (the district court "found that no prototypes of a jacketless injector had been made or described at the time of filing, and that the state of the art was such that a jacketless system with a disposable syringe would have been a 'true innovation'").

<sup>272.</sup> Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1340 (Fed. Cir. 2003).

"what was specifically desired but difficult to obtain."273 Monocot plants were known at the time of filing, and "stably-transformed monocot cells were highly desirable."274 Some might have been already.<sup>275</sup> produced Consequently, "monocots stably and transformed monocot cells were not an unknown concept that came into existence only after 1987."<sup>276</sup> This passage suggests that an afterarising technology might be relevant to enablement if it was already a "known concept"-something much sought after if not vet achieved. In Chiron, the court used the term "nascent technology" to describe fields so new that persons skilled in the art would be particularly dependent on the teachings of the patent disclosure.277 Perhaps Chiron's "nascent technology" can be stretched to include advancements that are on the horizon or the subject of continuing research. This distinction might relieve at least some of the existing confusion.

As it stands, the "state of the art" on patent enablement leaves much to be desired. The Wands factors help us decide whether particular embodiments are enabled, but they cannot tell us whether after-arising technologies are irrelevant or the very reason that an enabling disclosure falls short. Why was it enough in *CFMT* that the disclosed system accomplished some cleaning, although much less than what would be later achieved, but in *MagSil* the patentees were undone by their failure to enable the "modern dimensions of [the] art[?]<sup>278</sup> Can the principle that a specification must enable the "full scope" of the claimed invention be reconciled with the reality that open-ended patent claims regularly embrace countless improvements, often patentable in themselves, that await further technological advancements?<sup>279</sup> If our goal is to promote the progress of the useful arts, how should we balance the need to provide meaningful rewards to inventors responsible for breakthroughs in rapidly developing arts against the fear that further progress will be hindered by broad claims? In the following Part, I propose a framework for addressing

<sup>273.</sup> Id.

<sup>274.</sup> Id.

<sup>275.</sup> Id.

<sup>276.</sup> Id.

<sup>277.</sup> Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004).

<sup>278.</sup> MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1382 (Fed. Cir. 2012).

<sup>279.</sup> See Gen. Elec. Co. v. Int'l Trade Comm'n, 670 F.3d 1206, 1218 (Fed. Cir. 2012) ("[A] separately patented invention may indeed be within the scope of the claims of a dominating patent."); JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1333 (Fed. Cir. 2005) (added features and improvements do not avoid infringement).

nonenabled embodiments that would account for many of the distinctions and apparent contradictions found in existing case law, while attempting to provide appropriate incentives for advancements in rapidly developing fields.

## III. A FRAMEWORK FOR ADDRESSING EMBODIMENTS OF THE CLAIMED INVENTION THAT FILING-DATE TECHNOLOGY DID NOT ENABLE

#### The rule I propose, in a nutshell, is this:

If a claim includes embodiments that the specification does not enable, the claim is invalid *unless* an applicant could not reasonably have been expected to seek a claim that would have excluded them.

The exception applies where:

(1) The nonenabled embodiments were unforeseeable;

(2) The nonenabled aspects of those embodiments are tangential to the patentee's contribution to the art; or

(3) For some other reason, an applicant could not reasonably have drafted a claim more narrowly tailored to the enabled embodiments.

Readers familiar with patent law will recognize that the model for this rule comes from an unlikely source—the Supreme Court's decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*<sup>280</sup> It is an unlikely source because the *Festo* decision deals not with enablement but with prosecution history estoppel. Before discussing the proposed enablement rule in detail, it is worth considering what the Supreme Court did in *Festo* and why it may not be farfetched to pursue a similar approach in what is otherwise a very different area of patent law.

As previously discussed, the claims of a patent define the exclusive rights of the patent owner.<sup>281</sup> If all of the elements set forth in a claim are present in the accused product, that product literally infringes the claim.<sup>282</sup> Even if the accused product is *not* precisely what the claims require, the judicially developed doctrine of

<sup>280. 535</sup> U.S. 722 (2002).

<sup>281.</sup> See supra note 70 and accompanying text.

<sup>282.</sup> See TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed. Cir. 2002) ("To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system.").

equivalents allows infringement to be found where the differences are insubstantial.<sup>283</sup> One of the most important limitations on infringement by equivalence is the principle of prosecution history estoppel. Prosecution history estoppel bars a patentee from claiming as an equivalent any subject matter given up in order to secure the issuance of the patent.<sup>284</sup> For example, if a mousetrap inventor added a "two springs" limitation to a patent claim in order to avoid prior art with one spring, the inventor could not later argue that one spring and two springs are equivalent.

In Festo, the majority of the Federal Circuit endorsed a brightline rule for prosecution history estoppel: a patentee who amended a claim element during prosecution for any reason relating to patentability is completely barred from asserting the doctrine of equivalents with respect to that element.<sup>285</sup> On appeal, the Supreme Court reversed. The reason for the doctrine of equivalents, the Court explained, is that "the nature of language makes it impossible to capture the essence of a thing in a patent application."<sup>286</sup> Because "[t]hings are not made for the sake of words, but words for things,"287 the language of a patent claim "may not capture every nuance of the invention or describe with complete precision the range of its novelty."288 This may leave "unintended idea gaps"289-gaps that opportunists, if not for the doctrine of equivalents, could exploit. Even after amendment, "language remains an imperfect fit for invention."290 The Court therefore found "no more reason for holding the patentee to the literal terms of an amended claim than [for] abolishing the doctrine of equivalents altogether."291

The Supreme Court held that prosecution history estoppel must be applied in a flexible manner, bearing in mind what it was that an

<sup>283.</sup> See Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950) (the doctrine of equivalents reaches "insubstantial changes and substitutions... which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law").

<sup>284.</sup> Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 523 F.3d 1304, 1312 (Fed. Cir. 2008).

<sup>285.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 574 (Fed. Cir. 2000) (en banc).

<sup>286.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002).

<sup>287.</sup> Id. (quoting Autogiro Co. of Am. v. United States, 384 F.2d 391, 397 (Ct. Cl. 1967)).

<sup>288.</sup> Id.

<sup>289.</sup> Id. (quoting Autogiro Co. of Am. v. United States, 384 F.2d 391, 397 (Ct. Cl. 1967)).

<sup>290.</sup> Id. at 738.

<sup>291.</sup> Id.

applicant who narrowed a claim deliberately gave up.<sup>292</sup> An applicant who narrows a claim is *presumed* to have surrendered anything excluded by the amendment.<sup>293</sup> But the patentee can overcome the presumption by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."<sup>294</sup> Specifically, a narrowing amendment does not surrender an equivalent if (1) the equivalent was unforeseeable; (2) "the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question;" or (3) there is "some other reason" why the patentee could not have included the equivalent within the literal scope of the claim.<sup>295</sup> As to the details of the third, catchall category, the Court did not elaborate, but it may have had in mind those persistent "idea gaps" that make it difficult to capture the essence of an invention in language.

In some respects, prosecution history estoppel and scope enablement are opposite sides of the same coin. In the first instance, an applicant may, without intending to, exclude from the claims embodiments that are within the scope of the applicant's contribution to the art. In the second instance, an applicant may, without intending to, *include* within the scope of the claims embodiments that are *beyond* the scope of the applicant's contribution to the art. The Court's approach in *Festo* shows a desire to treat patent applicants fairly and to ensure that their rights are not undermined because of circumstances they cannot control. The same concerns should animate the rules of enablement. Although *Festo* certainly does not require a parallel approach, it is unsurprising, ultimately, that concepts introduced by the Court in the context of prosecution history estoppel could be usefully applied in the context of enablement.

#### A. Unforeseeable Embodiments

Courts often speak of a "reasonable" correlation between the scope of a patent claim and the scope of an enabling disclosure.<sup>296</sup>

<sup>292.</sup> Id. at 739–40.

<sup>293.</sup> *Id.* at 740 ("A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.").

<sup>294.</sup> Id. at 741.

<sup>295.</sup> Id. at 740-41.

<sup>296.</sup> See, e.g., Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007) ("[T]here 'must be "reasonable enablement of the scope of the range"....'" (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1380 (Fed.

When using the *Wands* factors, courts ask what one could reasonably expect from a person of ordinary skill in the art.<sup>297</sup> In the context of unforeseeable embodiments, they should ask what one can reasonably expect from an applicant. If, as *Festo* suggests, one should not deny the doctrine of equivalents to applicants who lack the gift of prophecy with respect to future embodiments, it is equally clear that one should not invalidate claims for the same failing. One can only expect an applicant to do what is reasonable.<sup>298</sup>

Courts have assured us that patent applicants are "not required... to predict every possible variation, improvement, or commercial embodiment of [the] invention."<sup>299</sup> The most unpredictable embodiments within the scope of a patent claim are those that come into being because of technological breakthroughs that a reasonable applicant would not have expected to occur. For example, in *United States Steel*, at the time the patent application was filed, "no one thought it possible" that propylene could be made with the high molecular weights later achieved.<sup>300</sup> The amorphous polymers of *Hogan* may fall in the same category.<sup>301</sup> An applicant who broadly claims a composition may reasonably believe at the time that the species disclosed in the specification adequately represent the entirety of the genus. To expect an applicant to predict breakthrough

298. If enablement standards reflected only the interests of the public—ignoring the limitations of a reasonable applicant—one might require that claims remain enabled after the patent filing date. That this is not the case, see *supra* notes 235–40 and accompanying text, which indicate that courts do not wish to impose, in the name of enablement, unreasonable burdens on patent applicants.

299. U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1250 (Fed. Cir. 1989) (quoting Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278, 1292 (D. Del. 1987)); see also Epistar Corp. v. Int'l Trade Comm'n, 566 F.3d 1321, 1336 (Fed. Cir. 2009) ("[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." (quoting Cordis Corp. v. Medtronic AVE Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003))); Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005) ("Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise.").

300. U.S. Steel, 865 F.2d at 1252.

301. See In re Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977).

Cir. 2007))); *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.").

<sup>297.</sup> See Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (experimentation is not "undue" if "such that an ordinarily skilled artisan would reasonably be expected to carry it out"); Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) (enablement is not precluded if a person of ordinary skill in the art would have to engage in "a reasonable amount of routine experimentation"); ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention, however, such experimentation must not be 'undue.'").

inventions that undermine that belief is to impose not only an unreasonable burden on patentees but an "impossible" one.<sup>302</sup>

1141

Similarly, an applicant who claims a range may reasonably believe that physical limits prevent the scope of the claim from greatly exceeding the scope of the disclosure—as an applicant claiming a pure composition expects 100% purity to be the most one could achieve.<sup>303</sup> To some extent, *MagSil* suggests that situation. At the time the patent application was filed the inventors apparently believed that resistance changes of 100% were the theoretical limit.<sup>304</sup> Later developments that produced resistance changes of more than 600% proved that understanding to have been wrong, but it may have been reasonable at the time. If the inventors had disclosed how to achieve something close to a 100% change in resistance, rather than the 11.8% they actually disclosed, then the inventors could reasonably have argued that the later developments should be discounted as unforeseeable.

On the other hand, just because an embodiment within the scope of a claim was invented after the filing date does not mean that it was unforeseeable. Often patentees can anticipate, and avoid by a narrower claim, embodiments that depend on subsequent advances in the art. In Hogan, for example, the issue should not have been whether amorphous polymers "existed" as of the filing date,<sup>305</sup> but whether their invention could reasonably have been expected. If so, they might easily have been excluded from the patentee's claims. The same is true of the chimeric antibodies discussed in Chiron. Even if their successful fabrication depended on after-arising technology, they might have been a foreseeable development. The Chiron court states that "[b]ecause the first publication documenting the successful creation of chimeric antibodies occurred after the filing [date,]" the chronology "shows that this new technology arose after the filing date and thus was, by definition, outside the bounds of the enablement requirement."<sup>306</sup> But it is possible that the applicants would have known, as of the filing date, that chimeric antibodies were on the

<sup>302.</sup> Id.

<sup>303.</sup> See supra note 262 and accompanying text.

<sup>304.</sup> See MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1382 (Fed. Cir. 2012).

<sup>305.</sup> See In re Hogan, 559 F.2d at 606 ("To now say that appellants should have disclosed in 1953 the amorphous form which...did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system."). To anticipate a variant that was foreseen, even if it did not yet exist, would not be an "impossible burden."

<sup>306.</sup> Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004).

horizon and to be expected during the term of the patent.<sup>307</sup> In *Plant Genetic Systems*, the court states that monocot plants existed in 1987 and that stably transformed monocots were "highly desirable."<sup>308</sup> Stable monocots were not, therefore, "an unknown concept that came into existence only after 1987."<sup>309</sup> Although the court did not use the word "foreseeable," a foreseeability test for enablement would explain why the court thought these distinctions important.

Demonstrating that an after-arising variant was or was not foreseeable would depend on the unique facts of each case. A number of factors previously discussed by the Federal Circuit could demonstrate that a nonenabled embodiment *was* foreseeable. As with the *Wands* factors, the following list should be regarded as representative rather than exclusive.<sup>310</sup>

#### 1. Claims Broadened to Include a Nonenabled Embodiment

One salient fact is whether the applicant began with claims that would have excluded the nonenabled embodiment, only to expand them later. This is what occurred in *Liebel-Flarsheim*, where the applicant removed pressure jacket limitations in the original claims in order to secure broader claims reading on a competitor's device.<sup>311</sup> In the context of prosecution history estoppel, the Supreme Court said in *Festo* that an applicant who narrowed original claims that once embraced an equivalent "cannot assert that he lacked the words to describe the subject matter in question."<sup>312</sup> On the contrary, the

<sup>307.</sup> After dismissing as speculative the "hypothetical possibility" that the applicants could have learned about chimeric antibodies through a prepublication leak, the court treated the possibility as, in any event, irrelevant, because "the enablement requirement does not extend to technology that arises after the time of filing." *Id.* at 1254–55.

<sup>308.</sup> Plant Genetic Sys., N.V. v. DeKalb Genetics Corp, 315 F.3d 1335, 1340 (Fed. Cir. 2003).

<sup>309.</sup> Id.

<sup>310.</sup> See supra note 43 and accompanying text. Courts determine basic enablement from the perspective of the patent application's filing date. Information that came to light after that date can neither help nor hurt the patentee. See supra notes 231–32 and accompanying text. Addressing the foreseeability of nonenabled embodiments requires a broader perspective. One should ask whether, at any time before the patent issued, the applicant could reasonably have foreseen and—by substituting a narrower claim—avoided including nonenabled embodiments within the scope of the patent. This would provide the right temporal perspective for considering claims that were broadened during prosecution. It would also account for situations where, before a patent issued, it became clear that natural limitations on the scope of the invention actually could be exceeded, or new species (like amorphous polymers) unexpectedly appeared within the range of a genus.

<sup>311.</sup> Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1374 (Fed. Cir. 2007); *see also* AK Steel Corp. v. Sollac, 344 F.3d 1234, 1237 (Fed. Cir. 2003) (the inventors obtained broader claims that included aluminum alloys).

<sup>312.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 734 (2002).

amendment of the original claims "establishe[s] that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter."<sup>313</sup> Similarly, the inventors in *Liebel-Flarsheim* were not taken off-guard by the possibility of a jacketless injector, as they might have been had their original claims omitted any reference to the presence or absence of a pressure jacket. They knew precisely what they were doing when they broadened the claims. Moreover, perhaps because they were aware of the enablement problems to come, they retained references to a pressure jacket in some of their narrower claims.<sup>314</sup> Consequently, invalidating the broader claims does not put the inventors to the "impossible burden" of predicting the future, nor does it strip them of all of their exclusive rights. Instead, they are left with claims that more closely parallel their disclosures.

#### 2. References to the Nonenabled Embodiment in the Specification

Another factor to consider is whether the specification itself demonstrates that the applicant was aware of a nonenabled alternative. In some cases, the evidence may be in the form of a specification that "teaches away" from the alternative. AK Steel is the best example of this. The specification "clearly and strongly warn[ed]" that Type 1 aluminum should be avoided because it would not adhere well to the steel substrate.<sup>315</sup> This shows that the applicants knew, when they expanded their claims, that they were embracing an embodiment excluded by their teachings. Liebel-Flarsheim is similar; there the applicants warned in their specification that jacketless injectors would be impractical.<sup>316</sup> In AK Steel, the court calls such teachings "[w]orse than being silent."<sup>317</sup> They are worse in the sense that they do not assist persons skilled in the art in the successful practice of the alternative; they are worse also in the sense that they show the applicant to have been fully aware of the alternativedeliberately excluding it from the original claims, and deliberately including it in the later ones.

<sup>313.</sup> *Id.* at 735.

<sup>314.</sup> See U.S. Patent No. 5,456,669 col. 18 ll. 16–17 (filed Nov. 30, 1993) (referring to a "tubular pressure jacket").

<sup>315.</sup> AK Steel, 344 F.3d at 1244.

<sup>316.</sup> *Liebel-Flarsheim*, 481 F.3d at 1379 (the specification "teaches away" from a jacketless injector, warning that disposable syringes for a system without pressure jackets would be "expensive and therefore impractical" (quoting '669 Patent col. 1 ll. 23–31)).

<sup>317.</sup> AK Steel, 344 F.3d at 1244.

A specification can demonstrate awareness of a nonenabled embodiment without also "teaching away" from it. In *Automotive Technologies*, the applicants said nothing to discourage the use of an electronic air bag sensor. On the contrary, they encouraged electronic sensors in a general way by including a "conceptional view" of such a sensor and by discussing the host of technologies that might be usefully applied in that application.<sup>318</sup> Although the teachings were "vague," they show that the applicants foresaw the use of electronic alternatives to a mechanical sensor.<sup>319</sup> They simply did not disclose *enough* about those alternatives to allow them to be practiced without undue experimentation.<sup>320</sup> The court stressed the contrast between the elaborate description of the mechanical sensor and the cursory description of the electronic one.<sup>321</sup> This contrast in itself shows that the applicants might have anticipated the enablement difficulties posed by electronic sensors.

One of the *Wands* factors used to determine whether an embodiment of the claimed invention could be practiced without undue experimentation is "the amount of direction or guidance" to be found in the patent specification.<sup>322</sup> In that context, more guidance is clearly better than less. When considering whether a nonenabled embodiment was foreseeable to the applicant, the reverse may be true. A certain amount of positive guidance is "worse than being silent[,]"<sup>323</sup> if it demonstrates the applicant's awareness of an alternative without being enough to enable it. It may seem perverse to, in a sense, punish an applicant for saying too much.<sup>324</sup> Yet, had the

321. See Auto. Techs., 501 F.3d at 1284.

<sup>318.</sup> Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1278 (Fed. Cir. 2007) (quoting U.S. Patent No. 5,231,253 col. 10 ll. 3–11 (filed June 2, 1992)).

<sup>319.</sup> Id. at 1278-80.

<sup>320.</sup> *Id.* at 1284 ("[T]he specification provides 'only a starting point, a direction for further research'...." (quoting Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997))); *see also* ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) (the specification referenced nonosmotic dosage forms but did not provide enough disclosure to allow them to be practiced without undue experimentation).

<sup>322.</sup> *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also* Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quoting *In re Wands*, 858 F.2d at 737); Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1288 (Fed. Cir. 2012) (same).

<sup>323.</sup> AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

<sup>324.</sup> It may seem perverse because patent law should encourage disclosures. Disclosures are a part of the patentee's "bargain." *See supra* note 17 and accompanying text. However, there are other instances in which saying too much in the specification can disadvantage the patentee. For example, a patentee who discloses an alternative, but does not claim it, may be found to have dedicated the alternative to the public. *See* Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc).

specification in *Automotive Technologies* said nothing about electronic sensors, it would have been easier to conclude that they were an unanticipated development and one that the applicants could not have been expected to avoid by drafting narrower claims.

Similarly, "teaching away" may have unique implications when the question is whether a nonenabled embodiment was foreseeable. If the claims in *Liebel-Flarsheim* had never mentioned a pressure jacket, one might conclude from the warnings in the specification that the applicants did not foresee jacketless injectors as a viable option. In such cases, "teaching away" from the nonenabled embodiment may be, from the patentee's perspective, *better* than being silent. It is only because the negative teachings in *Liebel-Flarsheim* were accompanied by expanded claims that those teachings reinforce the conclusion that nonenablement was foreseeable.<sup>325</sup>

A patentee facing allegations of nonenablement would have to decide whether to emphasize what the patent *does* teach, in hopes of showing that it teaches enough to allow the embodiments in question to be practiced, or what it *does not* teach, in hopes of showing that the nonenabled embodiments were unforeseeable. Parties challenging a patent would face a similar choice.<sup>326</sup> This is simply because the most problematic embodiments, from an enablement perspective, are those occupying a middle ground—too remote from a working example to be easily extrapolated, but not so remote as to be entirely unexpected.

#### 3. Failed Attempts to Practice the Nonenabled Embodiment

A number of cases refer to failures by the patentee to reduce to practice the nonenabled embodiment. In *Liebel-Flarsheim*, the inventors experimented with jacketless injector designs before

<sup>325.</sup> Because the claims issued in AK Steel explicitly cover aluminum alloys, it would have been difficult to argue, even if those were the original claims, that the use of something other than pure aluminum was unforeseen. On the other hand, if the original claims had simply included open-ended references to aluminum (which would have allowed, but not required, other materials to be added), then a specification that taught against an alloy might have led one to conclude that workable alloys were an unexpected advancement.

<sup>326.</sup> Patentees, and their opponents, face similar dilemmas now. For example, if a specification mentions an alternative to the preferred embodiment, the patentee may use it to justify an expansive claim interpretation. *See* Ronald A. Katz, Tech. Licensing LP v. Am. Airlines, Inc. (*In re* Katz Interactive Call Processing Patent Litig.), 639 F.3d 1303, 1324 (Fed. Cir. 2011) ("[T]here is a strong presumption against a claim construction that excludes a disclosed embodiment ...."). But if that effort fails, the same reference to an alternative may restrict the patentee's ability to employ the doctrine of equivalents. *See Johnson & Johnston*, 285 F.3d at 1054.

abandoning the effort as "too risky."<sup>327</sup> In AK Steel, the inventors' own experiments taught them that "their invention did not work well unless the aluminum [was] substantially pure[.]"328 In Enzo, the inventors could not successfully employ their antisense technology to control the expression of genes in eukaryotic organisms or any prokaryotic organism other than E. coli.<sup>329</sup> Such failures are important to a straightforward application of the Wands factors because patentees are usually highly skilled in the art,<sup>330</sup> and they have the benefit of the technology taught in their own patents. If they cannot successfully practice an alternative embodiment, then it is highly unlikely that persons of ordinary skill in the art could do better, at least without undue experimentation. Failures are also relevant to foreseeability. In the right case, they can show that an applicant was well aware that the claims embraced embodiments that the specification did not enable. However, this is another instance where the evidence might cut the other way. Failed experiments-whether those of the applicant or of others whose work was known in the art might lead an applicant to conclude that an alternative was impracticable. In Liebel-Flarsheim, for example, failures by the inventors to implement jacketless injectors might have led them to conclude that such injectors were not feasible.<sup>331</sup> In MagSil, the applicants' failure to achieve resistance changes of more than 11.8% might have led them to conclude that they were approaching a theoretical limit. Although other factors may have been more important in *Liebel-Flarsheim* and *MagSil*, it is easy to see how, under the right circumstances, failed experiments might disadvantage the patentee who tries to show that an alternative was enabled but might help the patentee who relies on unforeseeability instead.

#### 4. Progress in the Art Toward the Nonenabled Embodiment

Another factor relevant to foreseeability is the patentee's own progress, or progress in the art generally, toward practicing an alternative embodiment. Progress is a factor that, up to a point, works to the advantage of the patentee when one is applying the *Wands* 

<sup>327.</sup> Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379 (Fed. Cir. 2007).

<sup>328.</sup> AK Steel, 344 F.3d at 1236.

<sup>329.</sup> Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1372 (Fed. Cir. 1999).

<sup>330.</sup> Inventors are usually treated as persons of extraordinary skill. *See* Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000).

<sup>331.</sup> The district court in *Liebel-Flarsheim* found that at the time of filing "a jacketless system with a disposable syringe would have been a 'true innovation.'" *Liebel-Flarsheim*, 481 F.3d at 1375 (quoting Liebel-Flarsheim Co. v. Medrad, Inc., No. 1:01-CV-98-858, 2005 WL 2840744, at \*14 (S.D. Ohio Oct. 28, 2005)).

factors in the traditional manner. If the art has almost achieved an alternative embodiment, then it may be plausible to argue that, with the help of the patent disclosures, the alternative will be achieved without further undue experimentation. On the other hand, if the specification falls short of that standard, then the progress that has already been made, or the mere fact that research is ongoing, will make it difficult to argue that an alternative embodiment was unforeseeable. In Plant Genetic Systems, the court identified genetically transformed monocot plants as, at the time of filing, a "highly desirable" commodity.<sup>332</sup> That dicots had already been transformed likely marked progress toward the genetic transformation of all plant species. In Enzo, success with E. coli probably led to the expectation that antisense technology would eventually be used to control gene expression in all types of organisms. These yet-unattained goals were not, in the words of *Plant* Genetic Systems, "unknown concept[s]."333 Unless an applicant believed that there were insurmountable barriers to further progress, these circumstances would establish that the nonenabled alternative was foreseeable.

## 5. Categorical Distinctions Between the Enabled and Nonenabled Embodiments

Enablement cases often involve obvious categorical distinctions between the enabled and nonenabled embodiments. To botanists, the distinction between monocot and dicot plants is a fundamental taxonomic division.<sup>334</sup> To biologists, prokaryotic and eukaryotic organisms mark a similar divide.<sup>335</sup> Mechanical and electronic sensors require very different technologies,<sup>336</sup> as do video games and movies.<sup>337</sup> These kind of coarse-grained distinctions are important when deciding if the teachings of the specification with respect to one embodiment can be extrapolated to enable another.<sup>338</sup> A basic

<sup>332.</sup> Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1340 (Fed. Cir. 2003).

<sup>333.</sup> Id.

<sup>334.</sup> See *id.* at 1338 (explaining the difference between monocots and dicots); *In re* Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (the specification enabled the claimed invention in dicots but not in monocots).

<sup>335.</sup> *See* Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1372 (Fed. Cir. 1999) (concluding that the patents in question were "extraordinarily broad" for including both prokaryotes and eukaryotes).

<sup>336.</sup> See Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007).

<sup>337.</sup> See Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000 (Fed. Cir. 2008).

<sup>338.</sup> See supra Section II.A.

taxonomic distinction suggests that a nonenabled embodiment is not "just another species" of the same genus but a "distinctly different" thing.<sup>339</sup> These same distinctions affect foreseeability. An applicant in the botanical arts, for example, would understand that teachings applicable to dicot plants are not easily translated to monocot plants. Hence the enablement problems that arise in such circumstances are often foreseeable.

#### 6. Result-Oriented Claiming

Some applicants claim their invention in terms of results achieved rather than a specific means to achieve them. Samuel Morse, for example, claimed all means for using electromagnetism to transmit characters at a distance, rather than just the particular telegraph mechanism that he had devised.<sup>340</sup> In *In re Wright*,<sup>341</sup> the applicant claimed vaccines sharing the antigenic properties of viruses that trigger an immune response but not the pathogenic properties that cause a disease.<sup>342</sup> The patent described the genetic engineering techniques required to achieve this desirable result only in general terms, and it disclosed just one working example—a vaccine to treat a disease known as Prague Avian Sarcoma Virus.<sup>343</sup> In AK Steel, the claims that were broadened to include aluminum alloys still retained the proviso that the "coating layer [is] tightly adherent to the [steel] strip and resistant to crazing or flaking during bending."344 The specification did not disclose how to achieve that result except through the use of essentially pure Type 2 aluminum.<sup>345</sup> The Federal Circuit once analogized result-oriented claiming to an inventor who creates and discloses a specific fuel-efficient engine, only to claim

<sup>339.</sup> Auto. Techs., 501 F.3d at 1285.

<sup>340.</sup> O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112 (1853). Section 112(f) of the Patent Act allows a claim element to be expressed as a means to perform a function. 35 U.S.C. 112(f) (2012). A means-plus-function element covers a structure that performs the function recited in the claim if it is identical or equivalent to the corresponding structure disclosed in the specification. *See* Hearing Components, Inc. v. Shure Inc., 600 F.3d 1357, 1370 (Fed. Cir. 2010). This rule, however, only applies to elements in a claim consisting of a combination of elements. Applicants cannot obtain a "single means claim" that simply refers to any means of accomplishing a function. *See In re* Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983) (a single means claim "covers every conceivable means for achieving the stated result" and should be rejected on the ground that the enabling disclosure is not commensurate in scope with the claim).

<sup>341. 999</sup> F.2d 1557 (Fed. Cir. 1993).

<sup>342.</sup> Id. at 1559.

<sup>343.</sup> See id. at 1558–59.

<sup>344.</sup> AK Steel Corp. v. Sollac, 344 F.3d 1234, 1237 (Fed. Cir. 2003) (quoting U.S. Patent No. 5,066,549 col. 7 ll. 6–7 (filed Nov. 22, 1988)).

<sup>345.</sup> Id. at 1244.

"every possible type of fuel-efficient engine, no matter how different in structure or operation from the inventor's engine."<sup>346</sup> Although it may be permissible to define a claim element in terms of " 'what it does' rather than 'what it is,' "<sup>347</sup> applicants who choose "broad functional language"<sup>348</sup> do so at their peril.<sup>349</sup> Often there will be means of achieving a claimed result other than those enabled by the specification. Hence, an applicant's choice to employ result-oriented language may be considered some evidence that nonenabled embodiments were foreseeable.

In short, a variety of factors, analogous to the *Wands* factors, might be used to determine whether a reasonable applicant could have foreseen the hazards of nonenabled embodiments. Where the claims were broadened to include them, or where the specification discussed them, one can conclude that the applicant was aware of the nonenabled embodiments. Where progress in the art marked them as an expected development, one can conclude that the applicant *should have been* aware of the nonenabled embodiments. Finally, where the applicant drafted claims that ignored obvious taxonomic distinctions, or where the applicant neglected an opportunity to draft claims that would have avoided the nonenabled embodiments.

#### B. Tangential Embodiments

*Festo* provides an additional exception to prosecution history estoppel in cases where an equivalent might have been foreseeable when a claim was amended but "the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question."<sup>350</sup> For example, an applicant who added a "two springs" limitation to a mousetrap claim in order to avoid prior art with a single spring might argue successfully that a *three*-spring mousetrap is still an equivalent.<sup>351</sup> The rationale for the amendment

<sup>346.</sup> LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1346 (Fed. Cir. 2005).

<sup>347.</sup> *In re* Fuetterer, 319 F.2d 259, 264 (C.C.P.A. 1962); *see also* Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 371 (1938) ("A limited use of terms of effect or result, which accurately define the essential qualities of a product to one skilled in the art, may in some instances be permissible and even desirable .....").

<sup>348.</sup> Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1361 (Fed. Cir. 2007).

<sup>349.</sup> *See* MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012) ("[A] patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.").

<sup>350.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740 (2002).

<sup>351.</sup> See Alan L. Durham, Patent Law Essentials: A Concise Guide 198 (4th ed. 2013).

could have been that only multiple springs can provide the benefits attributed to the inventor's mousetrap. That rationale would be highly relevant to whether a one-spring trap is equivalent to the claimed invention but tangential (if not entirely irrelevant) to whether a three-spring trap is equivalent. In the context of enablement, there is no explicit "rationale" to consider. Problems often arise by omission—an applicant who could have settled for a narrower claim failing to limit it so. Hence the parallel to *Festo* is weaker here. Nevertheless, there is a counterpart in enablement to *Festo*'s "tangential" exception that is equally important. There are occasions where even foreseeable nonenabled embodiments within the scope of the claim are, in a real sense, beside the point.

As previously discussed, a typical open-ended patent claim embraces countless variants that cannot be made or used without undue experimentation.<sup>352</sup> The simplest mousetrap claim could be infringed by traps made from exotic materials or embellished with advanced technologies. A specification could not enable them all even if supplemented with knowledge available in the art and the potential for routine experimentation. The shortfall is not just foreseeable; it is inevitable. The only way to avoid it would be to insist on patent claims limited to the preferred embodiments and variants of those embodiments that are easily achieved. Such narrow rights "would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain."<sup>353</sup>

What is needed is a way to distinguish between the nonenabled embodiments that are merely a consequence of the open-ended nature of patent claims and those that demonstrate overreaching by the patent applicant. The best approach is to consider the relationship between the nonenabled embodiments and the applicant's contribution to the art. In some cases the aspects of the nonenabled embodiments that make them nonenabled are, in *Festo*'s terminology, "tangential" to the applicant's contribution.

In *In re Rassmussen*,<sup>354</sup> the court considered an application for a laminate made by winding a plastic film multiple times around a pair of spaced drums.<sup>355</sup> The claim language originally called for the use of adhesives, as taught in the specification.<sup>356</sup> When a claim was

<sup>352.</sup> See supra Section II.A.3.

<sup>353.</sup> Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005).

<sup>354. 650</sup> F.2d 1212 (C.C.P.A. 1981).

<sup>355.</sup> Id. at 1213.

<sup>356.</sup> Id.

expanded to include any method of "adheringly applying" additional layers, the examiner rejected it as no longer supported by the specification.<sup>357</sup> On appeal, the court observed that "the specification...describe[d] one method of 'adheringly applying' one layer to the other" and that it was "of no moment" that the claim was broader than the embodiment taught in the specification.<sup>358</sup> One could attribute this, in part, to the predictability of the art; perhaps a person skilled in the art could practice any method of adhering the layers without having to resort to undue experimentation. But there might be more to it than that, as suggested by the court's reference to a hypothetical patent claiming a "scales of justice" where the specification only discloses a one-pound lead counterweight.<sup>359</sup> "[B]roader claim language would be permitted[,]" said the court, "because the description of the use and function of the lead weight...would immediately convey to any person skilled in the scale art the knowledge that the applicant invented a scale with a [one]-pound counterbalance weight, regardless of its composition."<sup>360</sup> In this case, anyone skilled in the art reading the specification "would understand that it is unimportant how the layers are adhered, so long as they are adhered."<sup>361</sup> The court specifically addressed the written description requirement,<sup>362</sup> and the "scales of the justice" hypothetical refers to equivalents to the lead weight-like a pound of feathersthat are "undisclosed, but obviously art-recognized."363 Yet it is no great stretch to extend the same reasoning to the enablement requirement and to the substitution of after-arising materials (perhaps a pound of amorphous polymers) that would serve the same purpose as the lead weight. In the context of the scales of justice, the composition of the weight would still be immaterial to the hypothetical applicant's contribution to the art.

*In re Cook*<sup>364</sup> concerned zoom lens designs and the discovery that controlling the relationship between a small number of design parameters served to extend the range of a lens.<sup>365</sup> The Patent Office rejected the claims as nonenabled because, except for the six specific

<sup>357.</sup> See id. at 1213–14.

<sup>358.</sup> Id. at 1215.

<sup>359.</sup> Id. (quoting In re Smythe, 480 F.2d 1376, 1384 (C.C.P.A. 1973)).

<sup>360.</sup> Id. (emphasis omitted) (quoting In re Smythe, 480 F.2d 1376, 1384 (C.C.P.A. 1973)).

<sup>361.</sup> Id. (emphasis omitted).

<sup>362.</sup> See id. at 1214–15.

<sup>363.</sup> Id. at 1215 (quoting In re Smythe, 480 F.2d 1376, 1384 (C.C.P.A. 1973)).

<sup>364. 439</sup> F.2d 730 (C.C.P.A. 1971).

<sup>365.</sup> Id. at 731.

designs disclosed in the patent specification, it would have taken a skilled practitioner many months to design a zoom lens within the scope of the claims.<sup>366</sup> The Court of Customs and Patent Appeals reversed, noting that designing new zoom lenses had always been a demanding task.<sup>367</sup> The applicants "d[id] not purport to have solved all of the time-consuming problems involved in the design of a new lens;" in fact, by "add[ing] new calculations to the design of zoom lenses," they may have added to the designer's burden.<sup>368</sup> What they had discovered, and claimed, was a relationship that could be used to improve the performance of zoom lenses generally.<sup>369</sup> The court compared the applicants to a suspension-bridge designer who discovered that a specific relationship between the height of the piers and the distance between them will increase the strength of the bridge: "Disclosure ... of this relationship would certainly not solve all the time-consuming problems of bridge designing or building, but it would, we think, enable any person skilled in the art to practice the invention."<sup>370</sup> Although designing a new zoom lens within the scope of the claims would have required considerable effort, it was because zoom lens design is always difficult, not because the disclosure of the applicant's invention was incomplete.

If we focus on the inventor's contribution to the art, we can account for some of the "one mode is enough" cases that otherwise seem at odds with the usual "full scope of the claim" standard of enablement. In *Invitrogen Corp. v. Clontech Laboratories, Inc.*,<sup>371</sup> the patent claimed a genetically modified enzyme, reverse transcriptase ("RT"), used in the artificial replication of DNA.<sup>372</sup> The specification disclosed one method of modifying the enzyme (deletion mutation), but there was disagreement about the disclosure of others (including point mutation).<sup>373</sup> Although the claims did not exclude point-mutated RT and enablement applies to the "full scope of the claimed invention[,]"<sup>374</sup> the court did not find the disclosures inadequate. Had the patentee's claims been *limited* to point-modified RT, the

<sup>366.</sup> See id. at 732.

<sup>367.</sup> Id.

<sup>368.</sup> Id.

<sup>369.</sup> Id.

<sup>370.</sup> Id. at 732–33.

<sup>371. 429</sup> F.3d 1052 (Fed. Cir. 2005).

<sup>372.</sup> Id. at 1058.

<sup>373.</sup> *Id.* at 1070.

<sup>374.</sup> Id. (quoting Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1155 (Fed. Cir. 2004)).

disclosures might have been nonenabling.<sup>375</sup> Instead, they embraced *any* genetically modified RT, and the enablement requirement is satisfied by the disclosure of "any mode of making and using the invention."<sup>376</sup> The patentee's disclosures with respect to deletion mutation were "sufficient to satisfy [their] part of the patent bargain, as [they] fully teach[] *a* mode of making the claimed invention."<sup>377</sup> This passage is difficult to understand unless we take it to mean that the invention was about the modified RT itself, not about how it was made. A single method of making modified RT allowed one to practice the "full scope" of the invention because that single method produced the material that was the inventor's contribution to the art. Had the claims been to *methods* of producing modified RT—methods broad enough to include point mutation—the outcome might have been different.<sup>378</sup>

Amgen Inc. v. Hoechst Marion Roussel, Inc.<sup>379</sup> is a similar case. The patents concerned laboratory-cultured cells that excrete EPO—a hormone that controls the production of red blood cells.<sup>380</sup> The defendant argued that the specifications failed to enable the full scope of the invention because they did not teach how to produce EPO using human cells or endogenous human EPO DNA.<sup>381</sup> The district court concluded that "where the method is immaterial to the claim," the specification need not enable production techniques arising after the filing date of the patent.<sup>382</sup> Indeed, in the case of a composition claim, the specification need enable "only one mode of making and using [it]."<sup>383</sup> On appeal, the Federal Circuit did not find these conclusions erroneous.<sup>384</sup> As in *Invitrogen*, the composition of matter

<sup>375.</sup> *Id.* at 1071 ("[The] validity argument might have force had Invitrogen limited its claims to modified RT by reference to point mutation . . . .").

<sup>376.</sup> Id. (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1361 (Fed. Cir. 1998)).

<sup>377.</sup> Id. (emphasis added).

<sup>378.</sup> See *id.* (distinguishing *National Recovery* as a case concerning enablement of "a method, not a compound").

<sup>379. 314</sup> F.3d 1313 (Fed. Cir. 2003).

<sup>380.</sup> Id. at 1319.

<sup>381.</sup> Id. at 1334.

<sup>382.</sup> *Id.* at 1335 (quoting Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 160 (D. Mass. 2001)).

<sup>383.</sup> *Id.* (quoting Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 160 (D. Mass. 2001)).

<sup>384.</sup> *Id.* Judge Clevenger, writing in dissent, did protest that the difference between composition claims and method claims was one of form rather than substance. *Id.* at 1359 (Clevenger, J., dissenting). The majority's approach, he wrote, leaves "patentees... free to decorate their composition claims with source and process limitations without any concern for whether the full scope of those limitations is enabled or described." *Id.* The

constituted the inventor's contribution to the art; potential methods of making it were tangential to that contribution.

One way to consider whether nonenabled embodiments are "tangential" is to ask whether the undue experimentation required to practice them involves substituting something different for the patentee's<sup>385</sup> contribution to the art or adding something to it. Someone who labored over a zoom lens design, but who incorporated the formulas disclosed in Cook's specification, would be adding something to the applicant's contribution. Someone who built a mousetrap with the combination of elements recited in a patent claim, but who experimented with advanced materials or new features, would be doing the same. If a patentee's contribution can be accurately characterized as a new composition of matter, then laterdeveloped methods of making it are supplements to, not substitutes for, the basic idea. On the other hand, because the contexts are so different, implementing the invention claimed in Sitrick in motion pictures would require technology different from (not in addition to) the technology disclosed for video games.<sup>386</sup> The same may be true of the inventor's contribution to the art in Automotive Technologies, if that contribution is best described as a design for a mechanical air bag sensor. Anyone building an electronic sensor would have to devise something entirely different. These nonenabled embodiments are not tangential; they demonstrate that the patent claims include embodiments that do not, in any way, involve the patentee's contribution to the art.387

385. I use "patentee" in this discussion for the sake of convenience, but the same reasoning would apply to patent applicants when enablement challenges arise in the course of prosecution.

386. See supra notes 161–63 and accompanying text.

enablement requirement would be "waived so long as the patentee succeeds in characterizing [the] claims as 'product' claims." *Id.* In this case, he found that the cell claimed in the patents was "nothing more than a biological machine for making EPO" and that "one who is first to make a machine is not entitled as a matter of law to claim any or all machines so long as they perform the same function." *Id.* at 1360. The patentees, in his view, had invented one type of machine for making EPO but not all of the types included within the scope of the claims.

<sup>387.</sup> In *In re Fisher*, the court states that "an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings[:]" even if the new inventions were not obvious, they were "still within his contribution, since the improvement was made possible by his work." *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970). Considering the "contribution" of the first inventor is on the right track, but the issue should not be whether the patent's "teachings... made possible" later advancements. Someone can infringe a patent without being aware of it and without having the benefit of the patent's teachings. *See* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1519 (Fed. Cir. 1995) (en banc) ("A patent owner may exclude others from practicing the claimed invention, regardless of whether infringers

One could also say that these embodiments do not involve the patentee's *invention*. The problem is that "invention" is used with different meanings in patent law. Claim language, supplemented by the doctrine of equivalents, defines "the invention" for purposes of delimiting the patentee's exclusive rights.<sup>388</sup> But "the invention" can also refer to the patentee's contribution to the useful arts, as taught in the patent specification. "The invention," in that sense, is an idea. The claims do not define that idea per se; rather, the claims define a set of things in which the inventor's idea may be reduced to practice.<sup>389</sup> Accordingly, to decide whether a nonenabled embodiment is tangential to the patentee's contribution to the arts, we must look to the specification.<sup>390</sup>

Identifying the patentee's contribution to the art, and determining whether it is or is not represented in a particular nonenabled embodiment, would be easy in some cases (e.g., *Sitrick*) and more difficult in others. *ALZA Corp. v. Andrx Pharmaceuticals, LLC*<sup>391</sup> might be one of the difficult cases. There the patentees discovered that certain drugs for treating Attention Deficit and Hyperactivity Disorder ("ADHD") are more effective if delivered by an extended-release mechanism with an ascending rate of delivery.<sup>392</sup> The specification discussed at length "osmotic dosage forms."<sup>393</sup> These are pills with semipermeable walls and an opening through which the drug is "pushed" by the swelling of a "push layer."<sup>394</sup> The specification also mentioned nonosmotic dosage forms that do not have a "push layer."<sup>395</sup> The claims were broad enough to cover

even know of the patent...."), *rev'd on other grounds*, 520 U.S. 17 (1997). For enablement, the question should be whether a nonenabled embodiment within the scope of the claims still incorporates the inventor's contribution to the art, not whether that embodiment does or does not rely on information gleaned from the patent disclosure.

<sup>388.</sup> *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.2d 1336, 1347 (Fed. Cir. 2010) (en banc) (the "principal function" of patent claims "is to provide notice of the boundaries of the right to exclude and to define limits"); Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1368 (Fed. Cir. 2003) ("[T]he claims define the scope of an invention.").

<sup>389.</sup> See supra notes 70–73 and accompanying text.

<sup>390.</sup> This is consistent with other occasions in patent law where one must look beyond the claim language to determine what the inventor contributed to the progress of the useful arts. *See, e.g.*, MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1256 (Fed. Cir. 2012) ("An inventor is entitled to claim in a patent what he has invented, but no more."); Retractable Techs., Inc. v. Becton, Dickinson & Co., 653 F.3d 1296, 1305 (Fed. Cir. 2011) (limiting claim language to the examples in the specifications in order to "tether the claims to what the specifications indicate the inventor actually invented").

<sup>391. 603</sup> F.3d 935 (Fed. Cir. 2010).

<sup>392.</sup> Id. at 937.

<sup>393.</sup> Id.

<sup>394.</sup> Id. at 937 n.1

<sup>395.</sup> Id.

both.<sup>396</sup> Applying the *Wands* factors, the court determined that the claims were not enabled because the specification provided insufficient guidance to allow the development of nonosmotic dosage forms without undue experimentation.<sup>397</sup> What the court did not consider is whether the inventors' contribution to the art was a specific pill or the general discovery that ascending release rates could be used to more effectively treat ADHD. If, as appears to be the case, the inventors discovered the latter, then they should be able to claim their invention at that level of generality. If other release mechanisms were developed later, those would be contributions to the art of a different nature-contributions that might be used in conjunction with (but not instead of) the patentees' contribution. The situation might have been clearer if the claims at issue had been method claims. The validity of a claim to a method of treating ADHD by ascending releases of medication should not depend on whether the specification taught one how to make every type of pill that might provide that ascending release.

Liebel-Flarsheim is another case that raises doubts. The patent describes a configuration that allows a disposable syringe to be replaced in an injector mechanism rapidly and using only one hand.<sup>398</sup> This includes an arrangement where a used syringe can be withdrawn through an opening in the front of the pressure jacket; in earlier designs "[b]ecause the front end of the pressure jacket [was] closed, rear loading was necessary, and accessibility...was provided by hinging or rotating the jacket to allow for removal and replacement of the syringe from the rear."<sup>399</sup> If the inventors' contribution to the art was simply the introduction of a pressure jacket with forward accessibility, then the claims could not validly cover injector designs with no pressure jacket at all. Those designs would not employ the inventors' contribution to the art. But if the advancement taught in the patent was something more general than that—and the specification does refer to the need, in earlier designs, to engage in time-wasting steps when replacing a syringe that may be unrelated to the pressure jacket<sup>400</sup>—then the presence or absence of a pressure jacket may have been as tangential to the inventors' contribution to the art as the use of a particular material for the syringe. In other words, if the point of the invention was about something other than

<sup>396.</sup> *Id.* at 937.

<sup>397.</sup> Id. at 940–41.

<sup>398.</sup> See U.S. Patent No. 5,465,669 col. 5 ll. 8-14 (filed Nov. 30, 1993).

<sup>399.</sup> *Id.* at col. 1 ll. 39–43.

<sup>400.</sup> *See id.* at col. 2 ll. 2–15.

pressure jackets, the patentees could not reasonably be expected to exclude from the claims embodiments that do not need pressure jackets. Later inventors who find ways to eliminate the pressure jacket are making their own, distinct contribution to the art (a patentable contribution, if the difficulties were as great as the circumstances suggest), but if they are merely *adding* something to the original design, the validity of the basic patent should not be called into question.

This is one place where we need to distinguish between basic enablement<sup>401</sup> and scope enablement.<sup>402</sup> Someone who claims a mousetrap should have to disclose one means of making and using such a trap, even if that requires the inclusion of details that are tangential to the patentee's contribution to the art. For example, if a claimed mousetrap requires a spring with specialized properties, and how to make such a spring is unknown to others in the art, the patentee should have to teach how to make it-even if that means straying into the field of metallurgy rather than mousetrap design per se. A specification that did not teach any means to make the patented invention would lack the necessary quid pro quo. The burden of such a disclosure is relatively manageable, particularly for a patentee who has reduced the invention to practice and therefore knows how to overcome any technical hurdles that stand in the way of practicing the invention. The burden is altogether different (indeed, often impossible to meet) if the patentee must disclose in similar depth every means of practicing the invention that falls within the scope of an open-ended claim. Here it is only reasonable to expect a complete disclosure of the patentee's own contribution to the art.

## *C.* Other Embodiments That Could Not Reasonably Have Been Excluded from the Claim

In addition to unforeseeable and tangential equivalents, *Festo* includes a third, catchall category of instances where prosecution history estoppel should not apply to a patentee who narrowed a claim. This comes into play where "some other reason suggest[s] that the patentee could not reasonably be expected to have described the insubstantial substitute in question."<sup>403</sup> If only for the sake of completeness, we should include among the arguments for avoiding invalidity "some other reason" that the patent applicant could not

<sup>401.</sup> See supra Part I.

<sup>402.</sup> See supra Part II.

<sup>403.</sup> Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741 (2002).

reasonably be expected to have drafted a claim excluding nonenabled embodiments. For example, as the Court notes in *Festo*, the inherent limitations of language may sometimes leave a patent applicant without the words needed to delimit precisely the applicant's contribution to the art.<sup>404</sup> If the lack of a suitable vocabulary made it impossible for the applicant to exclude foreseeable, nontangential, and nonenabled embodiments without, at the same time, giving up territory to which the applicant could fairly lay claim, that circumstance would also justify preserving the validity of the claims.<sup>405</sup>

#### D. A Role for the Reverse Doctrine of Equivalents

If we recognize the exceptions listed above, there will be some occasions where a valid claim will cover embodiments—perhaps a significant number of embodiments—that are unrelated to the contribution to the art disclosed in the specification. For example, an applicant may not have been able to foresee, and therefore exclude, species within a claimed genus that are fundamentally different than the species taught in the patent. The nonenabled species, rather than building on the patentee's insights, may depend on entirely separate technology. The best response in such a case is not to invalidate the claim, which is overbroad through no fault of the patentee, but to limit its scope.

One option is to construe claims to cover only the enabled embodiments. In *Hogan*, Judge Miller's concurring opinion observed that claims should be construed in light of the art that was known at the time the patent application was filed.<sup>406</sup> If, at that time, the term "solid polymer" would have been construed as coextensive with the solid crystalline species then known, the generic term should not be given a broader meaning after the post-filing discovery of solid amorphous polymers.<sup>407</sup> This construction spares the patentee from the impossible burden of enabling a later-discovered species, but it leaves those species beyond the reach of the patent. Judge Bryson,

<sup>404.</sup> See *id.* at 731 ("Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application.").

<sup>405.</sup> Such cases may be rare, given the applicant's freedom to be "his own lexicographer." *See* Thorner v. Sony Comput. Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Remarks in *Festo* also suggest that it may be harder to say what an invention *is* than what it *is not. See Festo*, 535 U.S. at 738 ("The narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is."). Sometimes all an applicant will need to do to avoid foreseeable problems will be to state, in the claim, what the invention does *not* include.

<sup>406.</sup> *In re* Hogan, 559 F.2d 595, 610 (C.C.P.A. 1977) (Miller, J., concurring in part). 407. *Id.* 

concurring in *Chiron*, advanced a similar argument. Although he agreed that enablement must be judged in light of the art known when the patent application was filed, he would not interpret *Hogan* "to hold that claims...may be construed broadly enough to encompass technology that is not developed until later and [that] was not enabled by the original application."<sup>408</sup> "[T]he proper approach," he concluded, "is to address cases of new technology by construing claims, where possible, as they would have been understood by one of skill in the art at the time of the invention, and not construing them to reach as-yet-undeveloped technology that the applicant did not enable."<sup>409</sup> This would "preserve[] the benefits of patent protection for the invention that the applicant has actually conceived and enabled, without extending those benefits for an invention that the applicant may not have conceived and certainly has not enabled."<sup>410</sup>

Judge Bryson's approach is an appealing one as a matter of policy, ensuring that inventors obtain patent rights commensurate with, but no greater than, their contributions to the art. And it is well established that claims should be construed in light of the knowledge available to persons skilled in the art when the patent application was filed.<sup>411</sup> The problem is that sometimes the plain meaning of claim language is sufficiently open ended to include technologies that have not vet been discovered. If I refer, for example, to a "data storage device," this term includes storage devices that now exist and those yet to be devised. If someone invents, next year, an innovative storage device based on carbon nanotubes, it would unquestionably be a "data storage device" as that term was understood when I used it, even if I could not have foreseen the new variety. Construing claim language artificially so that it is always limited to the enabled species would not only give that language a meaning different than what would have been ascribed to it by persons skilled in the art, in effect it would allow the specification, rather than the claims, to define the limits of the patent grant.<sup>412</sup>

412. See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc) ("Consistent with its scope definition and notice functions, the claim

<sup>408.</sup> Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1262 (Fed. Cir. 2004) (Bryson, J., concurring). Bryson observes that "*Hogan* explicitly declined to construe the claims at issue in that case, although the court suggested in dictum that the scope of the claims might be broad enough to encompass the later-arising technology that was at issue." *Id.* at 1263.

<sup>409.</sup> Id. at 1263.

<sup>410.</sup> Id.

<sup>411.</sup> Trading Techs. Int'l, Inc. v. eSpeed, Inc., 595 F.3d 1340, 1351 (Fed. Cir. 2010) ("To construe a claim, courts must determine the meaning of disputed terms from the perspective of one of ordinary skill in the pertinent art at the time of filing.").

A more promising alternative may be found in the "reverse doctrine of equivalents," a doctrine intended "to prevent unwarranted extension of [patent] claims beyond a fair scope of the patentee's invention."<sup>413</sup> In cases where the accused product "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 reverse doctrine of equivalents "restrict[s] the claim and defeat[s] the patentee's action for infringement."<sup>414</sup> The reverse doctrine could be used to restrict the rights of patentees to their contributions to the art, while avoiding strained constructions of their claim language.

One of the few Federal Circuit cases to discuss the reverse doctrine in any depth is *SRI International v. Matsushita Electric Corp.* of America.<sup>415</sup> There the invention concerned a color television camera that generates different signals for the red and blue components of a scene through the use of superimposed color-transparent grids.<sup>416</sup> In the preferred embodiment, the grids for red and blue were positioned at different angles with respect to the scanning beam, so as the beam passed through them it produced signals of different frequencies for each color.<sup>417</sup> In the accused product, because the red and blue grids were positioned at the same (but opposite) angles with respect to the scanning beam, they produced signals of the same frequency.<sup>418</sup> The red and blue signals were distinguished, in this case, by timing differences rather than frequency differences.<sup>419</sup> The accused product literally infringed because the red and blue grids were, as the claims required, at

requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee's right to exclude."). Although the specification is an important tool for construing claim language, *see* Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) ("This court and its predecessors have long emphasized the importance of the specification in claim construction."), one cannot allow the disclosures of the specification to take the place of the claims in defining the limits of the patent grant, *see* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 336 U.S. 271, 276 (1949) ("It would accomplish little to require that claims be separately written if they are not to be separately read."), *aff'd on reh'g*, 339 U.S. 605 (1950).

<sup>413.</sup> Roche Palo Alto LLC v. Apotex, Inc., 531 F.3d 1372, 1377 (Fed. Cir. 2008) (quoting Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1581 (Fed. Cir. 1991)).

<sup>414.</sup> Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-09 (1950).

<sup>415. 775</sup> F.2d 1107 (Fed. Cir. 1985) (en banc).

<sup>416.</sup> *Id.* at 1111–12.

<sup>417.</sup> Id.

<sup>418.</sup> Id.

<sup>419.</sup> See id. at 1136–37 (Kashiwa, J., dissenting).

different angles *with respect to each other*,<sup>420</sup> but Matsushita argued that the accused camera, which did not employ that angle to generate different frequencies, operated in a substantially different way than the patentee's invention. The court observed that "one may only appear to have appropriated the patented contribution" in cases where the accused product falls within the literal terms of the patent claim.<sup>421</sup> If the accused product is, in fact, "so far changed in principle" that it operates in a "substantially different way[,]" the reverse doctrine of equivalents bars an action for infringement.<sup>422</sup> Here, the majority of the court found that factual disputes made summary judgment inappropriate.<sup>423</sup>

One can hypothesize that distinguishing color signals of the same frequency by timing differences required technological developments unforeseeable when the SRI patent application was filed. Perhaps, as far as the inventors knew, color grids that were angled with respect to each other would necessarily be angled with respect to the scanning beam; otherwise how would one distinguish the red signal from the blue? However, as it turned out, the specification did not enable every color television camera within the scope of the claims. Rather than invalidate the claims for a failing that the patentee could not have anticipated, it would make sense under those facts to limit the scope of the patent, by applying the reverse doctrine of equivalents, to cameras that rely on the patentee's technology. Hogan, the case that warns against the misuse of after-arising technology in enablement inquiries, suggests just such an approach: although "subsequently existing states of the art" have no bearing on validity, the reverse doctrine of equivalents, said the court, "may be safely relied upon to preclude improper enforcement against later developers."424

Not everyone would agree that the reverse doctrine of equivalents "may be safely relied upon," if only because it is invoked with success so infrequently that it is difficult to take it seriously. In *Roche Palo Alto LLC v. Apotex, Inc.*,<sup>425</sup> the Federal Circuit noted that the doctrine is "rarely applied" and that the court had never, in its history, "affirmed a finding of non-infringement under the reverse

<sup>420.</sup> The court noted that a concession of literal infringement "would have saved time and cost for all concerned." *Id.* at 1118 (majority opinion).

<sup>421.</sup> Id. at 1123.

<sup>422.</sup> Id. (emphasis omitted).

<sup>423.</sup> Id. at 1126.

<sup>424.</sup> In re Hogan, 559 F.2d 595, 607 (C.C.P.A. 1977) (emphasis omitted).

<sup>425. 531</sup> F.3d 1372 (Fed. Cir. 2008).

doctrine of equivalents."426 It is difficult to say why the reverse doctrine is largely theoretical, if it is merely the converse of the far more frequently applied doctrine of equivalents—"opposite sides of the same coin" as the court put it in SRI.<sup>427</sup> One problem is that the accused product must be literally what the claims describe, yet "so changed that it is no longer the same invention."428 If the claims define the scope of "the invention,"429 then this necessary condition for applying the reverse doctrine seems an impossibility. The doctrine can logically be applied only when courts recognize that, while the claims determine the outer limits of the patentee's rights,<sup>430</sup> for some purposes "the invention" is better seen as patentee's contribution to the art, as taught in the specification. In Roche Palo Alto, the court referred to this as the "principle" of the patent.<sup>431</sup> Another reason for the rare application of the reverse doctrine is that it may be seen as an anachronism<sup>432</sup>—a principle rendered unnecessary by rules, like enablement, requiring the claimed invention to adhere closely to the disclosures of the patent.<sup>433</sup> If those rules eliminate the possibility of a valid claim that encompasses any nonenabled embodiments, then the reverse doctrine of equivalents is, indeed, an anachronism. However, if the situation is more complicated, as I have suggested in this Article, then courts may find the reverse doctrine of equivalents to be a valuable and under-used resource-a useful complement to an enablement standard that accounts for the real difficulties that patent applicants routinely confront.

<sup>426.</sup> *Id.* at 1378.

<sup>427.</sup> *SRI*, 775 F.2d at 1125. In *Graver Tank*, the Supreme Court emphasized the symmetrical aspect when defending the role of equivalence in patent law: "The wholesome realism of [the doctrine of equivalents] is not always applied in favor of a patentee but is sometimes used against him." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950).

<sup>428.</sup> Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1351 (Fed. Cir. 2003) (quoting Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1325 (Fed. Cir. 1987)).

<sup>429.</sup> See Comput. Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1373 (Fed. Cir. 2008) ("The words of the claims define the scope of the patented invention.").

<sup>430.</sup> See Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (the "principal function" of the claims "is to provide notice of the boundaries of the right to exclude and to define limits").

<sup>431.</sup> *Roche Palo Alto*, 531 F.3d at 1378 (the defendant failed to establish a prima facie case of noninfringement under the reverse doctrine because it had not identified the "principle of the...patent," as it would be "determined in light of the specification, prosecution history, and the prior art").

<sup>432.</sup> Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002) (referring to the reverse doctrine of equivalents as an "anachronistic exception, long mentioned but rarely applied").

<sup>433.</sup> Id.

2016]

## PATENT SCOPE & ENABLEMENT

#### CONCLUSION

Like other branches of intellectual property, patent law is animated (or afflicted) by policy concerns "that tug in opposite directions."434 Lately, courts have been much occupied with the dangers of patent claims so broadly worded that they threaten to stand in the way of technological progress.<sup>435</sup> Yet, if we still trust in the constitutional premise that exclusive rights, as a rule, serve to "promote the Progress of ... [the] useful Arts[,]" we must equally guard against rules limiting patent claims so severely that fundamental advancements receive inadequate reward.<sup>436</sup> This tension lies at the heart of the enablement requirement as it is applied in the context of rapidly developing arts. Patentees should be expected to provide the traditional quid pro quo of teachings commensurate with their rights. At the same time, we must recognize that the most significant advancements are those capable of being exploited in a multitude of ways, some of them unanticipated by the original discoverer. The inventions that are the most fundamental, and the most susceptible to elaboration, should not for that very reason be denied meaningful protection.

Courts grappling with these concerns have left us with a collection of principles, observations, and results that are difficult to reconcile. The contradictions will be eased, and a better foundation established for promoting the progress of the useful arts, if we adopt the perspective of a reasonable patent applicant in cases where the claims are broader in scope than the enabling disclosures. If the overbreadth is attributable to the unforeseeability of new embodiments that arise in rapidly advancing arts, the claims should not be invalidated—though they may be limited in scope by application of the reverse doctrine of equivalents. If the nonenabled embodiments are "tangential"—if, in other words, they are nonenabled only because of aspects unrelated to the patentee's contribution to the art—then they should not affect the validity or

1163

<sup>434.</sup> Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014) ("To determine the proper office of the definiteness command...we must reconcile concerns that tug in opposite directions.").

<sup>435.</sup> See, e.g., Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (referring to the danger that patents encompassing basic tools will "inhibit future innovation premised upon them"—a result "at odds with the very point of patents, which exist to promote creation" (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012))).

<sup>436.</sup> *See* Lab Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from dismissal of the writ of certiorari) (referring to the "opposing and risky shoals" of overprotection and underprotection).

scope of the patent. They are simply the product of the open-ended nature of patent claims. Although this approach is not mandated by *Festo*, it is consistent with the spirit of that case in recognizing both the larger demands of policy and the practical difficulties that face even the best intentioned and most deserving patent applicants.