

# ARTICLE

## ENABLING PATENT LAW'S INHERENT ANTICIPATION DOCTRINE

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## I. INTRODUCTION

This Article seeks to clarify and to cabin a troublesome area of U.S. patent law: the doctrine of inherent anticipation. To be patentable, an invention must be novel.<sup>1</sup> Is an invention truly novel if the same invention (or an element thereof) existed in the prior art, but no one recognized it at the time?

For example, consider a patent claim to “a container structure comprising a plurality of hollow plastic ribs.” A document published before the patent’s critical date<sup>2</sup> depicts a container with several plastic ribs. The publication does not explicitly state that the ribs are hollow, but it does indicate that the ribs of the depicted container were formed by conventional blow-molding techniques. Resort to evidence beyond the publication is required to determine whether or not practice of these conventional blow molding techniques would have resulted in hollow ribs. If such evidence tends to establish that the blow-molded ribs would have been hollow, should this mean that the

1. 35 U.S.C. § 102 (2000). In addition, a patentable invention must be useful, nonobvious, and within the statutory categories of patentable subject matter. 35 U.S.C. §§ 101, 103 (2000).

2. A patent’s “critical date” is the date one year prior to the date on which the application for patent was filed in the U.S. Patent & Trademark Office (USPTO). *See* 35 U.S.C. § 102(b) (2000) (describing the circumstances in which prior publication, patenting, public use, or placement of the invention on sale destroys patentability); 2 DONALD S. CHISUM, CHISUM ON PATENTS § 6.02 (2008) (“Courts refer to the date one year before the effective application filing date as the ‘critical date.’”).

patented invention is not novel, i.e., that it has been anticipated, and thus is not patentable?

Professors Dan Burk and Mark Lemley have observed that “[i]nherency is . . . perhaps the most elusive doctrine in all of patent law.”<sup>3</sup> They conclude:

[T]he inherency cases are all ultimately about whether the public already gets the *benefit* of the claimed element or invention. If the public already benefits from the invention, even if they don’t know why, the invention is inherent in the prior art. If the public doesn’t benefit from the invention, there is no inherency.<sup>4</sup>

The Burk & Lemley “public benefit” test is a helpful approach for synthesizing the doctrinal morass of inherency law. But Burk & Lemley do not make sufficiently clear what “public benefit” means. We seek to refine the Burk & Lemley “public benefit” test by proposing a new standard of enablement for the prior art relied on to establish inherent anticipation.

In this Article we argue that the inherent anticipation doctrine should be narrowly and sparingly applied. Inherent anticipation requires true inevitability of result.<sup>5</sup> This inevitability requirement in turn demands that the prior art, which is relied upon to destroy novelty by establishing inherent anticipation under 35 U.S.C. § 102, must satisfy a more rigorous standard of enablement than the level of enablement required of patent-obtaining disclosures under the first paragraph of 35 U.S.C. § 112. Section 112 allows for a fairly extensive degree of experimentation by one seeking to make and use an invention in accordance with a patentee’s disclosure.<sup>6</sup> We posit that this

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3. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 373 (2005).

4. *Id.* at 374. Hereinafter we refer to the quoted Burk & Lemley test as the “public benefit” test.

5. *See infra* Part II (discussing case law surrounding, and general importance of, “inevitability of result” as it pertains to invalidating a claim based on anticipation by inherency).

6. 35 U.S.C. § 112 (2000). The foundational decision here is *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (listing multiple factors for determining whether the experimentation required for a person of ordinary skill to make and use a claimed invention in light of a patent’s disclosure would be undue). The *Wands* court observed:

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . . .

*Id.* at 737 (internal citations omitted); *see also* *Elan Pharms., Inc. v. Mayo Found.*, 346

liberal approach should not be countenanced in cases where a patent challenger seeks to *defeat* patentability under a theory of inherent anticipation. Rather, no more than *de minimis* experimentation should be required to achieve a later-claimed invention when an art worker carried out the instructions of an allegedly inherently anticipatory prior art reference or used an allegedly inherently anticipatory prior art device.

It is entirely logical to ask how a prior art document or device that does not explicitly disclose a later-claimed invention (or limitation thereof) can ever be enabling of that invention, let alone satisfy the heightened enablement standard we propose. By “enablement” as used herein, we are referring to the instructions, examples, or any other guidance provided by the prior art document or device which, if followed, would inevitably lead to the creation of the claimed invention, even though the person following the instructions would not be aware that in so doing she had created the claimed invention.

We acknowledge the irony that prior art that explicitly describes a claimed invention but does not enable at least its making (if not its use)<sup>7</sup> is *not* enough to anticipate (i.e., destroy novelty),<sup>8</sup> yet prior art that is silent as to an element of a claimed invention but which if practiced would inevitably result in the creation of that limitation *does* anticipate under the theory of inherency.<sup>9</sup> Recognition of this irony supports our argument for a heightened, more rigorous requirement for the enablement of prior art relied on to prove inherent anticipation. Our heightened

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F.3d 1051, 1052 (Fed. Cir. 2003) (clarifying in response to questions raised by petitions for reconsideration that “invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation”).

7. See *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969) (“[A] disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim.”); see also *In re Schoenwald*, 964 F.2d 1122, 1123–24 (Fed. Cir. 1992) (rejecting applicant’s argument that “an anticipatory reference must also disclose a use” and concluding that “it is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim to an old compound”).

8. See *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (“[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling.”); *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1965) (“[T]he criterion [for anticipation] should be whether the disclosure is *sufficient to enable one skilled in the art to reduce the disclosed invention to practice*. In other words, the disclosure must be such as will give possession of the invention to the person of ordinary skill.”).

9. See *infra* notes 35–46 and accompanying text (explaining anticipation through the theory of inherency).

enablement standard is driven by the need for a strict inevitability requirement.

Adopting our proposed standard for anticipation by inherency furthers the policy goal of encouraging investment, innovation, and disclosure through the patenting process. Excessive application of anticipation by inherency tends to chill this end. Consider, for example, the hypothetical invention of drug D, effective to cure Alzheimer's disease. This drug discovery required a multi-million dollar R&D effort and resulted in the grant of a patent. The patent is later challenged in litigation on the basis of a prior art reference disclosing that ingredients A and B could be combined in "approximately equal amounts" to make composition C, which was known to be useful for the tanning of leather.<sup>10</sup> As the basis for its anticipation defense, the accused infringer conducts tests proving that a small quantity of drug D inevitably results, along with the expected leather tanning composition C, *if* ingredients A and B are combined in a 60:40 ratio rather than a 50:50 ratio. No one knew or recognized this possibility until well after the patent on drug D issued, nor was it suggested in any way by the prior art because leather tanning composition C and drug D are structurally very different. After the drug D patent issued, the accused infringer used newly developed technology to analyze the chemical makeup of drug D; this analysis suggested some structural relationship between drug D and ingredients A and B, leading the accused infringer to the prior art reference directed to leather tanning composition C. To invalidate the patent on drug D, the cure for Alzheimer's, based on inherent anticipation by the prior art reference (which was completely silent as to the possible creation of drug D under *any* set of reaction conditions), would substantially chill any incentives to make similar investments to discover other life-saving drugs.

We likewise recognize the importance of the policy that the public (including a patentee's competitors) should be able to freely practice the prior art.<sup>11</sup> The patent on drug D should not bar the public's continued use of composition C for leather

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10. Our hypothetical is inspired by *In re Thuau*, 135 F.2d 344, 346 (C.C.P.A. 1943), involving an example of a known leather tanning compound later discovered to be an effective therapeutic drug.

11. See *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999) ("[I]f granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art."); *id.* at 1350 ("To uphold the Clay patent and its reissue would preclude the public from practicing the prior art.").

tanning purposes, even though composition C contains a small amount of drug D.

In some instances the Federal Circuit has broadly applied inherent anticipation in the service of this policy, especially when the court perceives attempted patent evergreening.<sup>12</sup> In this context, “evergreening” refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents by obtaining related patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like.<sup>13</sup> Regularly invalidating patents under an

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12. See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342–44 (Fed. Cir. 2005) (invalidating claim 1 of SmithKline’s ‘723 patent reciting “crystalline paroxetine hydrochloride hemihydrate” [PHC hemihydrate] as inherently anticipated under 35 U.S.C. § 102(b) by disclosure of patentee’s earlier ‘196 patent, which taught how to make PHC anhydrate but did not mention the hemihydrate form, on the basis that the ‘196 patent “discloses a method of manufacturing PHC anhydrate that naturally results in the production of PHC hemihydrate”); *id.* at 1345–46 (“SmithKline has sued Apotex for infringement of the ‘723 patent in an express attempt to prevent Apotex from practicing the ‘196 patent upon its expiration. . . . Invalidating claim 1 of the ‘723 patent for inherent anticipation by the ‘196 patent furthers th[e] policy of allowing the public to practice expired patents.”).

Drawing the line between improper attempts at evergreening and legitimate incremental innovation is a broad and difficult problem in patent law; a comprehensive review is beyond the scope of this Article. While some Federal Circuit decisions like *SmithKline*, are openly critical of perceived evergreening, others eschew making “value judgments” about patentee motives for obtaining follow-on patents. See, e.g., *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1373 (Fed. Cir. 2003) (affirming a district court’s holding that improvement patents directed to combination of antidiarrheal drug loperamide with antigas drug simethicone were invalid as obvious under 35 U.S.C. § 103 in view of prior art patents held by third parties, but reversing the district court’s award of attorney fees to patent challenger). The Federal Circuit in *McNeil-PPC, Inc. v. L. Perrigo Co.* noted the district court’s concern that the patentee had “set out as an objective developing products that extended the life of [its] basic patent on loperamide,” but declined to find the case exceptional under 35 U.S.C. § 285 (which would have supported an award of fees). *Id.* “While it may be considered more socially desirable for companies to seek truly novel inventions for maladies not yet treatable,” the Federal Circuit observed, “the patent laws set the standards of novelty, non-obviousness, and utility as the requirements for patentability, without making value judgments concerning the motives for making and attempting to patent new inventions of lesser medical value.” *Id.*

13. See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 401 n.44 (1999) (defining evergreening as “using a series of related patents (divisionals, continuations) covering different aspects of the same basic product invention in combination with patent term extensions to unduly prolong the exclusive market period.”); Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 30 (2005) (noting scholars’ concern over evergreening, the practice of attempts by patent holders “to refresh their patents by patenting updated versions, alternative delivery methods, or other variations of the original product,” and suggesting that patenting metabolites may also be a form of evergreening). Some advanced developing countries such as India have incorporated provisions in their patent laws to specifically target evergreening practices. See The Patents (Amendment) Act, No. 15 of 2005; INDIA CODE, § 3(d) (2005), available at <http://indiacode.nic.in>; Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 550–56 (2007).

expansive application of anticipation by inherency is an analytical shortcut, however; validity is better addressed in potential evergreening cases by more robust tools such as a comprehensive nonobviousness<sup>14</sup> or double patenting<sup>15</sup> analysis. In cases where validity is sustained, infringement liability may be tempered by narrower claim interpretation, the application of defenses such as practicing the prior art, or both.<sup>16</sup>

In many cases finding anticipation by inherency, the courts have interpreted a patent's claims so broadly as to encompass an embodiment of the invention that was allegedly present in the prior art through inherency but not recognized at the time.<sup>17</sup> We contend that in such cases a narrower claim interpretation would be justified as a means of lessening the courts' reliance on inherency principles. Specifically, in cases where anticipation by inherency is asserted, claims should be construed more narrowly so as to preserve their validity (at least against invalidation based on inherent anticipation).<sup>18</sup> Cabining inherency as we propose requires rethinking the artificial vacuum of claim interpretation sans consideration of the prior art.<sup>19</sup>

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(comparing § 3(d) of India's patent law with U.S. courts' responses to patent evergreening).

14. Nonobviousness, the ultimate condition of patentability, is analyzed under 35 U.S.C. § 103(a). It is a legal conclusion based on underlying facts. *See* *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (enumerating underlying factors as "the scope and content of the prior art," "differences between the prior art and the claims at issue," "the level of ordinary skill in the pertinent art," and "secondary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc."). In *KSR International Co. v. Teleflex, Inc.*, the Supreme Court's most recent decision addressing the nonobviousness analysis, the Court reaffirmed that the *Graham* factors "continue to define the inquiry that controls." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007).

15. Double patenting is a complex amalgam of statutory and case law. *See generally* 3A DONALD S. CHISUM, CHISUM ON PATENTS §§ 9.01–9.05 (2008); JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 48–52 (2d ed. 2006). At bottom, the double patenting doctrine prohibits a patent owner from unfairly extending its monopoly by acquiring more than one patent on a given invention. *See id.* at 48.

16. We discuss claim interpretation and defenses to infringement in *infra* Part IV.

17. *See, e.g.*, *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 17–19 (1892) (interpreting Holmes's prior use of paint on burglar wires to anticipate Cowles's claims employing paint as a wire insulator that also prevented combustion); *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1375–82 (Fed. Cir. 2003) (interpreting Schering Corporation's loratadine patent to anticipate its later claims to metabolite DCL).

18. Hence, we propose expanding this principle of claim interpretation to contexts beyond those contemplated in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327–28 (Fed. Cir. 2005) (en banc). The *Phillips* court noted that the principle that claims should be construed to preserve their validity has not been applied broadly and should be applied only when claim terms are still deemed ambiguous after consideration of all available tools of claim construction. *Id.* We detail our proposal for validity-saving claim interpretation in cases involving anticipation by inherency in *infra* Part IV.C.

19. The courts' need to rely on inherency would also be lessened if the defense of

Part II of this Article emphasizes that anticipation by inherency requires inevitability of result. Inherency must be certain, not based on probabilities.<sup>20</sup> To emphasize this requirement, we propose an alternative terminology of “inevitable anticipation,” which we use herein as synonymous with “inherent anticipation.” Although the inevitability standard is exacting, we agree with the prevailing Federal Circuit view that its satisfaction does not require a showing of contemporaneous recognition in the prior art of the missing (i.e., not explicitly described) component of a claimed invention. Part III is the primary contribution of our Article. In Part III we: (1) explain how the enablement requirement for anticipatory prior art developed; (2) describe how case law varies in application of the enablement standard; and (3) argue that prior art relied on to establish anticipation by inherency should satisfy a heightened enablement standard. We then apply our standard to the Federal Circuit’s controversial decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,<sup>21</sup> and conclude that the evidence there did not provide the degree of enablement we would require for inevitable anticipation. In Part IV, we explain why cabining the doctrine of anticipation by inherency makes good policy sense. We also respond to potential criticisms of our approach, and explore whether patent claim drafting techniques are sufficient to preempt inherent anticipation problems. Part V concludes.

## II. ANTICIPATION BY INHERENCY REQUIRES INEVITABILITY OF RESULT

The traditional “strict identity” rule of anticipation provides that, in order to establish lack of novelty of a claimed invention under 35 U.S.C. § 102, a single prior art reference must disclose

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practicing the prior art was fully recognized within the context of literal infringement, rather than its current limitation to infringement under the doctrine of equivalents. *See Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995) (rejecting the applicability of prior art defense to allegation of literal infringement). We propose an expansion of the defense of practicing the prior art for inherency cases in *infra* Part IV.B.

20. *See infra* text accompanying note 31.

21. *Schering Corp.*, 339 F.3d at 1373. The *Schering* decision drew critical commentary from Federal Circuit judges and patent law commentators. Two Federal Circuit judges authored opinions dissenting from the court’s refusal to rehear the appeal en banc, a third judge joined the vote to rehear en banc, and a fourth judge did not vote. *See Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (order denying petitions for panel rehearing and rehearing en banc). As of the June 2008 writing of this Article, the “JLR” file in Westlaw contained fifty-six articles citing the *Schering* panel decision.



every element of that invention, arranged as in the claim.<sup>22</sup> Well established in the case law,<sup>23</sup> the strict identity rule finds its statutory basis in 35 U.S.C. § 103(a). The preamble of that section provides that “[a] patent may not be obtained *though the invention is not identically disclosed or described as set forth in section 102 of this title*, if the [claimed invention] would have been obvious.”<sup>24</sup>

Recognition of anticipation by a theory of inherency means that patent law permits the destruction of novelty based on information not explicitly contained in a prior art reference.<sup>25</sup> Conceptually this can be viewed as either (1) an exception to the “single reference” component of the strict identity rule; or (2) an expansion of the strict identity rule such that the prior art reference’s “disclosure” can be considered inherent rather than explicit. The more realistic view is the former, for inherency cases typically involve resorting to information extrinsic to the allegedly anticipatory prior art reference.<sup>26</sup> The reference is by

22. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985) (“Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim. A prior art disclosure that ‘almost’ meets that standard may render the claim invalid under § 103; it does not ‘anticipate.’” (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (citations omitted))); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983) (“A party asserting that a patent claim is anticipated under 35 U.S.C. § 102 must demonstrate, among other things, identity of invention . . . [O]ne who seeks such a finding [of fact] must show that each element of the claim in issue is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.”).

23. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (noting the “many holdings of [the Federal Circuit] and its predecessors that anticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account”); *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 726–27 (Fed. Cir. 1984) (“It is hornbook law that anticipation must be found in a single reference, device, or process.”).

24. 35 U.S.C. § 103(a) (2000) (emphasis added).

25. See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.02[1][c] (2008) (“In *Helifix, Ltd. v. Blok-Lok, Ltd.* . . . the Federal Circuit noted that a publication that ‘does not expressly disclose in words’ one or more elements of a patent’s claims ‘might nevertheless be anticipating if a person of ordinary skill in the art would understand the [publication] as disclosing [the missing element or elements] . . . .’” (quoting *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1347 (Fed. Cir. 2000))).

26. The law recognizes situations in which extrinsic evidence can supplement the explicit teaching of a reference for purposes of establishing inherency. See, e.g., *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) (rejecting reexamination requester Baxter’s argument that extrinsic evidence such as depositions, declarations, and admissions may not be considered when determining the anticipatory teaching of a reference, and observing that “extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference”); Timothy R. Holbrook, *Possession in Patent Law*, 59 S.M.U. L. REV. 123, 172 n.273 (2006) (“Another exception to the ‘one reference’ rule for anticipation is inherent disclosure. A reference can be anticipatory even

definition silent as to the claimed feature inherently present in the prior art. As explained by the Federal Circuit, “To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence.”<sup>27</sup>

For example, consider the hypothetical above in which a patent claims “a container structure comprising a plurality of hollow plastic ribs.” The USPTO examiner has located a § 102(b) printed publication depicting a container with several plastic ribs. The prior art reference does not explicitly state that the ribs are hollow, but it does indicate that the ribs were formed by conventional blow-molding techniques. If other evidence (extrinsic to the reference) establishes that use of the blow molding process would always have resulted in hollow ribs, then the examiner would be justified in concluding that the reference inherently disclosed the “hollow” feature. In *ex parte* prosecution in the USPTO, the extrinsic evidence would likely be documentary evidence, while in litigation challenging the validity of an issued patent, the extrinsic evidence might be testimony of a technical expert. A rejection or invalidation of the claim as inherently anticipated would be proper under these circumstances.<sup>28</sup> If, however, the extrinsic evidence presents any question as to whether the blow molding process would have resulted in hollow ribs, then anticipation under a theory of inherency should be rejected.<sup>29</sup>

Conceptualizing anticipation by inherency as an exception to the single reference rule is yet another reason to apply inherency

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if part of the invention is not *expressly* disclosed but is inherently disclosed. Other prior art references can be used to show that the absent feature necessarily is present in the original piece of prior art.”).

27. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). The court in *Continental Can* also required that the necessarily present missing descriptive matter “would be so recognized by persons of ordinary skill,” a point with which we disagree. *Id.*; see also *infra* Part II.D.

28. *See Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1354–55 (Fed. Cir. 2005) (explaining that elements “necessarily present” in prior art may anticipate later claims despite the anticipated element not being explicitly discussed or disclosed in prior art).

29. *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 874 (E.D.N.C. 1993), is consistent with this approach. The district court in *Glaxo* rejected a defense of inherent anticipation because sometimes the practice of Example 32 in a prior art patent resulted in the claimed form of ranitidine hydrochloride, but sometimes resulted in the production of another form. *Id.* at 877. The Federal Circuit affirmed. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047–48 (Fed. Cir. 1995) (“[T]he district court found that the practice of Example 32 could yield crystals of either polymorph. It specifically found that Glaxo’s David Collin originally made Form 1 by practicing Example 32, and that Glaxo’s expert, Nicholas Crouch, did too. We are not persuaded that these findings are clearly erroneous. The district court correctly rejected the anticipation defense.”).

sparingly. We should permit the destruction of novelty by inherency principles only in a narrow set of circumstances that truly justify departure from the general rule. In particular, anticipation by inherency should be recognized only when the subject matter that is not explicitly taught by the prior art *inevitably* or always results from practice of that prior art.<sup>30</sup> In other words, inherency must be certain:

Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.<sup>31</sup>

The high standard of inevitability in turn drives the standard for enablement of prior art relied on to establish inherency. Contrary to some Federal Circuit decisions that view anticipation by inherency as conceptually separate from enablement of the prior art,<sup>32</sup> the two concepts are inextricably linked. We propose that a heightened standard of enablement be required of prior art relied on to establish anticipation by inherency.<sup>33</sup>

The remainder of this Part reviews the development of the doctrine of anticipation by inherency through decisions of the Supreme Court and the Federal Circuit. The earlier cases (mostly those of the Supreme Court) primarily involve fact patterns where inherent anticipation was proven by evidence of use of a prior art device. More recent cases rely primarily on the disclosure of prior art printed publications or patents to establish inherent anticipation. Borrowing from the insightful writings of Lord Hoffman of the United Kingdom's House of Lords, we will refer herein to these two varieties of anticipation by inherency as "anticipation by use" and "anticipation by disclosure."<sup>34</sup>

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30. We propose new terminology consistent with this view. Rather than debating "inherency" and "anticipation by inherency," courts instead should focus on the question of "inevitable anticipation." Accordingly, this Article will use the phrases "inherent anticipation" and "inevitable anticipation" as interchangeable, synonymous concepts.

31. *Continental Can*, 948 F.2d at 1269 (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)) (internal citations omitted).

32. See *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (observing that the appellant's arguments "are more properly characterized as enablement arguments rather than inherency arguments").

33. *Infra* Part III.

34. See *Merrell Dow Pharms. Inc. v. H.N. Norton & Co.*, [1996] R.P.C. 76, 84 (UKHL 1995). We discuss the *Merrell Dow* case in greater detail in *infra* Part II.C.

*A. Supreme Court Precedent*

The earliest Supreme Court case to find anticipation through a theory of inherency (although the Court never uses the word “inherency”) was probably its 1892 decision in *Ansonia Brass & Copper Co. v. Electrical Supply Co.*<sup>35</sup> In *Ansonia Brass* the accused infringer succeeded in proving anticipation not through the disclosure of a prior document or patent, but rather through the prior but then-unrecognized use of the same invention by a third party.<sup>36</sup> Identity of invention was established through testimony.<sup>37</sup>

Cowles, the inventor of the patent in suit, faced the problem of making an electrical wire that was not only insulated from moisture and the elements but also fireproof, such that the wire could not ignite if overheated by high-tension electrical current.<sup>38</sup> Cowles solved the problem by covering a copper wire with a layer of insulative and fibrous (e.g., cotton) braiding, then coating the braid-covered wire with a layer of paint (preferably a nonflammable lead- or zinc-containing paint), and finally covering the painted wire (while still wet) with a second layer of braiding.<sup>39</sup> Cowles’s patent claimed both his method and its end result, an “insulated and noncombustible covering for electric conductors.”<sup>40</sup>

The Court examined testimony given by one Holmes, a long-time manufacturer of electric burglar alarms, who made wire for his alarm systems with a construction similar to Cowles’s.<sup>41</sup> The Court also had before it testimony by the accused infringer’s expert that the tests he performed on the Holmes wire showed it was incombustible.<sup>42</sup> On this evidence the Court concluded that Holmes’s earlier use anticipated the claims of Cowles’s patent:

It is true that the insulator used by Holmes was not intended to be, and perhaps was not known to be, incombustible, since this feature of its incombustibility added nothing to its value for protecting a burglar-alarm wire, which carries a current of comparatively low tension; but, as already observed, the testimony indicates that the insulator employed by him was in fact nearly, if not quite,

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35. *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11 (1892).

36. *Id.* at 17–18.

37. *Id.* at 15.

38. *Id.* at 14.

39. *Id.* at 12.

40. *Id.* at 13.

41. *Id.* at 15–16.

42. *Id.* at 17.

as incombustible as that made by the plaintiff under the Cowles patent. If this be so, and the two insulators are practically the same in their method of construction, it is clear that Cowles has no right to claim the feature of incombustibility as his invention, since nothing is better settled in this court than that the application of an old process to a new and analogous purpose does not involve invention, even if the new result had not before been contemplated. It was said by Chief Justice Waite in *Roberts v. Ryer* that “it is no new invention to use an old machine for a new purpose. The inventor of a machine is entitled to all the uses to which it can be put, no matter whether he had conceived the idea of the use or not.”<sup>43</sup>

Thus, if a claimed invention has been previously used by others in this country, even though certain of its claim-recited features were not appreciated at the time of previous use, it cannot be considered novel. The invention may not have been “known” by others, but they “used” it.<sup>44</sup>

Although not expressly stated by the Supreme Court, it appears the basis for anticipation in *Ansonia Brass* was use in this country by another (here, Holmes) before the invention date of Cowles, under the statutory predecessor of 35 U.S.C. § 102(a). The lower court in the case focused on the state of affairs as of Cowles’s invention date, holding:

At the date of the invention [of Cowles], the public had had an electric wire insulated by means of a double covering of painted thread, but the public did not know that such a covering was also non-combustible. Although it did not know it, it had had a non-combustible insulator; for I cannot doubt that Holmes’ double covering was non-combustible in the same sense in which Cowles used the term.<sup>45</sup>

The lower court recognized that “[t]he public already had the article in use as a covering of an electric wire for purposes of insulation, and also had, in the article, the additional benefit of non-combustibility.”<sup>46</sup> Hence, *Ansonia Brass* represents what

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43. *Id.* at 17–18 (quoting *Roberts v. Ryer*, 91 U.S. 150, 157 (1875)) (internal citations omitted).

44. *See id.* at 17 (observing that though Holmes did not require incombustibility for his comparatively low tension burglar alarm wire, his insulation method nevertheless produced that result); *see also* 35 U.S.C. § 102(a) (2000) (dictating the destruction of novelty if “the invention was known or used by others in this country” before patentee’s invention date) (emphasis added).

45. *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 32 F. 81, 85 (C.C.D. Conn. 1887).

46. *Id.* at 86.

today might be termed a § 102(a) “use[] by others in this country” before the patentee’s invention date, although not a § 102(a) “known . . . by others in this country” before the patentee’s invention date.<sup>47</sup>

Federal Circuit case law provides that § 102(a) knowledge or use by others must be “accessible to the public” in order to anticipate.<sup>48</sup> This standard is satisfied by the facts of *Ansonia Brass*. Although the public did not have access to the knowledge that Holmes’s earlier wire was noncombustible, the public had unrestricted access to and use of the wire.<sup>49</sup> There was nothing secret, concealed, or suppressed about the Holmes wire, which was widely sold to the public as part of the burglar system installed by Holmes.<sup>50</sup> As the Federal Circuit has observed, “An inherent structure, composition, or function is not necessarily known.”<sup>51</sup>

A few years prior to *Ansonia Brass*, the Supreme Court decided *Tilghman v. Proctor*.<sup>52</sup> Although frequently discussed in analyses of inherent anticipation, *Tilghman* is *not* an example of inherent anticipation. Rather, it stands for the corollary proposition that when the claimed invention may have been *accidentally* made or practiced, but would *not* have inevitably resulted from such making or practicing, these accidental acts are not sufficient to count as anticipation.<sup>53</sup>

The plaintiff in *Tilghman* obtained a patent on a process for separating the component parts of fats and oils.<sup>54</sup> These components included a glycerine base and various “fat acids” such as stearic, margaric, and oleic acids, which were useful in the making of candles and soap.<sup>55</sup> Years before Tilghman’s invention, one Perkins had used tallow to lubricate the pistons of his steam engine.<sup>56</sup> The Supreme Court rejected the argument that this prior use by Perkins invalidated the patent:

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47. See 35 U.S.C. § 102(a) (2000).

48. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

49. *Ansonia Brass & Copper Co.*, 32 F. at 85–86.

50. See *id.* at 84 (noting that Holmes had been in the burglar alarm business for twenty-five years).

51. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1348–49 (Fed. Cir. 1999).

52. *Tilghman v. Proctor*, 102 U.S. 707 (1880).

53. *Id.* at 711–12.

54. *Id.* at 708.

55. *Id.* at 708–09.

56. *Id.* at 711. For additional background on Perkins’s use, see *Mitchell v. Tilghman*, 86 U.S. 287, 314–15 (1873), *overruled in part by* *Tilghman v. Proctor*, 102 U.S. 707 (1880).

We do not regard the accidental formation of fat acid in Perkins's steam cylinder from the tallow introduced to lubricate the piston (if the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence in this inquiry. What the process was by which it was generated or formed was never fully understood. Those engaged in the art of making candles, or in any other art in which fat acids are desirable, certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids.<sup>57</sup>

In the Court's view, the process claimed by Tilghman had not "been known and used before" by virtue of Perkins's activities.<sup>58</sup>

It might be argued that the Court did not find anticipation in *Tilghman* because prior artisans such as Perkins did not at the time recognize that they were practicing the same process that would later be claimed by the patentee. After all, the Court observes that no one really understood what was occurring in Perkins's steam cylinder.<sup>59</sup> Certainly no candle maker ever derived any useful information from Perkins's activities.<sup>60</sup>

A better view is that *Tilghman* is simply a case in which the evidence was insufficient to prove that the claimed process was the inevitable, certain, and necessary result of operating Perkins's engine.<sup>61</sup> The Court notes the evidentiary weaknesses by questioning whether "the scum which rose on the water issuing from the ejection pipe was fat acid," and by acknowledging that the process by which Perkins's scum was formed "was never fully understood."<sup>62</sup> It is unlikely that the

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57. *Tilghman*, 102 U.S. at 711. The Court continued in the same vein with respect to other prior art of record:

The accidental effects produced in Daniell's water barometer and in Walther's process for purifying fats and oils preparatory to soap-making, are of the same character. They revealed no process for the manufacture of fat acids. If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery.

*Id.* at 711–12.

58. *See id.* at 721–22 ("Had the process been known and used before, and not been Tilghman's invention, he could not then have claimed anything more than the particular apparatus described in his patent, but being the inventor of the process, as we are satisfied was the fact, he was entitled to claim it in the manner he did.").

59. *Id.* at 711.

60. *See infra* Part II.D (rejecting the reading of *Tilghman* as requiring contemporaneous recognition of inherent features by the prior art).

61. As the Federal Circuit has observed, the record in *Tilghman* "did not show conclusively that the claimed process occurred in the prior art." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003).

62. *Tilghman*, 102 U.S. at 711.

accused infringer in *Tilghman* ever attempted to reproduce Perkins and prove that the scum emanating from Perkins's engine truly was the fat acids recited in the patentee's process claims. Rather, the Supreme Court's opinion suggests that the witnesses who testified about Perkins's process merely provided speculative and biased opinions that the process actually produced fat acid.<sup>63</sup>

The prior art in *Tilghman*, as described through the testimony of witnesses, did *not* sufficiently enable the process later claimed by Tilghman.<sup>64</sup> Hence, the prior art use of Perkins's engine did not put the public in possession of Tilghman's claimed process, and that use therefore was not anticipatory.<sup>65</sup>

### B. Federal Circuit Inconsistency on Inevitability

Nominally, at least, Federal Circuit precedent is consistent with an inevitability requirement. The case law requires that the missing element(s) of a claimed invention not explicitly set forth in a prior art reference must *necessarily* be present, or inherent, in that reference.<sup>66</sup> Examination of several Federal Circuit inherency cases demonstrates that despite professing a

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63. The Court's opinion in *Mitchell v. Tilghman*, 86 U.S. 287, 411–12 (1873), which concerned the same Tilghman patent, supports this view. In *Mitchell*, the defendant and accused infringer introduced into evidence a document, marked "Exhibit E," which was "an extract from the *Journal of Science, London*, 1823, vol. xvi, p. 172, entitled 'Change of Fat in Perkins's Engine, by Water, Heat, and Pressure.'" *Id.* at 316. Mr. Verdin, a partner of the defendant Mitchell with an interest in avoiding any judgment for the patentee, testified about the Perkins engine in a different case in 1868 as follows:

Q. Would not any manufacturer of ordinary skill and information in his art, as current prior to 1854, have known from Exhibit E that fat-acids and glycerin were produced by the action of water at a high temperature and pressure, and does not the presence of acrolein involve the production of glycerin?

A. I should have known it, and I cannot doubt others would, as a person had only to subject the fat to the action of water at a temperature and pressure named to have acidified fats; acrolein cannot be formed without glycerin being formed first.

*Id.* Verdin's testimony was admitted into the record of the *Mitchell* case by consent. *Id.* Notably, in both *Mitchell v. Tilghman* and *Tilghman v. Proctor*, the Court does not refer to any testimony pertaining to actual reproduction of Perkins's engine for purposes of testing its product for the litigation at hand. *Tilghman*, 102 U.S. at 730; *Mitchell*, 86 U.S. at 395–412.

64. *Tilghman*, 102 U.S. at 711–13.

65. *Id.* at 717–22.

66. See, e.g., *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (reversing USPTO Board of Patent Appeals and Interference's ("Board's") finding of anticipation by inherency of claimed diaper mechanical fastening system); *Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency." (citing *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991))).



requirement of inevitability, the court has not interpreted and applied that requirement in a consistent fashion.

For example, the Federal Circuit found inherent anticipation in *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*,<sup>67</sup> setting forth the standard:

Anticipation based on a printed publication under Section 102(a) requires the presence in the publication of each and every limitation of the claimed invention. However, “a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing feature is *necessarily present, or inherent, in the single anticipating reference*.”<sup>68</sup>

The *Novo Nordisk* court affirmed a district court’s determination that claim 1 of the ‘352 patent in suit was invalid for anticipation, based in part on a theory of inherency.<sup>69</sup> The ‘352 patent was directed to “a process for producing ‘ripe’ human growth hormone (‘hGH’) protein in *E.Coli* bacteria through the use of recombinant DNA techniques.”<sup>70</sup> Claim 1 of the ‘352 patent recited “[b]iosynthetic ripe human growth hormone [hGH] free of contaminants from pituitary derived human growth hormone.”<sup>71</sup> The parties disputed whether the prior art disclosed the second and third limitations of the claim, i.e., “a protein that is composed of a 191-amino acid sequence identical to that of pituitary-derived hGH and that has the full biological activity of pituitary-derived hGH.”<sup>72</sup>

The Federal Circuit agreed with the district court that these limitations were disclosed in a printed publication by Pavlakis, titled “Expression of Two Human Growth Hormone Genes in Monkey Cells Infected by Simian Virus 40 Recombinants” and published in 1981.<sup>73</sup> Pavlakis taught a method of producing hGH

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67. *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1362–63 (Fed. Cir. 2005).

68. *Id.* at 1354–55 (emphasis added) (citations omitted). The Federal Circuit treats the question of “[w]hat a prior art reference discloses in an anticipation analysis,” including anticipation by inherency, as a fact question reviewed for clear error in a bench trial. *See id.* at 1355.

69. *Id.* at 1356.

70. *Id.* at 1349.

71. *Id.* at 1351. The Federal Circuit left undisturbed the district court’s interpretation of “ripe hGH” in claim 1 of the ‘352 patent as meaning “a protein produced by recombinant DNA techniques composed of a 191 amino acid sequence identical to that of hGH produced by the human pituitary gland with the full biological activity of hGH produced by the human pituitary gland, and free of the contaminants present in hGH produced by the human pituitary gland.” *See id.* at 1353 (quoting *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, No. Civ.02-332-SLR, 2004 WL 1739720, at \*18 (D. Del. Aug. 3, 2004)); *see also id.* at 1356 n.9 (declining to reach claim interpretation issue).

72. *Id.* at 1354.

73. *Id.* at 1353–54 (citing George N. Pavlakis et al., *Expression of Two Human*

protein with monkey kidney cells by applying a “secretion approach” to two different types of hGH genes, which he identified as “hGH1” and “hGH2.”<sup>74</sup> Extensively discussing various tests performed on the resulting proteins, Pavlakis concluded his hGH1 protein was in all respects identical to pituitary hGH, while his hGH2 protein was not.<sup>75</sup> The Federal Circuit concluded that Pavlakis’s production of his hGH1 protein must have necessarily resulted in the claimed invention, observing:

[T]he test results disclosed in the Pavlakis article indicated that the hGH1 protein had the same structure and chemical properties as pituitary-derived hGH. In other words, the test results indicated that the hGH1 protein contained the same 191 amino acid sequence and biological activity as pituitary-derived hGH. Accordingly, we hold that the article discloses a ripe hGH protein.<sup>76</sup>

In contrast with *Novo Nordisk*, the facts of *Atlas Powder Co. v. IRECO Inc.*<sup>77</sup> arguably do *not* satisfy the inevitability test for anticipation by inherency. The Clay patent in suit in *Atlas Powder* and its reissue were directed to certain composite explosive (blasting) compositions.<sup>78</sup> The parties disputed whether a claim limitation requiring that “sufficient aeration [be] entrapped to enhance sensitivity to a substantial degree” was inherently disclosed by prior art blasting compositions.<sup>79</sup> Test results presented during litigation established that the “sufficient aeration” condition was satisfied by the prior art compositions in some, but not all, cases.<sup>80</sup> Sufficient aeration existed when the numerical ranges of the substituent ingredients

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*Growth Hormone Genes in Monkey Cells Infected by Simian Virus 40 Recombinants*, 78 PROC. NAT’L ACAD. SCI. USA 7398 (1981)).

74. *Novo Nordisk*, 424 F.3d at 1353.

75. *Id.*

76. *Id.* at 1355–56. The Federal Circuit also rejected the patentee’s argument that the Pavlakis article was not enabling. *Id.* at 1356. The Federal Circuit concluded:

The 1981 Pavlakis article discloses the production of ripe hGH protein in an enabling manner because it discusses particular materials and a particular methodology (the secretion approach) to produce the hGH protein. In other words, the article relies on standard recombinant DNA techniques that would have been understood by one of ordinary skill in the art at the time of its publication. We see no reason to disturb the district court’s conclusion that the 1981 Pavlakis article is sufficiently enabling to serve as an anticipating reference.

*Id.*

77. *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342 (Fed. Cir. 1999).

78. *Id.* at 1343.

79. *Id.* at 1344.

80. *Id.* at 1348.

in the prior art compositions taught by Egly overlapped with the ranges recited for the corresponding ingredients in the claimed compositions.<sup>81</sup> However, the record affirmatively *disproved* that sufficient aeration was achieved in the Egly compositions when made from the same ingredients in disclosed percentages that did *not* overlap with the claimed composition.<sup>82</sup> Despite this demonstrated absence of inevitability for at least part of the prior art's disclosure, the Federal Circuit affirmed the district court's finding of anticipation by inherency.<sup>83</sup>

The inevitability finding in *Atlas Powder* is suspect for a second reason. The prior art Egly patent taught away from air entrapment, disclosing that it was “desirable to ‘fill all spaces in between each particle to give added density.’”<sup>84</sup> The record also showed that special mixing techniques—such as “grinding and screening the [ammonium nitrate] particles—remove interstitial air from the blasting compositions.”<sup>85</sup> In view of this evidence, the district court had to qualify its finding of anticipation by inherency by concluding that the prior art compositions satisfied the “sufficient aeration” limitation of the claimed blasting composition “unless extraordinary measures are taken to grind and screen ammonium nitrate.”<sup>86</sup> It was known in the art to take such measures, and it is reasonable to infer that a person of ordinary skill in the art might have done so in order to “fill all spaces in between” each particle as Egly recommended. This uncertainty over how a prior artisan would have actually practiced the Egly teaching, in combination with the absence of sufficient aeration in at least part of Egly's disclosed ranges, casts further doubt that the patentee's claimed composition “inevitably” resulted from practicing the prior art in *Atlas Powder*.

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81. *Id.*

82. For example, the claimed explosive composition of the Clay patent in suit comprised 10–40% of a water-in-oil emulsion containing, *inter alia*, ammonium nitrate. *See id.* at 1345. The Egly prior art explosive composition disclosed having 20–67% of the water-in-oil emulsion. *See id.* Evidence at trial established that “at emulsion levels *below* 40%, Egly compositions ‘inevitably and inherently’ trap sufficient amounts of air to enhance sensitivity.” *Id.* at 1349 (emphasis added). However, the evidence also established that “Egly compositions containing amounts approaching 67% by weight of water-in-oil emulsions may have *little or no* entrapped air.” *Id.* (emphasis added). Thus, the evidence did not establish that the prior art Egly explosive composition inevitably met the claimed “sufficient aeration” limitation over the entire numerical range disclosed in the Egly prior art patent, but rather only for the subset of that range which overlapped with the claimed composition. *Id.*

83. *Id.* at 1350.

84. *Id.* at 1349 (quoting prior art U.S. Patent No. 3,161,551 (filed Apr. 7, 1961)); *see also id.* at 1343.

85. *Id.* at 1349.

86. *Id.* at 1349–50.

The Federal Circuit's decision in *In re Robertson* offers a useful contrast to the uncertainty of *Atlas Powder*.<sup>87</sup> The *Robertson* court properly rejected an argument of inherent anticipation because the record did not establish that the inevitability standard had been satisfied.<sup>88</sup> The application on appeal claimed a diaper mechanical fastening system providing for convenient disposal of the used diaper.<sup>89</sup> The court interpreted application claim 76 as requiring "two mechanical fastening means to attach the diaper to the wearer and a third such means for securing the diaper for disposal."<sup>90</sup> A prior art patent to Wilson taught that a used diaper could be disposed "by rolling it up and employing the same fasteners used to attach the diaper to the wearer to form 'a closed compact package for disposal,'" but did not provide a separate fastening means to be used in disposing of the diaper.<sup>91</sup> The Federal Circuit reversed the USPTO Board of Patent Appeals and Interference's (Board's) finding that claim 76 was anticipated by inherency based on Wilson.<sup>92</sup> The Board "made no attempt to show that the fastening mechanisms of Wilson that were used to attach the diaper to the wearer also 'necessarily' disclosed the third separate fastening mechanism of claim 76 used to close the diaper for disposal."<sup>93</sup> Moreover, the Board "cited no extrinsic evidence so indicating."<sup>94</sup>

Another case in which the Federal Circuit properly rejected inherent anticipation based on a failure to satisfy the inevitability criterion is the court's nonprecedential decision in *Haberman v. Gerber Products Co.*<sup>95</sup> The Federal Circuit in *Haberman* reversed a district court's judgment based on a jury's verdict that a patent on the children's "Sippy Cup" was invalid.<sup>96</sup> The Federal Circuit considered the evidence inadequate to show that the prior art inevitably achieved the claimed effect of operation only by a predetermined amount of suction.<sup>97</sup> The evidence showed at best that the claimed effect "may" have

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87. *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999).

88. *Id.* at 745.

89. *Id.* at 744.

90. *Id.*

91. *Id.* at 745.

92. *Id.* at 746.

93. *Id.* at 745.

94. *Id.*

95. *Haberman v. Gerber Prods. Co.*, 236 F. App'x 592, 598 (Fed. Cir. 2007) (not designated for publication).

96. *Id.* at 602.

97. *Id.* at 598.

resulted.<sup>98</sup> The accused infringer failed to carry its clear and convincing burden of proof for invalidating an issued patent:

Indeed, no evidence was introduced at trial regarding the quantum of pressure necessary to allow the Brown [prior art] valve to open by squeezing the outside of the container, or the amount of pressure that oral suction can generate. At most, the testimony of Socier and Stull demonstrates that applying a predetermined level of oral suction *may* result in the drawing out of liquid via the Brown valve. Such evidence falls short of clear and convincing evidence that a valve operable by the sole application of a predetermined level of suction is necessarily present in Lampe or, stated another way, that applying a predetermined level of suction to the Lampe valve would inevitably result in the drawing out of liquid. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir.1991) (extrinsic evidence used to fill a gap in a reference “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill”) (citations omitted); *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981) (inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”) (quotation omitted).<sup>99</sup>

The Federal Circuit’s decision in *Titanium Metals Corp. of America v. Banner*<sup>100</sup> is often discussed as an example of inherent anticipation. *Titanium Metals* is an important case (often assigned by patent law professors), but it did not turn on an inherency rationale.<sup>101</sup> Data points in a graph of a prior art Russian journal article showed certain metallic alloys<sup>102</sup> had been made before the Titanium Metals patent applicants’ critical date.<sup>103</sup> These alloys fell within the scope of the applicants’ generic claims, thus anticipating the claims under the “species anticipates genus” axiom.<sup>104</sup> The patent applicants discovered that the alloy possessed the previously unrecognized property of

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98. *Id.*

99. *Id.*

100. *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

101. *See id.* at 780–82.

102. *Id.* at 777 (stating molybdenum and nickel alloys were on the graph).

103. *Id.* at 781 (noting that the Russian article was dated five years before the patent’s filing date).

104. *Id.* at 782 (“It is . . . an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.”).

corrosion resistance.<sup>105</sup> Their mistake was to claim more than they had discovered. Reciting the newly appreciated property of corrosion resistance in a claim to the alloy composition itself did not impart patentability to the otherwise old alloy composition, the Federal Circuit held.<sup>106</sup> In other words, the recited corrosion resistance property did not limit the scope of the patent claims. Thus, the data points in the prior art publication conclusively and explicitly showed that the claimed alloy was not new.<sup>107</sup>

Although the Federal Circuit has repeatedly characterized *Titanium Metals* as an inherency case,<sup>108</sup> this is inconsistent with the language and reasoning of the case. The *Titanium Metals* court emphasized that it was not necessary to determine whether the property of corrosion resistance was “inherently” present in the prior art alloys.<sup>109</sup> What mattered was that the claimed alloy had been made before.<sup>110</sup> The U.S. public was in possession of the claimed alloy by virtue of the Russian publication;<sup>111</sup> only the alloy’s noncorrosive property was not known or appreciated at the time of the Russian publication. Thus, *Titanium Metals* is not an inherency case vis-à-vis the claimed alloy itself, and the applicants’ claim to the alloy was not limited by its recitation of a noncorrosive property. Rather, *Titanium Metals* is better viewed as a case about traditional (explicit) anticipation as well as patent claim interpretation.

Federal Circuit cases are unclear as to the *timing* for inevitability, i.e., as of what date must inevitability be established? One might argue that inevitability of result in practicing the prior art must be shown to have existed no later than the critical date of the patent sought to be anticipated. A

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105. *Id.* at 780–82.

106. *Id.* at 782.

107. *Id.* at 781 (“As to that disclosed alloy of the prior art, there can be no question that claims 1 and 2 read on it and would be infringed by anyone making, using, or selling it. Therefore, the statute prohibits a patent containing them.”).

108. *See, e.g.,* Schering Corp. v. Geneva Pharms., Inc., 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting from denial of rehearing en banc) (contending that in *Titanium Metals*, “the court held that the discovery of the property of corrosion resistance of a known alloy did not impart patentability to the known alloy, for that property was inherent in the alloy”); Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349 (Fed. Cir. 1999) (“Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation. *See Titanium Metals*, 778 F.2d at 782.”).

109. *Titanium Metals*, 778 F.2d at 782 (“[I]t is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties.”).

110. *Id.*

111. No doubt existed that a prior artisan was enabled to make the alloys corresponding to the prior art Russian data points. *See id.* at 781 (“Enablement is not a problem in this case.”).

better approach would allow inevitability of result to be established at any time, i.e., the time of litigation. For example, inherent anticipation could be proven under this approach if an accused infringer established that, after being sued, it reproduced the pertinent prior art and found the inevitable result of its testing was the production of the patentee's claimed composition or device. In other words, the fact of inevitability need not be proved to have existed as of the effective date of the prior art reference, or more than a year before the filing date of the patent in suit. This latter approach is also consistent with the *Warner-Jenkinson* approach of establishing technological equivalence under the doctrine of equivalents at the time of infringement (not as of the date of the patent or some earlier date).<sup>112</sup>

### C. Comparing the United Kingdom Approach

The decision by the U.K. House of Lords in *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co.* offers an insightful analysis of inherency concepts.<sup>113</sup> Unfortunately, the decision has gone virtually unnoticed in the U.S. patent law literature. This lack of attention is surprising, for *Merrell Dow* is in many respects factually analogous to the Federal Circuit's "metabolite" cases such as *Schering*.<sup>114</sup> These cases concern attempts by pharmaceutical patent owners to enforce subsequent patents on the later-discovered metabolite forms of the drugs covered by their earlier patents.<sup>115</sup> A metabolite is the compound that forms inside a patient's body when she ingests a pharmaceutical; the pharmaceutical is chemically converted to the new metabolite compound.<sup>116</sup>

Lord Hoffman's opinion in *Merrell Dow* clarifies that arguments for inherency arise in two forms: "anticipation by use" and "anticipation by disclosure."<sup>117</sup> As detailed below, Lord Hoffman ultimately rejects the accused infringer's "anticipation by use" argument because of the "available to the public" statutory qualifier for anticipation under the U.K. Patent Act

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112. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997).

113. See generally *Merrell Dow Pharms. Inc. v. H.N. Norton Co.*, [1996] R.P.C. 76 (UKHL 1995).

114. Compare *id.* at 80, with *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1375–76 (Fed. Cir. 2003). We apply our proposed heightened enablement standard for inherency cases to the facts of *Schering* in Part III.D, *infra*.

115. See *Merrell Dow*, [1996] R.P.C. at 80.

116. *Schering*, 339 F.3d at 1375.

117. *Merrell Dow*, [1996] R.P.C. at 84.

and the European Patent Convention (EPC).<sup>118</sup> Instead, Lord Hoffman finds Merrell Dow's metabolite patent invalid under the "anticipation by disclosure" theory,<sup>119</sup> emphasizing the "inevitability" requirement for inherency. He concludes that the specification of Merrell Dow's prior art patent communicated information to the public that "enable[d] it to do an act having the *inevitable* consequence of making the acid metabolite."<sup>120</sup>

Merrell Dow first patented the antihistamine drug terfenadine in the United Kingdom in 1972.<sup>121</sup> After a period of extension, the patent expired in December 1992.<sup>122</sup> Merrell Dow obtained a second patent in 1980 that was to extend five years beyond the terfenadine patent.<sup>123</sup> The second patent claimed the acid metabolite of terfenadine.<sup>124</sup> Notably, the claim to the metabolite was interpreted broadly so as to encompass "the making of the acid metabolite in one's liver just as much as making it by synthetic process; in the body as well as in isolation."<sup>125</sup>

Lord Hoffman analyzed the appeal before him as alleging two types of anticipation. The first he termed "anticipation by use," which referred to the actual, inevitable production of the acid metabolite in the livers of patients who participated in clinical trials of terfenadine in 1977–1978, before the priority date of Merrell Dow's second patent claiming the acid metabolite.<sup>126</sup> The record made clear that "[p]articipants in clinical trials had actually been taking the drug [terfenadine]."<sup>127</sup> Counsel for the accused infringer argued that under § 2(2) of the U.K. Patents Act (1977), the claimed acid metabolite was in the state of the art and hence anticipated.<sup>128</sup> In particular, the invention had been "made available to the public by use," even though the clinical trials admittedly conveyed no information

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118. See *id.* at 86–87.

119. See *id.* at 87–91.

120. *Id.* at 91 (emphasis added).

121. *Id.* at 80.

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.* at 82. The metabolite claims in *Schering* were similarly interpreted in a broad fashion to encompass not only synthetically produced metabolites but also those metabolites made in a patient's body following ingestion of the drug product. See *infra* Part III.D. This expansive claim interpretation was central to the Federal Circuit's finding of anticipation by inherency in *Schering*. See *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).

126. See *Merrell Dow*, [1996] R.P.C. at 84.

127. *Id.* at 83.

128. *Id.* at 86.



about the acid metabolite to the public.<sup>129</sup> Lord Hoffman rejected the accused infringer's "anticipation by use" argument.<sup>130</sup> The need for U.K. patent law to comport with that of the EPC drove his rejection.<sup>131</sup> According to Lord Hoffman, "ma[king] available to the public" under § 2(2) requires *information* about the invention be made available, whether by use or publication.<sup>132</sup> In other words, "The use of a product makes the invention part of the state of the art only so far as that use makes available the necessary information."<sup>133</sup> Lord Hoffman relied primarily on a decision of the European Patent Office (EPO) interpreting Article 54 of the EPC.<sup>134</sup> In *Mobil/Friction Reducing Additive*, the Enlarged Board of Appeals rejected an argument of anticipation based on inherency, emphasizing:

[U]nder Article 54(2) EPC the question to be decided is what has been "made available" to the public: the question is not what may have been "inherent" in what was made available (by a prior written description, or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to validity of a European patent. In this respect, the provisions of the EPC may differ from the previous national laws of some Contracting States, and even from the current national laws of some non-Contracting States. Thus, the question of "inherency" does not arise as such under Article 54 EPC. Any vested right derived from prior use of an invention is a matter for national law.<sup>135</sup>

Thus, Merrell Dow's acid metabolite patent could not be invalidated "simply on the ground that making the acid metabolite is something which has been done before."<sup>136</sup> Under Lord Hoffman's interpretation of the relevant statutory language, no "anticipation by use" had occurred.<sup>137</sup>

Lord Hoffman next considered "anticipation by disclosure," which referred to the alleged disclosure of the claimed acid metabolite by the words in the specification of Merrell Dow's

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129. *Id.*

130. *Id.* at 85–87 (subsection (b) titled "The New Law").

131. *Id.* at 82.

132. *Id.* at 86.

133. *Id.*

134. *Id.* at 86–87.

135. *Id.* at 87 (quoting *Mobil/Friction Reducing Additive*, G2/88, [1990] OFFICIAL J. EPO 73, 88 (1990)).

136. *Id.* at 87.

137. *Id.* at 85–86.

earlier terfenadine patent.<sup>138</sup> The terfenadine patent, a document available to the public in 1972 before the priority date of the acid metabolite patent,<sup>139</sup> “told one how to make terfenadine and that it should be taken for its anti-histamine effect.”<sup>140</sup> “Full information about [terfenadine’s] chemical composition and method of use had been published in its patent specification in 1972.”<sup>141</sup> “Participants in clinical trials had actually been taking the drug.”<sup>142</sup> They “had made the acid metabolite in their livers and experienced its anti-histamine effects.”<sup>143</sup> The “*inevitable* result of following [the prior art patent’s] instructions was to make the acid metabolite,” Lord Hoffman concluded.<sup>144</sup> The prior art patent communicated information “which enable[d] [the public] to do an act having the *inevitable* consequence of making the acid metabolite.”<sup>145</sup>

Another and more recent patent decision from the U.K. courts lends additional support for rigorous application of the inevitability and enablement standards for inherent anticipation. In *Les Laboratoires Servier v. Apotex, Inc.*,<sup>146</sup> the Patents Court invalidated claims to a new alpha crystalline form of salt X of compound Y, based on a theory of inevitable anticipation by a prior art patent that described the industrial synthesis of compound Y.<sup>147</sup> Mister Justice Pumfrey acknowledged that a heightened degree of enablement is properly required for inevitable anticipation, in contrast to the more relaxed standard for enablement required of an applicant seeking a patent:

[T]he criteria for sufficiency of description on the one hand and the enablement of an inevitable result on the other are not the same. For purposes of anticipation, the prior documents must enable something which *inevitably* falls within the claim. *Where the prior art does not describe the end to be achieved, it is illegitimate to employ a refinement of technique or whatever to cause the desired result to be achieved.* Where the sufficiency of a disclosure of a method is under discussion, of course the skilled person is entitled

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138. *Id.* at 87.

139. *Id.* at 83.

140. *Id.* at 84.

141. *Id.* at 83.

142. *Id.*

143. *Id.* at 84.

144. *Id.* (emphasis added).

145. *Id.* at 91 (emphasis added).

146. *Les Laboratoires Servier v. Apotex, Inc.*, [2007] EWHC (Pat) 1538 (Eng.), available at <http://www.bailii.org/ew/cases/EWHC/Patents/2007/1538.html>.

147. *Id.*

to do such preliminary work and carry out such uninventive refinements, without undue effort, with a view to producing a product falling within the claim.<sup>148</sup>

Similarly, the court in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.* observed, “To anticipate the patentee’s claim the prior publication must contain *clear and unmistakable directions* to do what the patentee claims to have invented.”<sup>149</sup>

*D. Inherent Anticipation Does Not Require Contemporaneous Recognition in the Prior Art of Inevitable Result*

We agree with the line of Federal Circuit cases holding that inherent anticipation does not require contemporaneous recognition by the prior art worker, i.e., recognition that the claimed invention was being produced at the same time as the prior art device or compound was being made or practiced.<sup>150</sup> These Federal Circuit decisions are consistent with the pertinent Supreme Court precedent. As the Court stated in *Ansonia Brass*, even though the prior art insulator of Holmes perhaps “was not known to be” incombustible, this was irrelevant to its anticipatory effect.<sup>151</sup>

Writing for the Second Circuit, Judge Learned Hand provided what is arguably the most satisfactory reason why contemporaneous recognition should not be required for inherent

148. *Id.* (emphasis added).

149. *Gen. Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*, [1972] R.P.C. 457, 486 (CA) (Civ. Div.) (emphasis added).

150. *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (“[I]nherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created.”); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”); *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (“[T]his court rejects the contention that inherent anticipation requires recognition in the prior art. . . . [R]ecognition by a person of ordinary skill in the art before the critical date of the ‘716 patent [in suit] is not required to show anticipation by inherency [by Schering’s earlier ‘233 patent].”); *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349 (Fed. Cir. 1999) (“Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation.” (citing *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985))).

The contrary line of Federal Circuit authority is exemplified by *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), which stated that extrinsic evidence used to fill a gap in a reference “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Id.* at 1268 (emphasis added).

151. *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 17–18 (1892) (noting that “incombustibility added nothing to its value for protecting a burglar-alarm wire”).

anticipation, although never explicitly referring to the notion of “inherency.” Hand’s opinion in *H.K. Regar & Sons v. Scott & Williams*<sup>152</sup> also provides a corollary to the “no anticipation by accident” rule of *Tilghman*.<sup>153</sup> Hand explained in *Regar* that “when the result is a necessary consequence of what was deliberately intended, it is irrelevant that it was then valueless for the purposes in mind. Were that enough to prevent anticipation, it would be possible to patent a new use for an unchanged process, which is never true.”<sup>154</sup>

The claimed invention in *Regar* was a *method* for producing a scalloped edge on a seamless stocking. The prior art stockings “were turned over at the top so as to form a hem, and the edge so made was a definitely scalloped line, caused by the distortion of the solid knit ribs by the ‘tuck’ stitches in the open-work ribs.”<sup>155</sup> The patentee argued that the scalloped effect “was not intended” in the prior art stockings, and thus that the patented process was not anticipated.<sup>156</sup>

Judge Hand disagreed. The method claim was anticipated by the prior manufacture of a stocking having the same scalloped edge effect, even though the effect was “not intended” in the prior art stocking.<sup>157</sup> Importantly, the prior art process was not an “accidental use” in the sense of *Tilghman*.<sup>158</sup> In order to anticipate a claimed process, a prior art process “must give some assurance that the result can be reached another time, and of this there can be none unless the [prior art] process is deliberate and the means understood.”<sup>159</sup> In the case at bar, “the result [wa]s a necessary

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152. *H.K. Regar & Sons v. Scott & Williams*, 63 F.2d 229, 231 (2d Cir. 1933) (Hand, J.).

153. *Tilghman v. Proctor*, 102 U.S. 707, 711–12 (1881). We discussed *Tilghman* in Part II.A, *supra* text accompanying notes 52–64.

154. *H.K. Regar*, 63 F.2d at 231 (citing *Ansonia Brass & Copper Co.*, 144 U.S. at 18–19; *Roberts v. Ryer*, 91 U.S. 150, 159 (1875); and five regional circuit cases). In the cited *Roberts* case, the Supreme Court held that the inventor of a machine is entitled to *all* uses to which it can be put, whether he conceived of the idea of the use or not. *Roberts*, 91 U.S. at 157. If we apply this broad entitlement notion not just to an inventor who obtained a patent, but also to a prior artisan, then the prior artisan would likewise get the patent-defeating benefit of all utilities springing from her prior art device or process, even those utilities that the prior artisan did not contemplate or conceive. This result provides further ammunition against any contemporaneous recognition requirement for inherent anticipation.

155. *H.K. Regar*, 63 F.2d at 230.

156. *Id.* at 231.

157. *Id.* at 230–31.

158. *See id.* at 231 (“It is quite true that an accidental use will not anticipate a process, if the earlier practiser was not aware of what he was doing, or how he did it.”).

159. *Id.*

consequence of what was deliberately intended.”<sup>160</sup> The claimed process, if the claims were broadly interpreted, was anticipated because it “had been deliberately practised before.”<sup>161</sup> Even if the scalloped edge had “theretofore been thought useless,” but thereafter “women came to prize” the scalloped edge, “it was not possible to monopolize it by claiming as an invention the discovery that they prized it.”<sup>162</sup>

Although Judge Hand in *Regar* does not directly refer to the enablement of the prior art process, he does observe that “[t]here can be no question of the adequacy of the evidence.”<sup>163</sup> The accused infringers produced the actual prior art stockings, as well as the testimony of those who made them, which testimony “there [wa]s no reason to challenge.”<sup>164</sup> The case at bar was “not one where we must rely upon the recollection of events long past.”<sup>165</sup>

Although recently questioned by the Federal Circuit,<sup>166</sup> the maxim that “that which anticipates if earlier in time infringes if later in time” is venerable in patent law.<sup>167</sup> Direct liability for patent infringement does not require that the accused infringer realized its act of making, using, selling, offering to sell, or importing violates another’s patent, or even that such patent exists.<sup>168</sup> Likewise, anticipation by a theory of inherency should not require that the prior art worker realized or appreciated that its activity produced the thing that is the later-claimed invention. To modify the statement of Lord Hoffman to fit U.S. law, “[a]cts done secretly or without knowledge of the relevant facts, which

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. *See Zenith Elec. Corp. v. PDI Comm’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008) (stating that “anticipation cannot be proved by merely establishing that one ‘practices the prior art,’” and even that “mere proof that the prior art is identical, in all material respects, to an allegedly infringing product cannot constitute clear and convincing evidence of invalidity. Anticipation requires a showing that each element of the claim at issue, properly construed, is found in a single prior art reference.”).

167. *See generally* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.02[1][f] (2008) (subsection titled “Symmetry Between Anticipation and Infringement: ‘That Which Infringes If Later, Anticipates If Earlier’”). This maxim is more precise if modified such that “infringes” refers to literal infringement and excludes infringement under the doctrine of equivalents.

168. *See* 35 U.S.C. § 271(a) (2000) (enumerating acts of direct infringement). In contrast, establishing indirect liability for inducing or contributory infringement requires a showing of intent on the part of the accused infringer. *See* 35 U.S.C. §§ 271(b)–(c) (2000) (conferring liability upon parties who “actively induce” or “knowing[ly]” contribute to infringement).

would amount to infringements after the grant of the patent,” *should* “count as anticipations before.”<sup>169</sup>

We join in the view that inherent anticipation need not require contemporaneous recognition of the later-claimed invention or limitation thereof, but we recognize definite limits to the notion. Some commentators assert that requiring contemporaneous recognition or knowledge by the ordinarily skilled person of a missing feature would conflate the inherent anticipation doctrine to garden variety, explicit anticipation. For example, Professors Burk & Lemley contend:

[O]n reflection, application of a knowledge standard in inherency cases makes little sense. Inherency by definition concerns things that people of ordinary skill in the art do *not* know; if the person having ordinary skill in the art (PHOSITA) would know of the presence of an element based on the prior art disclosure, there is a straightforward case of anticipation based on that disclosure and no need for the inherency doctrine.<sup>170</sup>

Our concern with this contention is that it could be read to suggest conventional, explicit anticipation permits broad reliance on PHOSITA knowledge to supplement the disclosure of the allegedly anticipatory prior art reference.

Such broad reliance is not acceptable. Exceptions to the single-reference “four corners” rule should be applied sparingly because they tend to short circuit the complex, factually sensitive standard of nonobviousness.<sup>171</sup> The “four corners” rule states that “invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.”<sup>172</sup> Recognizing anticipation by inherency

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169. Merrell Dow Pharms. Inc. v. H.N. Norton & Co., [1996] R.P.C. 76, 86 (UKHL 1995) (stating that under U.K. law, “[a]cts done secretly or without knowledge of the relevant facts, which would amount to infringements after the grant of the patent, will not count as anticipations before”).

170. Burk & Lemley, *supra* note 3, at 374 (footnote omitted).

171. For example, factors such as a prior art reference’s “teaching away” from a claimed invention and a PHOSITA’s reasonable expectation of success in combining or modifying prior art disclosures are relevant to nonobviousness but not to anticipation. See *Celeritas Tech., Ltd. v. Rockwell Int’l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (“A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference ‘teaches away’ from the invention is inapplicable to an anticipation analysis.”); *In re O’Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) (discussing “reasonable expectation of success” as part of nonobviousness analysis under 35 U.S.C. § 103).

172. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

is a limited exception to the single-reference “four corners” rule; we argue herein that inherency should be recognized only when the evidence relied on to establish it satisfies a heightened standard of enablement.<sup>173</sup> Another limited exception to the “four corners” rule is the use of extrinsic evidence to interpret what an allegedly anticipatory reference discloses.<sup>174</sup> The latter exception should not be expanded from (1) the limited use of extrinsic evidence to interpret a prior art reference to (2) an unrestricted inquiry into what a PHOSITA would have known at the effective date of the prior art reference. We reject any notion that PHOSITA knowledge is an open-ended part of the mix when the issue is anticipation (rather than nonobviousness).<sup>175</sup>

### III. PRIOR ART RELIED ON TO ESTABLISH INHERENT ANTICIPATION MUST SATISFY A HEIGHTENED ENABLEMENT STANDARD

In this Part we show that the traditional standard for enablement of prior art references, engrafted by the courts onto the language of 35 U.S.C. § 102, should be modified when applied

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173. See *infra* Part III.

174. See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (“It is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value, for a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference.”); *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 726–27 (Fed. Cir. 1984) (affirming district court’s rejection of validity challenger’s attempt to prove anticipation by “combin[ing] the teachings of the references to build an anticipation;” it was improper for validity challenger to rely on “the Hall and Nash articles for a very specific teaching, not for any light they shed on what Fischer would have meant to those skilled in the art in his day”).

175. Following the Federal Circuit’s creation in 1982, the court has repeatedly rejected earlier authority suggesting that “substantial” identity was sufficient for anticipation. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985) (holding erroneous a jury instruction that patent’s claims were anticipated if the prior art “disclose[d] substantially the same things”). “[A]nticipation is not shown by a prior art disclosure which is only ‘substantially the same’ as the claimed invention.” *Id.* (quoting jury instructions). In *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983), the Federal Circuit rejected a district court’s assertions that “anticipation may be shown by less than ‘complete anticipation’ if one of ordinary skill may in reliance on the prior art ‘complete the work required for the invention,’” and that “it is sufficient for an anticipation ‘if the general aspects are the same and the differences in minor matters is only such as would suggest itself to one of ordinary skill in the art.’” *Id.* at 1548. The district court had erred because “[t]hose statements relate to obviousness, not anticipation.” *Id.* “A prior art disclosure that ‘almost’ meets that standard may render the claim invalid under § 103; it does not ‘anticipate.’” *Id.*

to prior art relied on to establish inevitable anticipation. When that prior art is a document, such as a printed publication or patent under § 102(a), (b), or (e), the document must provide a degree of detailed teaching such that a person of ordinary skill following its instructions would *inevitably* obtain the claimed subject matter. That is, no more than *de minimis* experimentation should be required or permitted if the document is relied upon to establish inherent anticipation.

We would apply a similarly high enablement standard when the prior art relied on to establish inherent anticipation is an event, such as a prior use by others in this country before an invention date under § 102(a), a placing of the invention on sale or in public use in this country before the critical date under § 102(b), or a making of the invention by others in this country under § 102(g)(2). In these cases, any nondocumentary evidence relied on to establish inherent anticipation (e.g., testimony about the prior art device or process, or introduction into evidence of the device itself) must establish that a person of ordinary skill could have inevitably achieved the claimed invention through practice of the device or process with no more than *de minimis* experimentation.<sup>176</sup>

176. Although the case law does not explicitly address enablement of the alleged inherently anticipatory event, we believe a heightened enablement requirement is implicit in the logic of the cases. For example, the court in *Abbott Labs v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999), held that anticipation by inherency can occur through a sale before the critical date of an item possessing all claimed characteristics of the later-patented invention, even if unrecognized at the time of the sale. *See id.* “If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics.” *Id.* Applying this rule, the *Abbott* court held invalid under 35 U.S.C. § 102(b) the patentee’s claim 4, directed to Form IV terazosin hydrochloride anhydrate (one of four anhydrous crystalline forms of terazosin hydrochloride). *See id.* at 1316–17. The court explained:

Even though the parties did not know it at the time, it is undisputed that Form IV was the subject matter of at least three commercial sales in the United States before the critical date. It is also clear that the invention was “ready for patenting” because at least two foreign manufacturers had already reduced it to practice. *See Pfaff*, 525 U.S. at [57] n.2 (“A composition of matter is reduced to practice when it is completely composed.”) (citing *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928)).

*Id.* at 1318 (parallel citations omitted). The *Abbott* court’s invocation of the “ready for patenting” standard of *Pfaff v. Wells Electronics, Inc.* brings enablement into the picture, for under *Pfaff*’s logic the prior art composition must have been already reduced to practice or, at least, an enabling description of the composition must have existed. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

Similar rules operate for the sale of processes rather than products. *See Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383–84 (Fed. Cir. 1999) (“If the process that was offered for sale inherently possessed each of the claim limitations, then the process was on sale, whether or not the seller recognized that his process possessed the claimed characteristics.”). The *Scaltech* court implicitly required an enablement



The enablement requirement under 35 U.S.C. § 112 is generally less rigorous than the standard we propose for inevitable anticipation. Under § 112, ¶ 1, experimentation by the art worker who seeks to make and use a claimed invention is permitted, so long as such experimentation is not “undue.”<sup>177</sup> What is “undue” in a given case is based on a multifactor analysis.<sup>178</sup> We reject acceptance of any significant degree of experimentation and propose a more rigorous enablement standard for prior art relied on to defeat patentability under a theory of inevitable anticipation than the enablement standard required of patent-obtaining disclosures under 35 U.S.C. § 112, ¶ 1.

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standard by requiring inevitability of result from normal operation of the process. The court stated that “if the natural result flowing from the operation of the process offered for sale would necessarily result in achievement of each of the claim limitations, then claimed invention was offered for sale.” *Id.* at 1384. It remanded the case to the district court to “determine if the process offered for sale, in its normal use, inherently satisfies each claim limitation.” *Id.*

We note that recent Federal Circuit authority explicitly rejects an enablement standard for anticipatory public uses under § 102(b). See *Zenith Electronics Corp. v. PDI Communication Systems, Inc.*, observing:

Contrary to Zenith’s arguments, however, we note that the public use itself need not be enabling. See *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (“Beyond this ‘in public use or on sale’ finding, there is no requirement for an enablement-type inquiry.”). Rather, we must simply determine whether the public use related to a device that embodied the invention. See *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1583 (Fed. Cir. 1986) (“[O]ur precedent holds that the question is not whether the sale, even a third party sale, ‘discloses’ the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention.” (emphasis in original)).

*Zenith Elecs. Corp. v. PDI Comm’n Sys., Inc.*, 522 F.3d 1348, 1356 (Fed. Cir. 2008). While purporting to reject an enablement requirement for § 102(b) prior public uses, the *Zenith* court seems instead to focus on the distinct notion that the prior art user or offeree need not be aware that the claims of the challenged patent in fact read on the device she is using or being offered for purchase. *Id.* at 1356, 1358. More importantly, the *Zenith* court’s rejection of an enablement standard for § 102(b) public uses does not contemplate *inherent* anticipation cases. *Zenith* is not an inherent anticipation case. Zenith’s ‘301 patent was directed to a method of operating a hospital room television by hardwired remote control devices also including internal speakers, referred to as “pillow speakers.” *Id.* at 1352–53. Affirming the district court’s grant of summary judgment of invalidity of claim 1, the Federal Circuit credited the accused infringer’s argument that the claim was anticipated by the public use before the ‘301 patent’s critical date of a prior art RCA brand television in combination with a digital pillow speaker manufactured by Curbell Electronics. *Id.* at 1359. Testimony of the accused infringer’s expert witness Mengel, as well as a corroborating witness, was dispositive. *Id.* at 1357–59. Mengel stated in expert reports and deposition testimony that based on his own testing and review of schematics, the prior art combination device performed each of the three steps recited in method claim 1 of Zenith’s ‘301 patent. See *id.* at 1358. No issue of inherent anticipation was raised by either party. See *id.* at 1352–54.

177. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (“[E]xperimentation needed to practice the invention must not be undue experimentation.”).

178. See *id.* (listing eight factors adopted from *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (B.P.A.I. 1986)).

In the remainder of this Part we first analyze the development through case law of the requirement that anticipatory references be enabling. We then argue that the enablement standard under both §§ 112 and 102 can vary according to the nature of the claimed subject matter at issue. We then propose adjusting the enablement requirement for prior art relied upon to establish inevitable anticipation by requiring a heightened enablement standard. Lastly, we apply our standard to the Federal Circuit's controversial decision in *Schering*<sup>179</sup> and conclude that the evidence in that case did not provide the degree of enablement we would require for inevitable anticipation.

A. *The Requirement that Anticipatory References Be Enabling: In General*

The U.S. Supreme Court expressed a general requirement that a prior art document used to defeat novelty be enabling in the same manner as the disclosure of a patent application as early as *Seymour v. Osborne*.<sup>180</sup> There the Court rejected the accused infringer's argument that the patentees were not the original and first inventors of what they claimed (a method of hanging a reel so as to dispense with any reel-bearer next to the standing grain)<sup>181</sup> because the same invention had previously been described in an article published in London, England in *Mechanics' Magazine*.<sup>182</sup> Although the parties' expert witnesses disagreed, the Court sided with those experts who concluded that neither the description nor the drawings of the magazine article showed the claimed invention.<sup>183</sup>

Patented inventions cannot be superseded by the mere introduction of a foreign publication of the kind, though of prior date, unless the description and drawings contain and exhibit a substantial representation of the patented improvement, in such full, clear, and exact terms as to enable any person skilled in the art or science to which it appertains, to make, construct, and practice the invention to the same practical extent as they would be enabled to do

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179. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

180. *Seymour v. Osborne*, 78 U.S. 516, 555 (1870). *But cf.* *Cohn v. U.S. Corset Co.*, 93 U.S. 366, 370 (1876) (suggesting in dictum that an anticipating publication need only be sufficient to "enable persons skilled in the art to which the invention is related to comprehend it . . . or to make it") (emphasis added). Nevertheless it is noteworthy that *Cohn* did not cite nor purport to overrule *Seymour*. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.04[1][a][ii] (2008).

181. *Seymour*, 78 U.S. at 554.

182. *Id.*

183. *See id.*

if the information was derived from a prior patent. Mere vague and general representations will not support such a defence, as the knowledge supposed to be derived from the publication must be sufficient to *enable* those skilled in the art or science to understand the nature and operation of the invention, and to carry it into practical use. Whatever may be the particular circumstances under which the publication takes place, the account published, to be of any effect to support such a defence, must be an account of a complete and operative invention capable of being put into practical operation.<sup>184</sup>

In support of its holding in *Seymour*, the Court cited the then-leading treatise *Curtis on Patents*.<sup>185</sup> Under the heading, “What, then, constitutes a ‘description’?”, Curtis observed (in 1867, pre-*Seymour*) that “[n]o judicial construction has yet been given to this term.”<sup>186</sup> In answering the question he posed, Curtis rejected the notion that “a mere suggestion of the possibility of constructing the machine, or other thing, which may have been subsequently patented, is what the statute intends” when it refers to a novelty-destroying “description.”<sup>187</sup> Curtis instead injected an enablement requirement into the meaning of “description.” In Curtis’s view, the law should not allow one to patent an invention that the public already possessed.<sup>188</sup> Unless the description in a prior art reference met the enablement standard, it “cannot be said that a knowledge of [the invention] is in the possession of the public.”<sup>189</sup> Curtis concluded:

[T]he description [in the prior art] must be such as to give the public the means of knowledge, or, in other words, must of itself enable the public to practice the invention. It is not necessary that the invention should have been reduced to practice; but unless the description would *enable the public, without further invention*, to put the thing in practice, it cannot be said that a knowledge of that thing is in the possession of the public.<sup>190</sup>

Curtis also considered the same level of disclosure required for anticipation by the content of an earlier-granted patent to a third party (as opposed to a nonpatent publication). The earlier

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184. *Id.* at 555 (footnote omitted) (emphasis added).

185. *Id.*

186. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS § 378 (3d ed. 1867).

187. *Id.*

188. *Id.*

189. *Id.*

190. *Id.* (emphasis added).

patent would not anticipate if it contained only “a mere hint of the invention for which th[e] subsequent patent was granted.”<sup>191</sup>

Curtis relied on and quoted from English cases declaring:

[A] barren, general description, probably containing some suggestive information, or involving some speculative theory, cannot be considered as anticipating, and therefore avoiding for want of novelty, a subsequent specification or invention, which involves a practical truth productive of beneficial effects, unless you ascertain that the antecedent publication involves the same amount of practical and useful information.<sup>192</sup>

Curtis also quoted from *Hills v. Evans*,<sup>193</sup> in which the Lord Chancellor ruled:

[T]he information as to the alleged invention given by the prior publication must, for the purposes of practical utility, be equal to that given by the subsequent patent. The invention must be shown to have been before made known. Whatever, therefore, is essential to the invention must be read out of [i.e., ascertainable from] the prior publication. If specific details are necessary for the practical working and real utility of the alleged invention, they must be found substantially in the prior publication.<sup>194</sup>

Shortly after its decision in *Seymour*, the Court in *In re Cawood Patent* observed with respect to the enablement requirement for prior art:

It is said, however, if the upper horizontal bar with its die and jointed levers were taken away [from the device disclosed in a prior art English patent], a mechanic might understand how the remnant could be altered and employed as a Cawood machine [i.e., the patented invention] is employed, and for the same uses. That, however, evades the question to be answered, which is, *whether the specification was sufficient to enable a mechanic skilled in mechanical arts to construct and carry into practical use the Cawood machine; or, in other words, whether whatever is essential to the Cawood machine could be read out of the prior specification.* We think no such information was given by the English patent.<sup>195</sup>

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191. *Id.* at § 378a.

192. *Id.* (quoting Lord Chancellor Westbury before the House of Lords, and citing as the “leading English cases” on the point “*Betts v. Menzies*, 7 Law Times, N.S. 110; 4 Best v. Smith, Q.B. 996”).

193. *Hills v. Evans*, (1862) 6 L.T. 90, 93.

194. *Id.*

195. *In re Cawood Patent*, 94 U.S. 695, 703–04 (1876) (emphasis added).

In *Carnegie Steel Co. v. Cambria Iron Co.*, the Court rejected the accused infringer's argument that the process of the patent in suit was anticipated.<sup>196</sup> With respect to the allegedly anticipatory prior art patent to Deighton, the Court concluded:

It is sufficient to say of it that it fails to disclose, fully and precisely, the essential features of the process covered by the Jones patent [in suit]. . . . [A] process patent can only be anticipated by a similar process. It is not sufficient to show a piece of mechanism by which the process *might* have been performed.<sup>197</sup>

Federal Circuit decisions are similarly uniform in requiring that a prior art reference used to establish anticipation be enabling.<sup>198</sup> The allegedly anticipatory reference must not only identically describe each limitation of the claimed invention, but also must "sufficiently describe the claimed invention to have placed the public in possession of it."<sup>199</sup> "[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling."<sup>200</sup>

Unlike § 112 of the Patent Act, which specifies the requirements for applicant-generated disclosures sufficient to obtain a patent,<sup>201</sup> § 102 of the Patent Act is a patent-defeating provision that says nothing at all about enablement.<sup>202</sup> Rather, the courts have read the enablement requirement into anticipation under § 102. For example, the Court of Customs and Patent Appeals (C.C.P.A.) recognized in *In re LeGrice* that the "described in a printed publication" clause of § 102(b) is interpreted "as a result of the judicially imposed limitation that

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196. *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 421–22 (1902).

197. *Id.* (emphasis in original).

198. *See, e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001) ("To anticipate, the reference must . . . enable one of skill in the art to make and use the claimed invention."); *Chester v. Miller*, 906 F.2d 1574, 1576 n.2 (Fed. Cir. 1990) ("To be prior art under section 102(b), the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure."); *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986) ("[T]he prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.").

199. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 665 (Fed. Cir. 1986).

200. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

201. *See* 35 U.S.C. § 112, ¶ 1 (2000) (mandating that patent specifications "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 . . . to make and use the same").

202. *See* 35 U.S.C. § 102 (2000) (listing events that destroy novelty of a claimed invention or that result in a loss of right to patent it due to delay in filing patent application).

this clause requires that the description of the invention in the printed publication must be an ‘enabling’ description.”<sup>203</sup> The Federal Circuit adopted the *LeGrice* reasoning in *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, agreeing that the basis for applying the enablement requirement to anticipatory prior art is “found in the description requirement of § 102(b).”<sup>204</sup> There are indeed valid policy reasons for this requirement, but nonetheless it is a judicial addition to the statutory language.<sup>205</sup> Hence, our proposed adjustment of the enablement requirement for situations alleging inevitable anticipation is likewise proper so long as based on legitimate policy rationales.

In importing the enablement requirement into § 102, the Federal Circuit has mechanically extended the “without undue experimentation” qualifier of patent-obtaining enablement under 35 U.S.C. § 112, ¶ 1, without considering whether that qualifier should apply to prior art relied on as proof of anticipation by inherency.<sup>206</sup> For example, in response to questions raised in a petition for reconsideration of an earlier (and subsequently vacated) panel opinion in the same case,<sup>207</sup> the Federal Circuit in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research* “clarif[ied] that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention *without undue experimentation*.”<sup>208</sup> Elan’s

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

204. *Paperless Accounting*, 804 F.2d at 665.

205. Professor Holbrook has pointed out that only the enablement requirement of the first paragraph of § 112 is applied to assess the adequacy of a prior art reference’s disclosure; the written description of the invention requirement, which the courts have identified as a separate disclosure requirement from enablement, “plays no such role.” Holbrook, *supra* note 26, at 161–62. Holbrook rightly contends that the written description requirement’s “lack of a role . . . in any guise on the validity side of patent law strongly suggests that enablement is the true test of possession and that the Federal Circuit’s expansion of the written description requirement [beyond its traditional role of preventing the addition of new matter to a patent application] is unfounded.” *Id.* at 162.

206. *See, e.g., Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005) (“In order to anticipate, a prior art disclosure must also be enabling, such that one of ordinary skill in the art could practice the invention without undue experimentation.” (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342 (Fed. Cir. 2005))). *Novo Nordisk* is an inherency case, discussed in *supra* Part II.B.

207. *See Elan Pharms., Inc. v. Mayo Found.*, 304 F.3d 1221, 1229 (Fed. Cir. 2002) (reversing grant of summary judgment for lack of evidence that persons of ordinary skill in the field of the invention would know and detect the inherent formation of Elan’s patented protein fragment), *vacated*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc), *rev’d*, 346 F.3d 1051 (Fed. Cir. 2003).

208. *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1052 (Fed. Cir. 2003) (emphasis added).

patents were directed to transgenic rodents whose genetic makeup had been modified to include a Swedish mutation, “an abnormal gene that was discovered on chromosome 21 in a Swedish family that has an unusually high incidence of early-onset Alzheimer’s disease.”<sup>209</sup> The district court found the patents anticipated on the ground that the claimed Elan mouse was inherently present in the prior art Mullan patent.<sup>210</sup>

Appealing the judgment of anticipation, patentee Elan contended that “although Mullan foresaw a transgenic mouse and presented a compilation of known methods of gene transfer, the [Mullan] reference does not teach or suggest which method might succeed in creating the desired mutated mouse.”<sup>211</sup> The Federal Circuit instructed that the factfinder should apply the multifactor test of *In re Wands*,<sup>212</sup> a § 112, ¶ 1 enablement case, in order to test whether the Mullan disclosure would enable the claimed mouse without undue experimentation.<sup>213</sup> Under the *Wands* standard, the *Elan* court observed that the level of permitted experimentation may be “considerable.”<sup>214</sup> The Federal Circuit remanded to the district court for determination of “whether the Mullan reference enabled persons of ordinary skill in the field of the invention to make the desired mutated mouse without undue experimentation.”<sup>215</sup>

We reject the Federal Circuit’s application of the “without undue experimentation” qualifier for enablement of prior art relied on to prove inherent anticipation. The court’s multifactored standard for determining whether experimentation by the art worker seeking to practice the prior art would be “undue” permits too much uncertainty for the inherency context. Such

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209. *Id.* at 1053 (footnote omitted).

210. *See id.* at 1054.

211. *Id.* at 1056.

212. Those factors include:

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

*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (B.P.A.I. 1986)).

213. *Elan*, 346 F.3d at 1054–55.

214. *Id.* at 1055 (quoting *Wands*, 858 F.2d at 737). Another example of the liberal degree of experimentation permitted under § 112, ¶ 1 for enablement of patent-obtaining disclosures is *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1359–61 (Fed. Cir. 1988), which found that the patent in suit satisfied the § 112 enablement requirement despite repeated failures to duplicate actual reduction to practice in inventors’ laboratories.

215. *Elan*, 346 F.3d at 1057.

uncertainty contravenes the inevitability principle on which anticipation by inherency is based.<sup>216</sup> Hence, we propose a heightened enablement standard for prior art relied on to establish inherent anticipation, such that no more than *de minimis* experimentation by the art worker would be countenanced.

Proof that the prior art device or composition was actually reduced to practice (i.e., that it was made, constructed, or synthesized) would *not* be necessary to satisfy our heightened enablement standard. Enablement may be more suspect in such cases, however, as we show by example below.

In the context of conventional (i.e., explicit) anticipation, Federal Circuit precedent confirms that the prior art item need not have been made in order to have anticipatory effect. For example, the applicant in *In re Donohue* claimed certain chemical compounds: namely, a “2,2',6,6'-tetramethylbiphenyl-4, 4'-dicarboxylic acid compound comprising said acid, an acyl halide derivative thereof, or a simple ester thereof.”<sup>217</sup> A previously published journal article by Nomura et al. disclosed several species falling within Donohue's generically claimed compound, as well as methods of preparing those species.<sup>218</sup> In an affidavit included in Donohue's prosecution record, a co-author of the Nomura reference confirmed that the dicarboxylic acid TMBP or dimethyl ester TMBP compounds disclosed by Nomura were never synthesized.<sup>219</sup> Donohue argued that a § 102(b) rejection should be sustained only if the claimed compound was actually made by the prior art worker.<sup>220</sup> The Federal Circuit disagreed, affirming the USPTO's finding that Donohue's claims were anticipated by Nomura's disclosure:

It is well settled that prior art under 35 U.S.C. § 102([b]) must sufficiently describe the claimed invention to have placed the public in possession of it. . . . [E]ven if the claimed invention is disclosed in a printed publication, that

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216. See *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) (rejecting accused infringer's inherency challenge to '390 patent claiming products made by patentee's process of rapidly stretching polytetrafluorethylene (PTFE), and observing that in view of “the unique nature of unsintered PTFE, we are not persuaded that the ‘effect’ of the processes disclosed in [the prior art references], an ‘effect’ undisclosed in those patents, would be always to inherently produce or be seen always to produce products meeting all of the claim limitations. Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references.”).

217. *In re Donohue*, 766 F.2d 531, 532 (Fed. Cir. 1985).

218. *Id.*

219. *Id.* at 532–33.

220. *Id.* at 533.



disclosure will not suffice as prior art if it was not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.<sup>221</sup>

The same rule (that the prior art device or composition need not have been actually reduced to practice) would at least nominally apply in the inherent anticipation situation, but in such situations satisfaction of the enablement standard we propose is less likely. We use the facts of *Schering* to illustrate.<sup>222</sup> Schering obtained a patent on loratadine in 1981,<sup>223</sup> and in 1987 Schering obtained a second patent on the drug's metabolite.<sup>224</sup> The primary dispute in *Schering* was whether the disclosure of the earlier patent inherently anticipated the metabolite claims of the later patent.<sup>225</sup> Schering's earlier patent included prophetic examples.<sup>226</sup> Prophetic Example 6 of the earlier patent described "preferred" pharmaceutical formulations of loratadine, while

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221. *Id.* (citations omitted). The *Donohue* court also found anticipation of dependent claims reciting particular properties of the claimed compounds. *See id.* at 534 (addressing the solubility characteristics and melting point range of dependent claims 25 and 28). The court concluded these properties were inherently present in the disclosure of the Nomura reference. *Id.* In particular, Donohue's claim 25 recited "[t]he acid of Claim 2, said acid being soluble in ether and N-methyl-2-pyrrolidone," and his claim 28 recited "[t]he dimethyl ester of Claim 7, having a melting point of 128–129°C." *Id.* at 534 n.9. Rejecting Donohue's argument that the prior art references did not explicitly teach the claimed solubility characteristics and melting point range, the Federal Circuit held that "where, as here, the dicarboxylic acid TMBP and dimethyl ester TMBP of Nomura are identical to the claimed invention, the properties of Nomura's compounds are inherently the same as those of the claimed invention in the absence of proof to the contrary." *Id.* at 534 (citing *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977)).

Rather than speculating about inherent properties of the prior art compounds (which had never been synthesized), the Federal Circuit should have resolved the patentability of dependent claims 25 and 28 in *Donohue* on another ground: that the recitation of a newly discovered property in a claim to a known chemical compound does not impart novelty to the compound claim. The compound already exists in the prior art, and its inherent properties need not be considered in order to conclude that a claim to the compound itself is anticipated. *See Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) ("[I]t is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties."). A method claim reciting the newly-discovered use, however, is another matter.

222. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). We discuss *Schering* in greater detail in *infra* Part III.D.

223. *Schering*, 339 F.3d at 1375–76. Loratadine is the active ingredient in the antihistamine sold under the brand name Claritin. *Id.* at 1375.

224. *Id.* A metabolite is "the compound formed in the patient's body upon ingestion of a pharmaceutical." *Id.*

225. *See id.* at 1376 (discussing Schering's decision to appeal the district court's finding that its '233 patent inherently anticipated claims 1 and 3 of the '716 patent).

226. *Id.* Prophetic examples are "set forth in the present tense to indicate that they were not carried out." *Id.* at 1376 n.1.

prophetic Example 7 did not.<sup>227</sup> Had prophetic and nonpreferred Example 7 actually been carried out by a prior art worker, it is unlikely that Example 7 would have *inevitably* resulted in production of the metabolite compound Schering subsequently claimed in its later patent. More than *de minimis* experimentation would have been required of the art worker who hypothetically carried out nonpreferred Example 7, in violation of the heightened enablement standard we propose. It is unduly speculative to conclude that practice of nonpreferred Example 7 would have inevitably produced the claimed metabolite. The inevitability standard for anticipation by inherency forbids that level of uncertainty.

*B. Recognized Variability of the Enablement Standard in both the § 102 and § 112 Contexts*

Variation or fine tuning of the enablement requirement for instances of patent-defeating inevitable anticipation is appropriate, just as the courts have sometimes varied the degree of enablement required of patentees and patent applicants seeking to *obtain* patents in accordance with the disclosure requirements of § 112, ¶ 1. For example, the patent in suit in *Genentech, Inc. v. Novo Nordisk, A/S* claimed a method of producing hGH using cleavable fusion expression.<sup>228</sup> Genentech filed its patent application in 1979.<sup>229</sup> The Federal Circuit held the patent's disclosure insufficient to satisfy the enablement requirement of § 112, ¶ 1 because it did not provide a "specific and useful teaching" of the patentee's "application of an unpredictable technology in the early stages of development."<sup>230</sup> Reliance on the knowledge of those skilled in the art could not make up for the lack of explicit enabling disclosure in the application.<sup>231</sup> The court instructed:

[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure

227. See U.S. Patent No. 4,282,233 col.4 ll.58–59 (filed June 19, 1980) (issued Aug. 4, 1981) ("Preferred formulations are more fully illustrated in Example 6.").

228. *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1363 (Fed. Cir. 1997).

229. *Id.* at 1364.

230. *Id.* at 1367–68.

231. See *id.* at 1366 ("While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.").

related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.<sup>232</sup>

The Federal Circuit again applied a heightened enablement standard in *Chiron Corp. v. Genentech, Inc.*<sup>233</sup> The *Chiron* court characterized the claimed genetically engineered chimeric antibodies as “nascent technology” in the pertinent 1985 and 1986 time period, existing somewhere on a development continuum between that which was well known (such as murine antibodies) and that which was considered after-arising technology (such as humanized antibodies).<sup>234</sup> For nascent technology, the court reaffirmed, an enabling disclosure must provide a “specific and useful teaching.”<sup>235</sup> This heightened level of disclosure is necessary for nascent technology because “a person of ordinary skill in the art has little or no knowledge independent from the patentee’s instruction.”<sup>236</sup>

Although *Genentech* and *Chiron* were biotechnology cases, the Federal Circuit also applies a similarly rigorous enablement standard in certain electromechanical cases. In *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, the Federal Circuit affirmed a district court’s invalidation of a patent directed to side impact sensors for automotive airbags because its disclosure failed to satisfy the enablement requirement of § 112, ¶ 1.<sup>237</sup> The court emphasized that the sensors of the invention were its “novel aspect” and considered a “breakthrough.”<sup>238</sup> The patent’s claims were broadly construed (at the patentee’s behest) to cover side impact sensing with both

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232. *Id.*

233. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004). The asserted claims of the *Chiron* patent in suit were directed to monoclonal antibodies that bind to human c-erbB-2 antigen (HER2) associated with breast cancer cells. *Id.* at 1250. The suit brought by *Chiron* against *Genentech* was based on infringement by *Genentech* as to its sales of *Herceptin*, a humanized antibody used for long-term treatment of breast cancer. *Id.* at 1252. A district court broadly interpreted *Chiron*’s claims as encompassing not only monoclonal antibodies made using traditional hybridoma (murine) technology, but also as including those antibodies made using modern genetic engineering techniques. *Id.* The latter type of antibodies included “chimeric” antibodies that combine DNA encoding regions from more than one type of species, and “humanized” antibodies that comprise DNA encoding regions primarily from humans (i.e., the type of antibodies used in *Genentech*’s accused product). *Id.* at 1250.

234. *Id.* at 1256–57.

235. *Id.* at 1254 (citing *Genentech*, 108 F.3d at 1368).

236. *Id.*

237. *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282 (Fed. Cir. 2007).

238. *Id.* at 1283.

mechanical and electrical sensors.<sup>239</sup> With respect to the electrical sensor embodiment of the invention, the Federal Circuit concluded that the patent's disclosure taught nothing more than a "concept."<sup>240</sup> The court agreed with the validity challenger that the patentee "could not rely on the knowledge of one of ordinary skill in the art to supply the missing details" about the invention,<sup>241</sup> which involved the then "new field" of side impact sensing.<sup>242</sup> The court emphasized that it was "especially important for the specification to discuss how an electronic sensor would operate to detect side impacts and to provide details of its construction."<sup>243</sup> Relying on *Genentech*, the Federal Circuit concluded that "[a]lthough the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent."<sup>244</sup>

The justifications for a heightened enablement standard that the Federal Circuit has articulated in the *Genentech*, *Chiron*, and *Automotive Technologies* decisions apply with equal (or perhaps even greater) force in the context of inevitable anticipation, where the prior art reference is by definition silent as to the claimed subject matter that is allegedly present through inherency. In such cases, as in the "nascent" or "breakthrough" technologies of *Genentech*, *Chiron*, and *Automotive Technologies*, it is entirely appropriate to require a heightened level of enabling disclosure. Reliance on the knowledge of one skilled in the art should be minimal, if permitted at all. In order to establish anticipation by inherency, it must be shown that one of ordinary skill in the art, by following the examples, illustrations, or other guidance given by the prior art, would inevitably have produced or created the claimed invention (despite not recognizing it at the time).

### C. Adjusting the Enablement Requirement for Inherency

In the patent-obtaining context, the first paragraph of 35 U.S.C. § 112 requires that the patent applicant provide an enabling disclosure of how to make and use the invention she is

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239. *Id.* at 1282.

240. *Id.* at 1283.

241. *Id.* at 1281–82.

242. *Id.* at 1284.

243. *Id.*

244. *Id.* at 1283. The court observed that, "As was the case in *Genentech*, the specification provides 'only a starting point, a direction for further research' on using electronic sensors for sensing side impact crashes; it does not provide guidance to a person of ordinary skill in the art on how to make or use an electronic side impact sensor." *Id.* at 1284 (quoting *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

claiming.<sup>245</sup> Case law has interpreted this statutory requirement as allowing experimentation by an art worker who seeks to replicate the invention, so long as the degree of experimentation is not “undue.”<sup>246</sup> The Federal Circuit has recognized that the phrase “without undue experimentation” is nonstatutory gloss added by the courts to the literal language of § 112, ¶ 1.<sup>247</sup> In determining whether experimentation would be “undue” in a particular case, the Federal Circuit applies a multifactored totality of the circumstances approach. In its foundational decision in this area, *In re Wands*, the court (adopting the analysis used by the USPTO Board in *Forman*) declared that an “undue experimentation” analysis should include the following factors: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.<sup>248</sup>

This traditional allowance in the § 112, ¶ 1 context for what may amount to a fairly extensive amount of experimentation<sup>249</sup> should not be countenanced in cases where a patent challenger seeks to *defeat* patentability under a theory of inevitable anticipation. In such cases, we argue that the level of enablement provided by the prior art through examples, instructions, or other guidance must be such that if followed, the prior artisan would inevitably achieve the claimed invention with at most *de minimis* experimentation. Such experimentation would be limited to trivial choices and would not permit the conventional trial-and-

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245. See 35 U.S.C. § 112, ¶ 1 (2000) (“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.”).

246. See, e.g., *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (“[E]xperimentation needed to practice the invention must not be undue experimentation.”).

247. *Id.* at 737.

248. *Id.* (citing *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (B.P.A.I. 1986)). The *Wands* analysis for “undue experimentation” is routinely applied in genus–species cases, where the applicant or patentee has disclosed one or more specific examples of her invention but claims the invention much more broadly. See, e.g., *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212–14 (Fed. Cir. 1991) (affirming a district court’s invalidation of generic DNA sequence claims as nonenabled under § 112, ¶ 1).

249. See *Wands*, 858 F.2d at 737 (“The [undue experimentation] test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . .”).

error testing expected of those who want to replicate a patented invention by following the patentee's teachings.

For example, consider a hypothetical patent claim to "a composition of matter comprising ingredient X." Assume also that a prior art printed publication disclosed a pharmaceutical composition comprising active ingredient Y along with conventional fillers, and gave examples of three different ways to prepare ingredient Y. Following each of these examples would result in the production of three slightly different forms of ingredient Y (i.e., alpha-Y, beta-Y, and gamma-Y). As of the effective date of the prior art publication, it was not known or recognized that human ingestion of the beta-Y form inevitably produced compound X. Nor was it known or recognized on that date that human ingestion of the alpha-Y form or the gamma-Y form would usually *not* produce compound X. This hypothetical prior art publication would *not* satisfy the heightened enablement standard we propose because it provides no suggestion or guidance to the art worker to choose the beta-Y form over the other two forms. If the prior art worker had been required to practice all three forms of Y in order to obtain (without knowing) compound X, this would constitute more than *de minimis* experimentation. An even more extreme failure of enablement under our standard would be if the prior art publication had designated the alpha-Y form as "preferred," thus leading the prior art worker even farther from the beta-Y form.

In contrast, our hypothetical prior art publication would meet our proposed enablement standard if it disclosed *only* the method of making the beta-Y form and did not include the distractor teachings of how to make the alpha-Y and gamma-Y forms.

In the case of the publication disclosing only how to make the beta-Y form, we would still permit minor, *de minimis*, or trivial variations. For example, suppose the prior art publication disclosed a range of reaction temperatures at which the beta-Y form could be synthesized. So long as any temperature within the range would produce the beta-Y form, which in turn inevitably produced compound X upon ingestion by a human, the prior artisan's choice or selection from among the range of disclosed temperatures for making the beta-Y form would be permitted as *de minimis* experimentation under our heightened enablement standard.

Probably the most difficult variation on the above hypothetical would ask whether our proposed heightened enablement standard would be satisfied if the printed publication disclosed methods of making all three forms of ingredient Y (i.e.,

alpha-Y, beta-Y, and gamma-Y) but additionally denominated the beta-Y form (which is later discovered to inevitably produce compound X) as the “preferred” form of ingredient Y. Here the question becomes whether a PHOSITA’s understanding of what the publication taught, in combination with the entirety of the publication’s explicit teaching, would have led the PHOSITA to always choose to make the beta-Y form instead of the alpha-Y or gamma-Y forms. The factfinder must identify the reason *why* the beta-Y form was denominated as preferred. If production of the beta-Y form was called out as the best mode for reasons having nothing to do with the then-undiscovered compound X, or if the PHOSITA would consider the beta-Y form as the preferred form for a similarly unrelated-to-X reason, our heightened enablement standard would not be satisfied. For example, we would not find inherent anticipation if the beta-Y form was preferred because it worked best at treating disease Z, having nothing to do with then-undiscovered compound X. On the other hand, if the beta-Y form was preferred because it was cheaper to make than the alpha-Y or gamma-Y forms, this would more likely have led the art worker to always choose to make the beta-Y form.

*D. Applying Our Heightened Enablement Standard to Schering v. Geneva*

In this Subpart we apply our heightened enablement standard to the facts of *Schering*.<sup>250</sup> For the reasons explained below, we disagree with the Federal Circuit’s finding of inherent anticipation in *Schering*. We view *Schering* as another instance of the Federal Circuit contorting the inherency doctrine to combat a patentee’s attempted evergreening.<sup>251</sup>

In 1981, Schering Corporation (“Schering”) obtained U.S. Patent No. 4,282,233 (‘233 patent) on the antihistamine

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250. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

251. The *Schering* panel opinion does not explicitly admit to concern about evergreening, but another member of the Federal Circuit alludes to the issue. *See Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 996 (Fed. Cir. 2003) (Lourie, J., dissenting from denial of petition for rehearing en banc) (“It may be asked why, if a developer of a new product has a patent on that product, does it also need a patent on its metabolite.”). The *Schering* panel may also have considered that Schering had previously obtained two extensions of the basic Claritin patent, adding up to an extra two-and-a-half years of patent protection. Pursuant to 35 U.S.C. § 156 (which concerns patent term extensions due to delay in FDA marketing approval), Schering received a two-year extension of the term of the ‘233 patent, from June 19, 2000 to June 19, 2002. *See* U.S. Patent and Trademark Office, “Patent Terms Extended Under 35 U.S.C. § 156” (table), <http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html> (last visited Nov. 13, 2008). Schering thereafter obtained an additional six-month extension. *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 535 (D.N.J. 2002).

loratadine, the active ingredient in Schering's extremely successful pharmaceutical product Claritin.<sup>252</sup> Schering obtained a separate patent in 1987, U.S. Patent No. 4,659,716 ('716 patent), which claimed descarboethoxyloratadine (DCL), a metabolite of loratadine.<sup>253</sup> A metabolite is the compound that forms inside a patient's body when she ingests a pharmaceutical; the pharmaceutical is chemically converted to the new metabolite compound.<sup>254</sup> Schering identified the metabolite DCL while carrying out the laboratory animal experiments and human clinical trials required to gain regulatory approval to market loratadine.<sup>255</sup> Importantly, the earlier '233 patent was completely silent about any metabolites of loratadine.<sup>256</sup>

A group of Abbreviated New Drug Application (ANDA) filers including the generic manufacturer Geneva Pharmaceuticals, Inc. ("Geneva") asserted that the disclosure of Schering's earlier '233 patent on loratadine rendered the metabolite claims of the later '716 patent invalid as anticipated under § 102(b) by a theory of inherency.<sup>257</sup> The district court, in agreement with both parties, construed the metabolite claims as encompassing "DCL in all its forms, including 'metabolized within the human body' and 'synthetically produced in a purified and isolated form.'"<sup>258</sup> Although the prior art '233 patent did not explicitly disclose any metabolites of loratadine, the district court found that the metabolite DCL "was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent."<sup>259</sup> The district court relied primarily on evidence of tests conducted by

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252. *Schering*, 339 F.3d at 1375–76. The '233 patent is titled "Antihistaminic 11-(4-Piperidylidene)-5H-benzo-[5,6]-cyclohepta-[1,2-b]-pyridines." U.S. Patent No. 4,282,233 (filed June 19, 1980) (issued Aug. 4, 1981).

253. *Schering*, 339 F.3d at 1375. The '716 patent is titled "Antihistaminic 8-(halo)-substituted-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridines." U.S. Patent No. 4,659,716 (filed Mar. 12, 1986, as a continuation-in-part of Application Serial No. 580,304, filed Feb. 15, 1984) (issued Apr. 21, 1987).

254. *Schering*, 339 F.3d at 1375.

255. *Schering*, 275 F. Supp. 2d at 536.

256. *See Schering*, 339 F.3d at 1376 ("The '233 patent does not expressly disclose DCL and does not refer to metabolites of loratadine."); *see also* U.S. Patent No. 4,282,233 (filed June 19, 1980) (failing to mention any metabolites).

257. *Schering*, 275 F. Supp. 2d at 540. As a matter of timing, the earlier '233 patent qualifies as prior art against the later '716 patent because the former was granted (and hence published) in 1981, more than one year before the latter patent's application was filed. *See* 35 U.S.C. § 102(b) (2000) (providing that a person shall not be entitled to a patent if "the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States").

258. *Schering*, 339 F.3d at 1376.

259. *Id.*



both Schering and Geneva in which loratadine was administered to a total of 1,008 human patients; a measurable amount of the metabolite DCL was detected in each of the 1,008 patients.<sup>260</sup> The district court granted Geneva's motion for summary judgment of invalidity of claims 1 and 3 of the '716 metabolite patent, and Schering appealed.<sup>261</sup>

The Federal Circuit affirmed the district court's judgment of anticipation, emphasizing the inevitability of the asserted anticipation.<sup>262</sup> According to the appellate court, the record showed "that DCL necessarily and inevitably forms from loratadine under *normal* conditions," and that "DCL is a necessary consequence of administering loratadine to patients."<sup>263</sup> The Federal Circuit's "normal conditions" phrasing suggests that under "nonnormal" conditions, DCL might not have formed, rendering the court's inevitability finding suspect. Nevertheless, the Federal Circuit concluded that DCL formation was the "inherent result of administering loratadine to a patient," and that "[t]he '233 patent discloses administering loratadine to a patient."<sup>264</sup>

The Federal Circuit did not consider it relevant whether patients had actually ingested loratadine before the § 102(b) critical date of the '716 metabolite patent.<sup>265</sup> If one views *Schering* as an "anticipation by disclosure" case rather than an "anticipation by use" case,<sup>266</sup> then the Federal Circuit was correct as a legal matter when it asserted that "actual administration of [the prior art compound] loratadine . . . before the critical date of

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260. *Schering*, 275 F. Supp. 2d at 537. Neither the district court's nor the Federal Circuit's opinions in *Schering* make clear exactly when these tests were conducted. The district court states Schering's own tests detecting the metabolite DCL following administration of loratadine were conducted "prior to May 1, 1987," but does not specify when the tests began. *Id.*

261. *Schering*, 339 F.3d at 1376.

262. *Id.* at 1374.

263. *Id.* at 1378 (emphasis added).

264. *Id.* at 1381.

265. *Id.* at 1380. The application leading to the '716 patent was filed as a continuation-in-part of Application Serial No. 580,304 ('304 patent application), which itself was filed February 15, 1984 and later abandoned. U.S. Patent No. 4,659,716 (filed Mar. 12, 1986). Depending upon whether the subject matter claimed in the '716 patent was adequately supported under 35 U.S.C. § 112, ¶ 1 by the disclosure in the '304 parent application, the § 102(b) critical date for the '716 patent is either February 15, 1983 or March 12, 1985.

266. See *Merrell Dow Pharms. Inc. v H.N. Norton & Co.*, [1996] R.P.C. 76, 84 (UKHL 1995) (separating arguments of anticipation into inventions that had been used before the priority date and inventions that had been disclosed before the priority date). We summarized Lord Hoffman's analysis in *Merrell Dow* of "anticipation by use" versus "anticipation by disclosure" *supra* Part II.C.

the ‘716 [metabolite] patent is irrelevant.”<sup>267</sup> The Federal Circuit most likely treated *Schering* as an “anticipation by disclosure” case because the appeal was brought from a grant of summary judgment of invalidity.<sup>268</sup> The Federal Circuit was able to affirm the district court’s judgment by focusing on the disclosure provided by the ‘233 patent itself, rather than relying primarily on the extrinsic evidence consisting of later-conducted test results (as did the district court).<sup>269</sup>

The appellate court framed the issue before it as whether the prior art ‘233 patent “disclose[d] in an enabling manner the administration of loratadine to patients.”<sup>270</sup> It concluded that the enablement standard was satisfied because a “person of ordinary skill in the art could practice the ‘233 patent without undue experimentation.”<sup>271</sup> For the reasons detailed above, we disagree with the *Schering* court’s use of the nonstatutory “undue experimentation” qualifier for enablement of the prior art in inherency cases.<sup>272</sup> Given the uncertainty in the guidance, teaching, and examples provided by the ‘233 patent, more than *de minimis* experimentation would have been required to inevitably produce the metabolite claimed in the later ‘716 patent. Thus, *Schering* does not satisfy our proposed enablement standard. The *Schering* court extended inherency principles too far by extrapolating from its view that “[a] person of ordinary skill in the art could practice the ‘233 patent without undue experimentation” to the conclusion that “[t]he inherent result of administering loratadine to a patient is the formation of [the metabolite] DCL.”<sup>273</sup>

Several aspects of the *Schering* decision compel our conclusion that the prior art ‘233 patent lacked adequate disclosure to inevitably anticipate the metabolite invention of the ‘716 patent. First, the ‘233 patent describes administration of loratadine only in *prophetic* examples. The ‘233 patent discloses in the present tense that “[t]he compounds of the present invention are administered in pharmaceutical formulations comprising the compound in admixture with a pharmaceutical carrier suitable for enteral or parenteral administration.”<sup>274</sup> The

267. *Schering*, 339 F.3d at 1380.

268. *See id.* at 1376.

269. *Id.* at 1380.

270. *Id.*

271. *Id.* at 1381.

272. *See supra* Part III.C (titled “Adjusting the Enablement Requirement for Inherency”).

273. *Schering*, 339 F.3d at 1381.

274. U.S. Patent No. 4,282,233 col.4 ll.47–50 (filed June 19, 1980).

patent describes pharmaceutical formulations in two different examples. Example 6 of the '233 patent discloses "[p]referred formulations"<sup>275</sup> in the form of a "syrup comprising a compound of the present invention (Active Compound) . . . prepared from" a list of ingredients including the Active Compound, sucrose, propylene glycol, flavorings, and dyes.<sup>276</sup> Example 7 of the '233 patent, apparently *not* preferred, discloses preparation of a tablet made from the Active Ingredient and additional ingredients.<sup>277</sup> Because both of these examples are written in the present tense, they signify that "they were not carried out."<sup>278</sup> In other words, pharmaceutical compositions comprising loratadine had not even been prepared, let alone ingested by any patients whose internal organs might have converted loratadine to its DCL metabolite, as of the 1980 filing date of the application leading to the '233 patent. This fact alone raises a red flag about whether the '233 patent qualifies as prior art sufficient to inherently anticipate the '716 patent's metabolite claims.

Second, in a dissent from denial of rehearing en banc in *Schering*, Federal Circuit Judge Lourie criticizes the panel's decision as "hold[ing] that an enabling disclosure of 'how to make' metabolites is provided by the mere recitation that one can administer a prior art compound to humans."<sup>279</sup> Judge Lourie admits that if the '233 patent "really taught how to make metabolites, it might be another story."<sup>280</sup> In Judge Lourie's view, however, the "minimal, boilerplate" disclosure of the '233 patent "is hardly an enabling disclosure of how to make any metabolites, whatever they might turn out to be, sufficient to anticipate them by inherency."<sup>281</sup> Judge Lourie admits that the '233 patent's disclosure provides a boilerplate statement of "how to use" the claimed products, "sufficient to satisfy the requirements of 35 U.S.C. § 112."<sup>282</sup> But that disclosure was "far from the careful and thorough prescribing information required by the FDA."<sup>283</sup> While we do not contend that the enablement requirement for prior art requires a showing of compliance with Food and Drug

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275. '233 Patent col.4 ll.58–59.

276. '233 Patent col.5 ll.3–20.

277. '233 Patent col.5 ll.22–42.

278. See *Schering*, 339 F.3d at 1376 n.1 (citing *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1578 (Fed. Cir. 1984)).

279. *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 996 (Fed. Cir. 2003) (Lourie, J., dissenting).

280. *Id.*

281. *Id.*

282. *Id.*

283. *Id.*

Administration prescribing standards (as Judge Lourie's opinion seems to suggest), we nevertheless conclude that the facts of *Schering* demonstrate more than enough uncertainty to seriously question the Federal Circuit's finding of anticipation by inherency.

Third, the Federal Circuit's opinion admits that the record "contain[s] expert testimony, including a proposed metabolic scheme and animal data, that questions whether ingestion of loratadine always forms [the metabolite] DCL."<sup>284</sup> But the appellate court downplayed this evidentiary uncertainty by deeming it insufficient to create a genuine fact issue precluding summary judgment.<sup>285</sup> According to the Federal Circuit, no data on humans suggested a genuine issue about the formation of the metabolite DCL following ingestion of loratadine.<sup>286</sup> The '716 patent's claims are not limited to a product ingested by humans, however.<sup>287</sup> The record in *Schering* reveals substantial uncertainty in the formation of the claimed DCL metabolite depending on whether loratadine was administered to laboratory animals or human patients (both groups falling within the scope of the challenged claims).<sup>288</sup> In fact, Schering testified before the district court that "its studies on animals have allowed it to develop its current proposed *non*-DCL mediated pathway for the metabolism of loratadine in humans."<sup>289</sup>

Professors Burk & Lemley believe a requirement of evidentiary certainty for anticipation by inherency "overstate[s] the rule."<sup>290</sup> Burk & Lemley assert, "The right question is whether we are confident that the patented invention was present in the prior art, even if it was not always present."<sup>291</sup> We

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284. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003).

285. *See id.* at 1381–82 (explaining that even though the record included expert testimony questioning whether ingesting loratadine always leads to the body creating DCL, the court found the evidence that it does so overwhelming that no reasonable jury could find otherwise).

286. *Id.* at 1382 (noting even Schering's expert "testified that no human has been found that does not metabolize loratadine to DCL, and that '[t]here is no scientific data in the published literature that says that DCL is not formed from loratadine in humans'").

287. Claim 1 of the '716 patent does not limit its scope to any particular class of patients. *See* U.S. Patent No. 4,659,716 col.25 ll.48–64 (filed Mar. 12, 1986) (claiming compound or pharmaceutically acceptable salt thereof); *see also* *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 535 n.1 (D.N.J. 2002) ("Plaintiff argues strenuously that humans are not the *only* intended recipients of the '233 compounds.>").

288. *Schering*, 275 F. Supp. 2d at 535–38 (explaining that the parties dispute whether all humans produce DCL as a result of taking loratadine, as the parties claim differing results from animals and humans).

289. *Id.* at 537–38 (emphasis added).

290. Burk & Lemley, *supra* note 3, at 388 n.104.

291. *Id.* Burk & Lemley do recognize that "if the evidence does not *prove* that the

disagree.<sup>292</sup> Our enablement standard for anticipation by inherency requires proof of inevitability of result. If the evidence suggests (as it did in *Schering*) that the patented invention “was not always present” in the prior art, then it does not meet our proposed heightened enablement standard. The disclosure of the prior art ‘233 patent in *Schering* simply does not provide sufficient certainty to *inevitably* guide one of ordinary skill in the art to make the later-claimed metabolite. The ‘233 patent’s limited disclosure fails to satisfy the heightened enablement standard that we believe the courts should apply in inherency cases.

Rather than holding Schering’s ‘716 patent invalid as anticipated under a strained application of inherency principles, the Federal Circuit (and the district court) in *Schering* might have reached the same result (i.e., invalidity) by means of a more robust, factually sensitive analysis: considering whether the ‘716 metabolite claims would have been obvious under 35 U.S.C. § 103. Had that analysis been made, it would have considered whether the differences between the ‘233 patent’s disclosure of loratadine (in combination with other pertinent prior art) and the ‘716 patent’s claimed metabolites were such that a hypothetical person of ordinary skill in the art (PHOSITA) would have considered the metabolite invention obvious as of its invention date.<sup>293</sup> The presumptive invention date of the ‘716 patent is its 1984 filing date.<sup>294</sup> The U.K. *Merrell Dow* case convincingly demonstrates that several years before 1984, pharmaceutical companies knew about (and were patenting) the metabolites that form in patients’ bodies following ingestion of antihistamines.<sup>295</sup>

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invention was present at all in the prior art, there can be no inherency.” *Id.*

292. Given the evidentiary uncertainty permitted by *Burk & Lemley*, it is difficult to see how their “confidence” test would satisfy a validity challenger’s clear-and-convincing burden of proof with respect to rebutting the presumed novelty of an invention claimed in an issued patent. See 35 U.S.C. § 282 (2000) (“A patent shall be presumed valid.”). The presumption of validity is understood as encompassing all aspects of validity, including novelty.

293. See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (enumerating the factors to be considered in a nonobviousness analysis under 35 U.S.C. § 103 as “the scope and content of the prior art;” “differences between the prior art and the claims at issue;” “the level of ordinary skill in the pertinent art;” and “secondary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc.”). The Supreme Court recently reaffirmed that the *Graham* factors “continue to define the inquiry that controls” a nonobviousness analysis. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007).

294. See U.S. Patent No. 4,659,716 (filed Mar. 12, 1986 as a continuation-in-part of Application Serial No. 580,304, filed Feb. 15, 1984).

295. *Merrell Dow* had identified the chemical composition of the acid metabolite formed in patients’ livers upon ingestion of the antihistamine terfenadine and had obtained a patent claiming that metabolite by 1980. See *Merrell Dow Pharms. Inc. v. H.N. Norton & Co.*, [1996] R.P.C. 76, 80 (UKHL 1995).

Not surprisingly, by 1985 Schering and its scientists were “consistently characteriz[ing] DCL as the ‘active metabolite’ of loratadine in humans, a ‘primary metabolite’ of loratadine in humans, the ‘major active circulating metabolite’ of loratadine in humans, and a ‘known active metabolite’ of loratadine in humans, in scientific publications and SEC filings.”<sup>296</sup> The Federal Circuit in *Schering* observed that loratadine and its metabolite DCL are structurally similar; they “differ only in that loratadine has a carboethoxy group (i.e., -COOEt) on a ring nitrogen, while DCL has a hydrogen atom on that ring nitrogen.”<sup>297</sup> Loratadine and its metabolite DCL also share a similar property: both avoid patient drowsiness.<sup>298</sup> This evidence raises a legitimate challenge to the ‘716 patent’s validity on the ground of obviousness. Regrettably, both the district court and the Federal Circuit chose to bypass a factually complex obviousness analysis in favor of forcing the square peg of *Schering* into the round hole of anticipation by inherency.

#### IV. TOWARD MORE LIMITED RELIANCE ON ANTICIPATION BY INHERENCY

We contend that the doctrine of anticipation by inherency, which we have also referred to herein as “inevitable anticipation,” should be applied sparingly to defeat patentability. In this Part we explore the policy justifications for our position and respond to potential criticisms. We also consider whether changes in patent claim drafting techniques are a viable tool for addressing the conceptual difficulties of inevitable anticipation.

##### A. Policy Justifications

The paramount policy furthered by recognition of inevitable anticipation is to channel patent protection to subject matter that is truly novel and not already in the public’s possession (whether or not the public knew about it).<sup>299</sup> Recognizing inherency assures

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296. *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 538 (D.N.J. 2002) (quoting Geneva’s Opposition Facts submission).

297. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1375 (Fed. Cir. 2003).

298. *See id.*

299. *Cf. In re Schoenwald*, 964 F.2d 1122, 1123 (Fed. Cir. 1992) (“Paramount among the patentability requirements is that which is sought to be patented must be new.”); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (noting “the basic principle (to which there are minor exceptions) that no patent should be granted which withdraws from the public domain technology already available to the public” (citing *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966))). Contemporaneous recognition by the public of the inevitable result is not required for anticipation by inherency. *See supra* Part II.D.

that “[t]he public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup of the underlying scientific principles which allow them to operate.”<sup>300</sup>

On the other hand, recognition of inevitable anticipation runs counter to another policy central to the patent system, that of promoting the dissemination of new technological information.<sup>301</sup> The public does not gain such information from subject matter that the prior art inevitably produced but did not disclose or teach in any explicit way. In the words of Lord Hoffman, the anticipation is by means of an “uninformative use.”<sup>302</sup> Although the public may have gained certain benefits when an invention was inherently present in the prior art (as argued by Burk & Lemley),<sup>303</sup> this public benefit seems at best indirect or incidental. In some instances, the benefit is purely theoretical.

A related policy reason to cabin the inevitable anticipation doctrine is that its use involves a type of “secret” prior art. Such secret prior art is traditionally disfavored in U.S. patent law.<sup>304</sup> Recognition of inevitable anticipation means that the novelty of a claimed invention is destroyed because the invention already existed, even though persons of ordinary skill did not recognize its existence at the time. Finding anticipation based on a theory of inherency thus can be conceptualized as another type of reliance on “secret” or “noninforming” prior art. Among the traditional “secret” prior art categories are another’s description of the invention in an earlier-filed U.S. patent application (35 U.S.C. § 102(e)) or the earlier making of the invention by another

300. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999).

301. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (“[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure.”); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (listing as one of the purposes of the federal patent system to “promote[] disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires”).

302. *Merrell Dow Pharms. Inc. v. H.N. Norton & Co.*, [1996] R.P.C. 76, 85–86 (UKHL 1995) (arguing under the Patent Acts of 1949, Merrell Dow’s patent of metabolites would have been invalid because the metabolite had been used prior to the patent application).

303. *See Burk & Lemley*, *supra* note 3, at 374.

304. *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997) (“[T]he patent laws have not generally recognized as prior art that which is not accessible to the public.”); *Kimberly-Clark Corp.*, 745 F.2d at 1453–54 (“[T]he real meaning of ‘prior art’ in legal theory . . . is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.”); 3 R. CARL MOY, *MOY’S WALKER ON PATENTS* § 9.28 (2004) (noting some commentators’ criticism of including secret events in the concept of prior art because this effectively “hold[s] the patentee responsible for knowing things that are in fact unknowable”); *id.* (noting also the practice of most foreign patent systems to exclude contents of prior-filed, unpublished patent applications from the prior art considered in determinations of inventive step).

in this country (35 U.S.C. § 102(g)(2)). When these categories of secret prior art are relied on for conventional (i.e., explicit) anticipation, U.S. patent law requires that their teachings ultimately obtain a degree of “publicness.” For instance, a § 102(e) patent or application does not “vest” as available prior art until it is issued or published.<sup>305</sup> A § 102(g)(2) making of the invention only counts as prior art if the invention, once made, was not thereafter “abandoned, suppressed, or concealed.”<sup>306</sup> When we rely on inevitable anticipation, there is no analogous publicity requirement because the prior art is completely silent on the missing limitation of the claimed invention. This is problematic from a policy standpoint.

Admittedly, the Burk & Lemley test discussed *supra* requires some form of “publicness;” i.e., the “benefit” must be “public.”<sup>307</sup> But it is difficult to discern that benefit in cases where practice of the prior art would not inevitably result in creation of the later-claimed invention or limitation thereof. Consider, for example, our hypothetical discovery of drug D as a cure for Alzheimer’s disease. Assume further that the chemical structure of drug D was explicitly disclosed in the prior art, but buried in a nonpreferred, prophetic example listing D as one of several different chemical compositions potentially useful as solvents for dry cleaning clothes. Has the public really benefitted with respect to curing Alzheimer’s by the fact of D’s existence in the prior art?

The “public benefit” theory must be balanced against the policy goal of encouraging investment, innovation, and disclosure through the patenting process. Excessive application of anticipation by inherency tends to chill this goal. We believe that the courts have stretched inherency too far as a facile means of combating overreaching by patent owners. When validity challengers raise anticipation by inherency, courts should first consider whether other tools, such as the more factually robust analysis required for nonobviousness under 35 U.S.C. § 103, would better serve the patent system. Drawing the line between improper patentee evergreening (and similar types of

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305. See 35 U.S.C. § 102(e) (2000 & Supp. V 2006) (recognizing anticipation by description of the claimed invention in another’s earlier-filed patent application that (1) has been published; or (2) for which a patent has been granted).

306. See 35 U.S.C. § 102(g)(2) (2000) (recognizing anticipation when, before the invention date, “the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it”).

307. See Burk & Lemley, *supra* note 3, at 374 (“[T]he inherency cases are all ultimately about whether the public already gets the *benefit* of the claimed element or invention. If the public already benefits from the invention, even if they don’t know why, the invention is inherent in the prior art.”).



overreaching) versus legitimate sequential innovation is a complex task. A quick-fire application of anticipation by inherency short circuits this formidable challenge.

*B. Responses to Potential Negative Consequences of Our Approach*

Adopting the heightened enablement standard we propose means that fewer patents may be invalidated on the ground of anticipation by inherency. In some cases raising a constricted inevitable anticipation defense, patentees will—and should—succeed against accused infringers. It does not follow, however, that patentees will inevitably prevail. Rather, we argue that tools other than the inherency doctrine should be explored to confine inappropriate assertions of patent infringement liability. Our proposal to cabin anticipation by inherency suggests the following:

- 1) Before invalidating a patent for anticipation by inherency, courts should consider performing a nonobviousness analysis (assuming that the accused infringer asserted an obviousness defense). This would expand the factual basis for determining validity to consider evidence such as the patentee's reasonable expectation of success (or lack thereof) in combining or modifying the disclosures of the prior art; the level of ordinary skill in the pertinent art; the effect on a PHOSITA of any "teaching away" in the prior art; and objective evidence such as commercial success, failure of others, and the like. By applying the Supreme Court's most recent interpretation of the nonobviousness requirement in *KSR International Co. v. Teleflex Inc.*, courts can consider whether an invention would have been obvious from the perspective of a PHOSITA endowed with "common sense" who is not an "automaton."<sup>308</sup> These various factors that inform nonobviousness permit a much richer analysis of patent validity than does anticipation.
- 2) Courts should consider interpreting patent claims more narrowly in cases where the defense of inherent anticipation is raised. In such cases the claims should be assigned a literal scope no broader than that allowed by the explicit disclosures of the prior art. Although currently moribund, this notion of "validity-saving" claim

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308. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742–43 (2007) ("Rigid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under our case law nor consistent with it."); *id.* at 1742 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

interpretation should be resuscitated and expanded to contexts beyond the limited scenario contemplated in *Phillips v. AWH Corp.*<sup>309</sup> The benefit of this approach is not necessarily limited to patent owners. Even if a patentee's claims survived challenges for obviousness as well as anticipation, their relatively narrower scope would increase the defendant's chances of avoiding infringement liability. Had this approach been applied in *Schering*,<sup>310</sup> the '716 patent claims would have been limited to synthetically produced metabolites and would have excluded metabolites produced within the body upon ingestion of loratadine. Hence, the patients that ingested loratadine (Claritin) would not directly infringe by "making" the metabolite of the '716 patent's claims,<sup>311</sup> and the firms selling generic equivalents of Claritin (following expiration of the '233 loratadine patent) would not be liable for contributory infringement or inducing infringement of the '716 patent.<sup>312</sup>

- 3) Recognition of inherency should be symmetrical with respect to validity and infringement. The defense of "practicing the prior art" should encompass subject matter that the prior art inherently disclosed. Courts should permit broader use of the practicing the prior art defense, such that it applies equally in literal infringement cases as in those asserting infringement under the doctrine of equivalents. Thus we propose an expansion of the defense beyond the limits currently identified for it in *Baxter Healthcare Corp. v. Spectramed, Inc.*<sup>313</sup>
- 4) If an accused infringer had actually reduced to practice an embodiment of a claimed invention allegedly present in the prior art through inherency, and this reduction to practice occurred prior to the patentee's § 102(b) critical date, courts should allow the accused infringer to defend

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309. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327–28 (Fed. Cir. 2005) (en banc) (observing that the principle of construing claims so as to preserve their validity has not been applied broadly, and should be applied only when claim terms are still deemed ambiguous after consideration of all available tools of claim construction). We further discuss the role of claim interpretation in inherency cases in *infra* Part IV.C.

310. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).

311. *See* 35 U.S.C. § 271(a) (2000) (enumerating acts of direct infringement to include making a patented invention without authority).

312. *See* 35 U.S.C. § 271(b) (2000) (defining active inducement); 35 U.S.C. § 271(c) (2000) (defining contributory infringement).

313. *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995) (rejecting the applicability of prior art defense to allegation of literal infringement).

based on a prior user right. Currently, the U.S. prior user right is narrowly limited to practice of business methods.<sup>314</sup> The United States should adopt a broader, general purpose prior user right, as many foreign countries have already implemented.<sup>315</sup>

- 5) If an accused infringer used an embodiment of the invention allegedly present through inherency only for personal use, e.g., a patient who ingested loratadine and made its metabolite in his or her body, courts should recognize a personal use exemption to shield the individual from liability. Many countries other than the United States have already implemented a personal use exemption from patent infringement.<sup>316</sup>

A potential critique of our proposed cabining of inevitable anticipation by adjusting enablement would contend that the proposal is moot. Even if an invention is not anticipated by inherency because the pertinent prior art would not satisfy our heightened enablement standard, the invention may still be invalid for obviousness. As Lord Justice Sachs stated the point in *General Tire & Rubber Co.*:

If . . . the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness.<sup>317</sup>

Moreover, the Federal Circuit position is that a prior art reference need not be enabling when used to establish obviousness (as opposed to anticipation);<sup>318</sup> in obviousness cases a reference is considered good "for all that it teaches."<sup>319</sup>

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314. See 35 U.S.C. § 273(b)(1) (2000) (establishing defense for practice of "claims for a method"); 35 U.S.C. § 273(a)(3) (2000) (defining "method" as a "method of doing or conducting business").

315. See, e.g., German Patent Law of December 16, 1980 (amended 1998), § 12(1), available at [http://www.wipo.int/clea/en/text\\_html.jsp?lang=EN&id=1035#JD\\_DE081\\_S139](http://www.wipo.int/clea/en/text_html.jsp?lang=EN&id=1035#JD_DE081_S139) ("A patent shall have no effect against a person who, at the time of the filing of the application, had already begun to use the invention in Germany, or had made the necessary arrangements for so doing.").

316. See *id.* at § 11(1) ("The effects of a patent shall not extend to . . . acts done privately and for non-commercial purposes.").

317. *Gen. Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*, [1972] R.P.C. 457, 486.

318. See *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) ("While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103.").

319. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989).

We absolutely agree that in some cases where anticipation by inherency could be asserted, the same result (invalidity) might be reached through application of the nonobviousness requirement; *Schering* is an example.<sup>320</sup> This in no way moots our proposal to cabin anticipation by inherency, however. We are suggesting courts consider other tools for policing validity before turning to anticipation by inherency. When inherency is raised, courts should more routinely examine whether the challenged invention would have been obvious. Transparency and clarity of analysis are essential; courts must maintain a clear conceptual division between anticipation and obviousness. Although anticipation has been called the “epitome of obviousness,” Federal Circuit precedent distinguishes the two concepts.<sup>321</sup> The court has correctly rejected reliance on obviousness principles when analyzing anticipation by inherency,<sup>322</sup> and vice versa.<sup>323</sup>

320. See *supra* Part III.D (discussing evidence on which Schering’s ‘716 metabolite patent might have been held obvious). In other cases, a court may conclude that an invention challenged as inherently anticipated is neither anticipated nor obvious. Returning to the first hypothetical of this Article, one cannot realistically argue that drug D would have been obvious in view of prior art ingredients A and B or the leather tanning composition C that A and B produced in combination. As of the invention date of D, nothing in the prior art would have led a PHOSITA to make or modify A, B, or C in order to obtain drug D. Recall that C and D are not structurally similar, nor do they share a similar utility. The structural similarity between A and B and drug D only came to light due to later-developed technology used by the accused infringer of our hypothetical to analyze drug D years after its invention date.

321. See *Jones v. Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (holding that the district court’s conclusion that patentee’s “discovery of a use of an inherent quality of a product well known in the art is not patentable because of obviousness . . . confuses anticipation by inherency, i.e., lack of novelty, with obviousness, which, though anticipation is the epitome of obviousness, are separate and distinct concepts”). But see *In re Bass*, 474 F.2d 1276, 1285 (C.C.P.A. 1973) (noting “the way in which full anticipation situations under § 102 shade into obviousness rejections under § 103 because of discernable differences”).

322. See, e.g., *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295–96 (Fed. Cir. 2002) (vacating district court’s judgment that patentee’s claim 3 was inherently anticipated); *Jones*, 727 F.2d at 1529 (rejecting district court’s conclusion that patentee’s “discovery of a use of an inherent quality of a product well known in the art is not patentable because of obviousness”). In *Trintec*, claim 3 recited a method for making multiple color faces for instruments, such as watches, by using a “color photocopier.” *Trintec*, 295 F.3d at 1295. Allegedly, an anticipatory prior art reference disclosed a color printer but not a color photocopier (which requires ability both to copy and to print). *Id.* The Federal Circuit held that although the “difference between a printer and a photocopier may be minimal and obvious to those of skill in this art . . . obviousness is not inherent anticipation.” *Id.* at 1296. Moreover, anticipation by inherency is considered a factual determination, see *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997), while obviousness is a legal conclusion based on underlying facts, see *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

323. See *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (“That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown. Such a retrospective view of inherency is not a substitute for some teaching or

*C. Narrower Claiming to Avoid Inherent Anticipation*

In many of the inherent anticipation cases we have discussed, the patent owner effectively helped to invalidate its own patent by seeking a broad claim construction. Courts held patentees to the broad claim scope they requested, and thereafter found that the claims read on subject matter inherently present in the prior art. For example, more precise claim drafting might have mooted the anticipation problem encountered in *Ansonia Brass* (although the current peripheral claiming style admittedly was not yet well developed in the nineteenth century).<sup>324</sup> A narrower claim limited to a particular degree of noncombustibility might have avoided the prior art Holmes wire.<sup>325</sup> In the metabolite cases such as *Schering* and *Merrell Dow*, the claimed metabolite compounds were vulnerable to anticipation by inherency because the courts interpreted the claims broadly (at the behest of the parties) to include the metabolic product formed in a patient's body as well as synthesized forms of the metabolite.<sup>326</sup>

These cases suggest patentees should consider narrowing claim scope as a means of avoiding anticipation by inherency. The formidable claim drafting challenge here is to foresee the future and avoid prior art of which the drafter may be unaware. The drafter is unaware because the prior art device possesses a property or quality not yet discovered by anyone. The problem is particularly acute in the inherent anticipation context, where the prior art documents or usage of a prior art device typically do not signal any recognition of the feature later discovered and sought to be included in the patentee's claims (such as the incombustibility property claimed by Cowles).

Drawing the line between foreseeable and unforeseeable variations of claimed inventions is the subject of ongoing

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suggestion supporting an obviousness rejection." (citations omitted)); *In re Mills*, 916 F.2d 680, 682–83 (Fed. Cir. 1990) (reversing USPTO Board's rejection of applicant's patent claims as obvious, and distinguishing analytical approach for obviousness from that for anticipation; explaining that when the issue is anticipation (i.e., lack of novelty), an applicant's showing that "a prior art reference cited as anticipating a claimed invention . . . lack[ed] the characteristics of the claimed invention" would "negate the assertion that the claimed invention was described in the prior art," while in an obviousness inquiry like that at bar, it was "not pertinent whether the prior art device possesses the functional characteristics of the claimed invention if the reference does not describe or suggest its structure").

324. For a discussion of *Ansonia Brass*, see *supra* Part II.A.

325. See *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 17–18 (1892) ("[T]he [prior art] insulator employed by [Holmes] was in fact nearly, if not quite, as incombustible as that made by the plaintiff under the Cowles patent.").

326. We discussed *Schering* in *supra* Part III.D and *Merrell Dow* in *supra* Part II.C.

evolution in Federal Circuit case law.<sup>327</sup> In the doctrine of equivalents context, the task is to draft claims *broadly* enough to ensnare equivalents of which the drafter may be unaware at the time of amendment. The Federal Circuit has held that with respect to rebutting a presumption of prosecution history estoppel under the “unforeseeability” criterion of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, the accused equivalent must not have been *known* to persons of ordinary skill in the pertinent art at the time of claim drafting.<sup>328</sup> It is not enough that the accused equivalent was known in the art but considered to work in a “way” that was more than insubstantially different than the “way” in which the relevant claim limitation operates.<sup>329</sup>

In the context of avoiding inevitable anticipation, the task is to draft claims *narrowly* enough so that they do not read on properties that may be discovered later. If a PTO examiner rejects application claims as inherently anticipated, the patent applicant may lack the § 112, ¶ 1 support to “carve out” of her claims the particular property or variation that the examiner contends was inherently present in the prior art.<sup>330</sup>

More typically, the inherent anticipation problem does not come to light until a claim’s validity is challenged in litigation. In

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327. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1380–81 (Fed. Cir. 2007) (noting that more than insubstantially different “function/way/result” of accused equivalent is not proper test for establishing unforeseeability sufficient to rebut *Festo* presumption of prosecution history estoppel; rather, “an equivalent is foreseeable if the equivalent was generally known to those skilled in the art at the time of amendment as available in the field of the invention as defined by the pre-amendment claim scope”); see also *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007) (stating that claim language “defines the field within which foreseeability may be considered”); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) (“[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.”).

328. See *Festo Corp.*, 493 F.3d at 1378 (“[W]e have consistently held that an equivalent is foreseeable when the equivalent is known in the pertinent prior art at the time of amendment.”).

329. See *id.* at 1379–82.

330. In contrast with USPTO practice, the European Patent Office in certain circumstances allows claim-narrowing amendments by use of a “disclaimer” to exclude features that were not disclosed in the as-filed application. For example, a disclaimer can be used to restore novelty over a disclosure under EPC Art. 54(3), which would otherwise treat the content of a published, earlier-filed European patent application as novelty-destroying prior art. See EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EPO § 5.3.11 (2007) (section titled “Disclaimers not disclosed in the application as filed”), available at [http://www.epo.org/patents/law/legal-texts/html/guix/e/c\\_vi\\_5\\_3\\_11.htm](http://www.epo.org/patents/law/legal-texts/html/guix/e/c_vi_5_3_11.htm). Such a disclaimer would not violate EPC Art. 123(2), which requires that a “European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.” CONCISE EUROPEAN PATENT LAW 171 (Richard Hacon & Jochen Pagenberg eds., 2007).

such cases the patentee may need to ask the court to construe its claims narrowly so as to preserve validity. As noted above, this rule of construction is not generally favored under current law absent certain narrow exceptions.<sup>331</sup> We contend that the inevitable anticipation context should be recognized as another of the exceptions that justify a narrow, validity-saving claim interpretation.

The Federal Circuit regularly relies on inherency concepts to allow patent owners to assert infringement under the doctrine of equivalents. For example, in *Bose v. JBL*, the court held that amending an “ellipse” limitation to add “having a major diameter” was not a narrowing amendment that would trigger a presumption of prosecution history estoppel because all ellipses inherently have a major diameter.<sup>332</sup> In *Primos, Inc. v. Hunter’s Specialties, Inc.*, the court similarly held the amendment of “plate” to “plate having a length” was not a narrowing amendment “because every physical object has a length.”<sup>333</sup>

If the courts regularly allow patentees to use inherency principles to gain the benefits of the doctrine of equivalents, it would seem inconsistent to deny patentees the ability to argue for narrow claim scope in order to avoid anticipation by inherency. We do not advocate a one-sided, pro-patentee approach, however. We suggested in the previous Subpart several ways in which defendants should be permitted to counter allegations of infringement in cases where they might previously have succeeded in invalidating the claims asserted against them through a theory of anticipation by inherency.<sup>334</sup>

## V. CONCLUSION

In cases such as *Schering*, the Federal Circuit has wielded the doctrine of anticipation by inherency as a rather blunt instrument to combat perceived patent evergreening. We support cabining the doctrine in favor of more robust tools for policing patent validity, such as the nonobviousness requirement. Patent claims (or limitations thereof) should be held anticipated under principles of inherency only when the inherency is truly inevitable. Inevitability turns on the quality of the prior art’s

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331. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1327–28 (Fed. Cir. 2005) (en banc) (noting the principle that claims should be construed to preserve their validity has not been applied broadly in recent years, and should be applied only when claim terms are still deemed ambiguous after consideration of all available tools of claim construction).

332. *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359–60 (Fed. Cir. 2001).

333. *Primos, Inc. v. Hunter’s Specialties, Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006).

334. See *supra* Part IV.B.

disclosure. To establish that one practicing the prior art would inevitably have produced a claimed invention, that prior art must satisfy a heightened level of enablement. Despite the silence of the prior art as to the later-claimed invention (or limitation thereof), focus on the prior art's enablement is the key to inherency. Whatever teaching was explicitly provided by prior art, be it instructions, examples, or other guidance, such teaching must be so clear that when replicated, no more than *de minimis* experimentation would be required to obtain the claimed invention. If the art worker would have to experiment beyond this minimal degree, a finding of anticipation by inherency is not appropriate.