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# The Federal Circuit's Unbounded Conception Of Inherency In Patent Law

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# THE FEDERAL CIRCUIT'S UNBOUNDED CONCEPTION OF INHERENCY IN PATENT LAW

*Matthew Kaiser\**

*This Note examines the doctrine of inherency in patent law, which relates to the Patent Act's novelty requirement, and—theoretically—seeks to ensure that inventions that are already within the public domain are not wrenched away from the public through a later patent grant. Unfortunately, a lack of recent Supreme Court guidance and a conflict within the Federal Circuit concerning what is necessary to prove inherency have led to a confusing and unpredictable body of inherency law. This Note begins by outlining the increased concern for uniformity and predictability in patent law; it then traces the early treatment of inherent anticipation by the Supreme Court, as well as the Federal Circuit and its predecessor court. Next, it argues that the Federal Circuit's more recent inherency jurisprudence has expanded the scope of inherency, particularly with respect to patents covering pharmaceuticals, introducing dangerous and costly unpredictability into the patent system. Finally, it proposes a common-sense solution aimed at abrogating the current boundless conception of inherency in order to allow patent law and inherency to perform their central functions: to provide predictability and ensure the important patent policy of rewarding new inventions that are not already within the public domain.*

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## I. INTRODUCTION

The importance of uniform application of the law can hardly be contested in any context. Patent law is no exception. In fact, legislative history demonstrates a heightened concern for consistent, predictable application of the law in the context of patents.<sup>1</sup> Uniformity creates predictability, and predictability in turn provides inventors with the ability to prudently invest in research and development.<sup>2</sup> However, the Federal Circuit's recent decisions concerning the doctrine of inherent anticipation represent a troubling expansion of the doctrine that injects new and costly uncertainty into the patent system.<sup>3</sup>

Inherent anticipation is an admittedly difficult concept, even for the most skilled patent attorneys.<sup>4</sup> It relates to the statutory requirement that an invention be novel—that is, something undisclosed to the public.<sup>5</sup> When an invention or a written description of an invention predates the invention on which a patent application is filed, the prior invention or disclosure is deemed “prior art.”<sup>6</sup> If a prior art reference published more than one year before the

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1. Federal patent law and the Court of Appeals for the Federal Circuit were created to promote fair, uniform, and predictable application of patent law. See Edward C. Walterscheid, *To Promote the Progress of Useful Arts: American Patent Law and Administration, 1787–1836 (Part I)*, 79 J. PAT & TRADEMARK OFF. SOC'Y 61, 65 (1997) (discussing the constitutional framers' decision to create federal patent law in light of the inevitable conflict that would be created by allowing different patent laws to the promulgated by the states; Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1985) (merging the Court of Claims and Court of Customs and Patent Appeals to form the Federal Circuit). See also H.R. REP. NO. 97-312 at 20–22 (1981) (arguing in favor of creating the Federal Circuit in order to combat the effects of “pro-patent” and “anti-patent” jurisdictions); Pauline Newman, *The Federal Circuit: Judicial Stability or Judicial Activism?*, 42 AM. U. L. REV. 683, 685 (1993) (asserting Congress created the Federal Circuit to allow for “consistent application of the law . . . [which] would have a direct and salutary effect on industrial innovation, and thereby on the nation's technological strength and international competitiveness”).

2. See Newman *supra* note 1, at 685.

3. See, e.g., *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012).

4. *Id.* at 1383 (Lourie, J., dissenting) (“Inherency is a very tricky concept in patent law.”).

5. See *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342 (Fed. Cir. 2005) (“A patent claim is not valid if ‘the invention was patented or described in a printed publication in this . . . country . . . more than one year prior to the date of the application for patent in the United States.’” (citing 35 U.S.C. § 102(b) (2000))).

6. See *In re Montgomery*, 677 F.3d at 1377–78 (majority opinion) (discussing prior art references and their interaction with the underlying patent claims at issue).

effective filing date of a patent application contains all of the same claims as the later patent application, the prior art is said to “anticipate” the claims.<sup>7</sup> Anticipation negates novelty, and therefore no patent can issue on anticipated subject matter.<sup>8</sup>

For example, if a professor of pharmacology publishes a 2010 dissertation disclosing that administration of captopril, an angiotensin-converting enzyme inhibitor, to patients at risk for stroke effectively reduces the patient’s risk of stroke, that dissertation is deemed prior art with respect to any subsequent patent applications pertaining to the administration of captopril to stroke-prone patients. Accordingly, if an inventor files a patent application in 2012 claiming administration of captopril to stroke-prone patients for the treatment or prevention of stroke, the claims are anticipated by the prior art dissertation and therefore invalid. Once the professor made the 2010 disclosure, the use of captopril for the treatment of stroke became part of the public domain; it follows that any later claims to the same use of captopril should be denied.<sup>9</sup>

Unfortunately, anticipation often becomes more convoluted than this example suggests. The anticipation analysis becomes considerably less clear when the prior art does not expressly disclose all of the claims of the subsequent invention.<sup>10</sup> Even when a prior art disclosure does not expressly disclose all the claim limitations of a later invention, but performance of the method described in the prior art necessarily contains the undisclosed characteristics, the prior art still negates novelty because the undisclosed results are said to be “inherent” in the prior art.<sup>11</sup> Properly understood, inherent

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7. See *SmithKline Beecham Corp.*, 403 F.3d at 1342. Section 102(b) is sometimes referred to as the “statutory bar,” as distinguished from § 102(a), the “novelty” requirement. See *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1351–53 (Fed. Cir. 2002) (discussing the “statutory bars”). Congress recently amended the Patent Act by adopting the Leahy-Smith America Invents Act (the AIA). See 35 U.S.C. § 102(a)–(b) (2011); H.R. REP. NO. 112-1249 (2011). The AIA represents a massive shift in the way U.S. patents are granted under § 102(a), but does not appear to meaningfully change the operation of § 102(b) as it relates to inherent anticipation. See 35 U.S.C. § 102(a)–(b). For further reading on the AIA, see Jason Rantanen & Lee Petherbridge, Ph.D., *Toward A System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24 (2011).

8. See 35 U.S.C. § 102(b).

9. See *id.*

10. See *In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting) (“Inherency is a very tricky concept in patent law.”).

11. See *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

anticipation serves as a gatekeeper, ensuring the important patent policy of promoting disclosure and only rewarding new inventions that are not already within the public domain.<sup>12</sup> However, the Federal Circuit's recent case law on inherent anticipation<sup>13</sup> has produced a boundless conception of inherency that calls into question the doctrine's fundamental purpose, casts a cloud of uncertainty over patent law, and threatens to undermine the vitality of the pharmaceutical industry, one of the most important industries in modern society.

This Note argues that the Federal Circuit's recent decisions disregard decades of precedent on inherency, thereby creating an unbounded doctrine that not only fails to provide adequate predictability for inventors but also undermines the policy germane to inherency, and to patent law in general. Part II begins by examining the general framework of patentability and the historical policy considerations that have come to shape the Patent Act today. It then focuses on the early history of inherency through a series of Supreme Court and Court of Customs and Patent Appeals<sup>14</sup> cases, and argues that inevitability was always the driving force in inherency. Finally, it inspects the Federal Circuit's more recent, conflicting case law on recognition and inevitability.

Part III begins by analyzing the Federal Circuit's recent discordant approach to inherency. It highlights the lack of predictability in inherency over the last two decades, before focusing on the Federal Circuit's recent inherency decision in *In re Montgomery*,<sup>15</sup> in which the court called into question the meaning of inevitability, and therefore the scope and predictability of inherency generally. Part III then addresses the disconnect between the public policy underlying inherency and the use of bright line rules intended to promote the policy. The problematic nature of bright line rules in patent law is demonstrated by reference to another area of patent law—the requirement that a patented invention be

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12. See *In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting).

13. E.g., *id.*; *Schering*, 339 F.3d 1373.

14. The Court of Customs and Patent Appeals (CCPA) was the Federal Circuit's predecessor court. See Newman, *supra* note 1, at 685.

15. 677 F.3d 1375.

nonobvious—in which the Supreme Court rejected the Federal Circuit’s similar use of rigid, bright line rules.

Part IV sets forth a proposal that seeks to restore predictability to inherency by aligning the inherency analysis directly with the patent policy it seeks to promote. Finally, Part V concludes by reiterating the seriousness of the predictability problem in inherent anticipation, and calls for the appropriate institutional response.

## II. BACKGROUND

Congress has the power to grant patents under Article I, Section 8, Clause 8 of the U.S. Constitution, commonly referred to as the Progress Clause.<sup>16</sup> This clause is particularly unique, in that it describes the only enumerated power to set forth the specific means of exercising that power.<sup>17</sup> It states that Congress shall have the power “[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>18</sup> This limited grant is the result of a balancing of two critical concerns.<sup>19</sup> On one hand, the framers wanted to promote scientific and technological invention, and thought patents were an effective means of carrying out such an endeavor.<sup>20</sup> On the other hand, the framers were no doubt aware of the history of monopolistic abuses in England and thus wanted to ensure that patents were only granted on subject matter that actually advanced society by improving the arts and sciences.<sup>21</sup> Thus, over time Congress has developed patentability requirements to ensure that issued patents do, indeed, “promote the Progress of Science and useful Arts.”<sup>22</sup>

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16. U.S. CONST. art. I, § 8, cl. 8.

17. See *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966).

18. U.S. CONST. art. I, § 8, cl. 8.

19. See W.S. Holdsworth, *The Common Debates 1621*, 52 L. Q. REV. 481, 487 (1936) (discussing King James I’s granting of odious monopolies); Walterscheid, *supra* note 1, at 65.

20. See Walterscheid, *supra* note 1, at 76.

21. See Holdsworth, *supra* note 19, at 487; Walterscheid, *supra* note 1, at 76;.

22. See, e.g., 35 U.S.C. §§ 101–103 (2000); see also Newman, *supra* note 1, at 685 (discussing Congress’s creation of the Federal Circuit to promote uniformity in patent law).

### A. Patentability

In order for a patent to issue, the applicant must prove, among other things, that his or her invention is novel, useful, and nonobvious.<sup>23</sup> The applicant must also disclose his or her method of making and using an invention in a manner sufficient to allow a person of ordinary skill in the field of the invention to make and use it.<sup>24</sup> With only minor exceptions, the patentee's disclosure of what constitutes his or her invention is the fundamental basis of U.S. patent protection.<sup>25</sup> That is, a patentee is entitled to enforce his or her patent only against unauthorized uses that encompass the patent application's claims, and insufficient disclosure is a ground for invalidating patent claims.<sup>26</sup>

Put another way, the inventor's disclosure in the patent application is the quid, and the twenty-year right to exclusive use is the quo. Without adequate disclosure, there is no quid pro quo; the public does not receive anything—or at least not enough—in exchange for the limited-term monopoly that is provided to the patentee.<sup>27</sup> The novelty and disclosure requirements thus ensure that patents are issued on a limited set of inventions, and that the public and other PHOSITAS<sup>28</sup> reap the benefits of the patented invention.<sup>29</sup>

The framers were concerned not only with striking this balance but also with predictability.<sup>30</sup> The Articles of Confederation contained no provisions for federal patent protection, effectively

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23. 35 U.S.C. §§ 101–103.

24. *See id.* § 112.

25. *See SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (holding that it is only what the inventor “claims” in his or her invention that is protected).

26. *See id.* In addition, 35 U.S.C. § 282(b)(3) sets forth failure to comply with any § 112 disclosure requirement as an affirmative defense to infringement.

27. *Evans v. Eaton*, 20 U.S. 356, 433–34 (1822) (arguing that the § 112 disclosures serve two goals: (1) to enable an artisan to make and use the invention; and (2) to put the public in possession of what the patentee claims as his own invention, “so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented”).

28. A person having ordinary skill in the art is commonly referred to by the acronym “PHOSITA.”

29. *Evans*, 20 U.S. at 435.

30. *See Walterschied*, *supra* note 1, at 66 (discussing the constitutional framers' decision to create federal patent law in light of the inevitable conflict that would be created by allowing different patent laws to be promulgated by the states, as was allowed in the Articles of Confederation).



leaving patent protection to the individual states.<sup>31</sup> Concerned over the inevitable conflict that would result from state patent protection, the framers later included the Progress Clause in the U.S. Constitution.<sup>32</sup>

More recently, Congress has shown additional concern over uniformity and predictability in patent law.<sup>33</sup> Its decision to create the Court of Appeals for the Federal Circuit was motivated, at least in part, by concerns over inconsistent approaches of the regional circuits and the inevitable forum-shopping that resulted.<sup>34</sup> Thus, the Progress Clause, which gives birth to the Patent Act itself, along with the appellate court designed to oversee patent law make clear that predictability is central to the U.S. patent system.<sup>35</sup>

### B. *Inherent Anticipation*

The novelty requirement ensures that patents are only granted where an applicant contributes something new to society—thus striking a balance between affording patent protections to inventors and protecting the public from unreasonable expenses.<sup>36</sup> To that end, if an invention was previously patented or described in a printed publication more than one year before the inventor files his or her patent application, the invention is said to be “anticipated” by the “prior art.”<sup>37</sup> Anticipation negates novelty under § 102, and thus no patent can issue on anticipated subject matter.<sup>38</sup>

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31. *See id.*

32. *See id.*

33. *See* H.R. REP. NO. 97-312, at 20–22 (1981) (arguing in favor of creating the Federal Circuit in order to combat the effects of “pro-patent” and “anti-patent” jurisdictions); Newman, *supra* note 1, at 685 (asserting Congress created the Federal Circuit to allow for “consistent application of the law”).

34. Newman, *supra* note 1, at 685.

35. *See* H.R. REP. NO. 97-312, at 20–22 (1981); Walterschied, *supra* note 1, at 66.

36. *See In re Montgomery*, 677 F.3d 1375, 1383 (Fed. Cir. 2012) (Lourie, J., dissenting) (explaining that inherency’s “salutary goal is to prevent subject matter that is effectively in the public’s possession from being retrieved by a patent and withdrawn from the public domain”).

37. 35 U.S.C. § 102 states, “A person shall be entitled to a patent unless . . . (b) 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.” Section 102(b) is sometimes referred to as the “statutory bar” as opposed to § 102(a), which is deemed the “true novelty” requirement; however, the anticipation analysis is the same under both sections. *See* 35 U.S.C. § 102(a)–(b) (2000).

38. *Id.* *See also* *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980) (stating that a core concept of patent law is that anticipation undermines patentability).

Anticipation involves a two-step analysis.<sup>39</sup> The first step requires construction of the claims at issue.<sup>40</sup> Claim construction is a question of law in which the court gives the claims in question their broadest reasonable interpretation consistent with the patent specifications.<sup>41</sup> Once claim construction is complete, the second step of the anticipation analysis involves comparing the claims in question to the prior art.<sup>42</sup> Ordinarily, a single prior art reference anticipates a patent claim when it expressly discloses every claim limitation.<sup>43</sup> However, the public can gain more from prior art than what is expressly disclosed. Thus, even where a single prior art reference does not expressly disclose all the limitations of the claimed invention, it may still anticipate inherently “if [the] missing characteristic[s] [are] necessarily present, or inherent, in the single anticipating reference.”<sup>44</sup>

Inherent anticipation is admittedly a tricky concept—it has puzzled judges, lawyers, inventors, and jurors for decades.<sup>45</sup> Nonetheless, the Supreme Court and the Federal Circuit, along with its predecessor courts, have long agreed that a given characteristic could only anticipate inherently if it necessarily exists within a single prior art reference.<sup>46</sup> In 1991, the Federal Circuit held that anticipation required not only that the undisclosed characteristics be inherent, but also that the missing characteristics be recognized by a person having ordinary skill in the art.<sup>47</sup> This change in the law was short lived. Recent panel decisions have rejected the recognition

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39. *In re Montgomery*, 677 F.3d at 1379.

40. *Id.*

41. *Id.* at 1380–81.

42. *Id.*

43. *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1336–37 (Fed. Cir. 2010).

44. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (citing *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). See also *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (“[P]rior art [must] necessarily function[] in accordance with, or include[], the claimed limitations.”).

45. See *In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting) (“Inherency is a very tricky concept in patent law.”); Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 372 (2005); Newman, *supra* note 1, at 685 (discussing the numerous concepts in patent law that puzzle jurors, judges, and lawyers alike).

46. *E.g.*, *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)); *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939).

47. See *Cont'l Can*, 948 F.2d at 1268.

requirement and held that anticipation requires only that the undisclosed characteristics inevitably flow from the single prior art reference and that the prior art enable a PHOSITA to practice the later claimed invention.<sup>48</sup> Although the clash over recognition was short lived, it caused intra-circuit conflict and continues to cast a cloud of confusion over inherency.<sup>49</sup>

### 1. *Tilghman*, *Eibel*, and Other Early Inherency Cases

Inherency is often traced back to the Supreme Court's decision in *Tilghman v. Proctor*.<sup>50</sup> There, the patent in question claimed a method of forming fatty acids and glycerin by heating fats with water at high pressure.<sup>51</sup> The prior art involved animal fat employed to lubricate pistons of steam engines, which might have produced fatty acids.<sup>52</sup> The Court held that even if fatty acids were produced in the prior art, the prior art would not anticipate, because a PHOSITA "certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids."<sup>53</sup>

Another early Supreme Court anticipation case is *Eibel Process Company v. Minnesota & Ontario Paper Company*.<sup>54</sup> Eibel's claims involved a papermaking machine that employed paper-forming mesh with an elevated pitch that improved the quality of the resulting paper.<sup>55</sup> Some prior art papermaking machines appeared to have employed pitched mesh, but not to the same degree as Eibel's invention, and only for drainage.<sup>56</sup> Citing *Tilghman*, the Court held

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48. See *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). In this context, enablement—or an enabling disclosure—means that the disclosure was sufficient to allow a PHOSITA to practice the claimed invention.

49. See *Schering Corp. v. Geneva Pharm.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (Newman, J., dissenting from denial of petition for rehearing en banc); *id.* at 995–96 (Lourie, J., dissenting from denial of petition for rehearing en banc); Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1132 (2008); Alfredo De La Rosa, *A Hard Pill to Swallow: Does Schering v. Geneva Endanger Innovation Within the Pharmaceutical Industry?*, 8 COLUM. SCI. & TECH. L. REV. 37 (2007).

50. 102 U.S. 707 (1880).

51. *Id.* at 709.

52. *Id.* at 711.

53. *Id.*

54. 261 U.S. 45 (1923).

55. *Id.* at 65.

56. *Id.* at 66–67.

the prior art did not anticipate the new papermaking machines because,

[i]n the first place, we find no evidence that any pitch of the wire, used before Eibel, had brought about such a result as that sought by him, and in the second place if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.<sup>57</sup>

The Federal Circuit's predecessor patent court—the CCPA—adopted the reasoning of *Tilghman* and *Eibel*, at least insofar as those cases held inherency requires inevitability.<sup>58</sup> For example, in the 1964 case *In re Seaborg*,<sup>59</sup> the CCPA considered claims drawn to an isotope of americium, made by nuclear reaction.<sup>60</sup> A prior art patent disclosed a similar nuclear reaction process, but did not disclose the claimed isotope.<sup>61</sup> The court held the prior art process did not anticipate the claims because the isotope, “if it was produced in the [prior art] process, was produced in such minuscule amounts and under such conditions that its presence was undetectable.”<sup>62</sup> *Seaborg* makes clear that the mere fact that a certain thing might result from a given set of circumstances is insufficient to support a finding of inherency.<sup>63</sup>

It is important to note, however, that *Seaborg* contains no express language whatsoever regarding recognition.<sup>64</sup> In fact, even as early as 1939 in *Hansgirk v. Kemmer*,<sup>65</sup> the CCPA seemed only to

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57. *Id.* at 66 (citing *Tilghman*, 102 U.S. at 711).

58. *See, e.g., In re Oelrich*, 666 F.2d 578 (C.C.P.A. 1981); *In re Marshall*, 578 F.2d 301 (C.C.P.A. 1978); *In re Felton*, 484 F.2d 495 (C.C.P.A. 1973); *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964).

59. 328 F.2d 996 (C.C.P.A. 1964).

60. *Id.* at 996. Americium (Am) is element 95 on the periodic table. *Id.* It may strike some readers as strange that an element on the periodic table can be patented. A naturally occurring mineral, such as iron, even if newly discovered, cannot be patented because such subject matter is deemed patent ineligible. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.”). However, americium is a “man made” radioactive isotope that does not exist in nature, which means it is not subject matter ineligible. *See, e.g., id.* at 310 (explaining that the patentee’s modified bacteria had “markedly different characteristics from any found in nature” and was “not nature’s handiwork, but his own,” thus rendering it patentable subject matter).

61. *In re Seaborg*, 328 F.2d at 996–97.

62. *Id.* at 998–99.

63. *Id.*

64. *Id.*

65. 102 F.2d 212, 214 (C.C.P.A. 1939).

focus on inevitability and enablement.<sup>66</sup> In *Hansgirk*, the court held inherency requires “that the natural [i.e., inevitable] result flowing from the operation as taught would result in the performance of the questioned function.”<sup>67</sup> The court’s emphasis on “as taught” is important: it did not hold that a PHOSITA needed to apprehend the undisclosed result; rather, it required that the prior art “teach”—that is, enable one of ordinary skill to carry out—an operation that would inevitably produce the undisclosed result.<sup>68</sup> However, in the 1991 case of *Continental Can Co. USA, Inc. v. Monsanto Co.*,<sup>69</sup> the Federal Circuit held otherwise.<sup>70</sup>

## 2. *Continental Can* and the Short-Lived Per Se Recognition Requirement

Judge Newman, writing for a unanimous panel in *Continental Can*, explained that inherent anticipation required that the pertinent evidence “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.”<sup>71</sup> Subsequently, courts cited *Continental Can* with apparent approval in anticipation cases through 1999,<sup>72</sup> until the tide turned yet again.<sup>73</sup>

Toward the end of 1999, the Federal Circuit began chipping away at the recognition requirement announced in *Continental Can*.<sup>74</sup> In *Atlas Powder v. Ireco, Inc.*,<sup>75</sup> writing for a unanimous panel of the court, Judge Rader opined, “Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent

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66. *See id.*

67. *Id.*

68. *Id.*

69. 948 F.2d 1264 (Fed. Cir. 1991).

70. *Id.* at 1268 (“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. Such evidence 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.*” (emphasis added)).

71. *Id.*

72. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (applying the anticipation analysis from *Continental Can*).

73. *See, e.g., Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342 (Fed. Cir. 1999).

74. *Id.*

75. *Id.* at 1347.

characteristics or functioning of the prior art.”<sup>76</sup> Judge Rader went on to explain that the purpose of § 102 is to ensure that a claimed invention does not take something away from the public that is already in its possession.<sup>77</sup> Thus, it should be irrelevant “whether or not [a PHOSITA] understand[s] [the prior art’s] complete makeup or the underlying scientific principles which allow [it] to operate.”<sup>78</sup>

*Atlas Powder* did not uniformly reject the recognition requirement; instead it explained that recognition was not probative of inherency on that set of facts.<sup>79</sup> Four years later, the panel in *Schering Corp. v. Geneva Pharmaceuticals*<sup>80</sup> uniformly rejected recognition, in an attempt to return the law of inherency to its pre-*Continental Can* roots.<sup>81</sup> However, the Federal Circuit declined to restore full clarity to inherency by deciding the case en banc.<sup>82</sup>

*Schering* concerned a prior art patent for the antihistamine loratadine—marketed by Schering as Claritin®—and a subsequent patent granted to Schering for a metabolite of loratadine, descarboethoxyloratadine (DCL).<sup>83</sup> DCL formed naturally upon human consumption and metabolization of loratadine, which was patented more than one year before Schering filed their patent application on DCL.<sup>84</sup> Upon expiration of the loratadine patent, Geneva Pharmaceuticals sought to enter the loratadine market.<sup>85</sup> Schering filed suit alleging infringement of their DCL patent on the ground that DCL forms upon consumption of loratadine.<sup>86</sup> The district court granted summary judgment in favor of Geneva, holding

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76. *Id.*

77. *Id.* at 1348 (“The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.”).

78. *Id.*

79. *See id.*

80. 339 F.3d 1373 (Fed. Cir. 2003).

81. *Id.* at 1377.

82. *See Schering Corp. v. Geneva Pharm.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (denying rehearing en banc); *see also id.* at 993 (Newman, J., dissenting from denial of petition for rehearing en banc); *id.* at 995–96 (Lourie, J., dissenting from denial of petition for rehearing en banc).

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

84. *Id.*

85. *Id.* at 1376.

86. *Id.*

that the claims in the loratadine patent inherently anticipated the DCL claims, which were therefore invalid.<sup>87</sup>

On appeal, the Federal Circuit began its opinion by boldly asserting, “At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art.”<sup>88</sup> Interestingly, the *Schering* panel distinguished *Continental Can* procedurally by characterizing *Continental Can* as merely vacating a summary judgment grant based on conflicting testimony regarding whether the claimed process was necessarily formed in the prior art.<sup>89</sup> In other words, Judge Newman’s language regarding recognition was cloaked as mere dicta. Likewise, *Tilghman* and *Eibel* were said to have involved a *lack* of evidence that the allegedly inherent subject matter was present in the prior art—not the issue of recognition.<sup>90</sup> Accordingly, because Schering’s loratadine patent, the pertinent prior art, disclosed administration of loratadine to people, and the administration of loratadine to people inevitably produces DCL, the loratadine patent inherently anticipated the DCL claim.<sup>91</sup>

### 3. *In re Montgomery*—The End of Inevitability?

On May 8, 2012, nearly a decade after deciding *Schering*, the Federal Circuit decided *In re Montgomery*.<sup>92</sup> There, Montgomery filed an application for a method of use patent claiming the treatment or prevention of stroke by administering ramipril, a rennin-angiotensin system (RAS) inhibitor, to stroke-prone patients.<sup>93</sup> The

87. *Id.*

88. *Id.* at 1377.

89. *Id.* (“In *Continental Can*, this court vacated summary judgment of anticipation of claims reciting a plastic bottle with hollow ribs over a prior art reference disclosing a plastic bottle . . . [because] [t]he record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid.”).

90. *Id.* at 1378.

91. *Id.* at 1380.

92. 677 F.3d 1375 (Fed. Cir. 2012).

93. *Id.* at 1377. There were actually three claims at issue in *In re Montgomery*, which read as follows:

42. A method for the treatment or prevention of stroke or its recurrence, wherein said method comprises administering, to a patient diagnosed as in need of such treatment or prevention, an inhibitor of the rennin-angiotensin system, said inhibitor having a Clog P of greater than about 1.

43. The method as claimed in claim 42, wherein the inhibitor of the rennin-angiotensin system comprises at least one inhibitor of angiotensin-converting enzyme.

application was filed on April 25, 2005, claiming priority to United Kingdom patent applications dated October 17, 1997, and May 20, 1998, respectively.<sup>94</sup> The PTO examiner rejected Montgomery's claims as anticipated, and the Board of Patent Appeals and Interferences affirmed the examiner's rejection.<sup>95</sup>

Montgomery appealed the rejection to the Federal Circuit, arguing that the prior art reference at issue in the appeal—a publication describing the HOPE<sup>96</sup> study—was merely a proposal for future research and that the publication failed to enable a PHOSITA to practice the claimed invention.<sup>97</sup> HOPE was published in February 1996, more than one year before Montgomery's priority date, and describes the “design” of “a large, randomized clinical trial of the efficacy of . . . ramipril, and of a naturally occurring antioxidant, vitamin E, in reducing myocardial infarction (MI), stroke, or [cardiovascular disease] death in over 9000 men and women at high risk of CVD.”<sup>98</sup>

In other words, HOPE described a study that sought to test whether or not a combination of ramipril and vitamin E would reduce the risk of death from stroke and other cardiovascular diseases in a random sample of patients.<sup>99</sup> It provided no disclosure that ramipril *would* reduce the risk of stroke death—effectively leaving those who read it to speculate whether it would increase or decrease that risk.<sup>100</sup> HOPE even “provide[ed] specific criteria for ‘early termination’ if the proposed treatment [was] ineffective.”<sup>101</sup>

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45. The method as claimed in claim 43, wherein the inhibitor of angiotensin-converting enzyme comprises ramipril.

*Id.* (emphasis omitted). Because the parties agreed that claim 45 incorporates claims 42 and 43, the court only addressed claim 45. *Id.* at 1380 n.9.

94. *Id.* at 1376.

95. *Id.* at 1377–78.

96. HOPE is an acronym for Heart Outcomes Prevention Evaluation. The HOPE Study Investigators, *The HOPE (Heart Outcomes Prevention Evaluation) Study: The Design of a Large, Simple Randomized Trial of an Angiotensin–Converting Enzyme Inhibitor (Ramipril) and Vitamin E in Patients at High Risk of Cardiovascular Events*, 12 CAN. J. CARDIOLOGY 127 (1996) [hereinafter HOPE].

97. *In re Montgomery*, 677 F.3d at 1379.

98. *Id.* at 1378; HOPE, *supra* note 96, at 127.

99. *See In re Montgomery*, 677 F.3d at 1378.

100. *Id.* at 1381–83.

101. *Id.* at 1385 (Lourie, J., dissenting).



This exit strategy is significant, but not surprising. RAS inhibitors, like ramipril, reduce hypertension yet, at the time, had been shown to paradoxically increase stroke risk.<sup>102</sup> In fact, AIRE, one of the four studies cited by the Board in its rejection of Montgomery's claims, found that ramipril actually increased the risk of stroke.<sup>103</sup> In 2000, years after Montgomery's priority date, the authors of HOPE published the results of the study they described, which found that administration of ramipril to stroke-prone patients effectively decreased the risk of stroke-related deaths.<sup>104</sup> However, because the second HOPE reference was published years after Montgomery's priority date, the entire panel agreed it was "irrelevant" to the anticipation analysis.<sup>105</sup>

A majority of the three-judge Federal Circuit panel rejected Montgomery's arguments and held that HOPE inherently anticipated his claims.<sup>106</sup> Judge Lourie, who had also dissented from the denial of rehearing en banc in *Schering*, filed a dissenting opinion.<sup>107</sup> The entire panel agreed that HOPE did not expressly disclose effective treatment or prevention of stroke, such that it could only anticipate Montgomery's claims inherently; it diverged, however, on whether treatment of stroke was inevitable based on the HOPE reference and on whether HOPE was enabling.<sup>108</sup>

The majority held that because "HOPE disclose[d] a protocol for the administration of ramipril to stroke-prone patients, and administering ramipril to stroke-prone patients inevitably treats or prevents stroke," HOPE inherently anticipated Montgomery's

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102. Brief for Appellant at 2–4, *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2003) (No. 11-1367), 2011 WL 454279, at \*2–6 (reproducing the results of the AIRE study to demonstrate ramipril increased the risk of stroke by 43 percent); The Acute Infarction Ramipril Efficacy (AIRE) Study Investigators, *Effect of Ramipril on Mortality and Morbidity of Survivors of Acute Myocardial Infarction with Clinical Evidence of Heart Failure*, 342 LANCET 821 (1993) [hereinafter AIRE].

103. See Brief for Appellant, *supra* note 102, at 2–4 (reproducing the results of the AIRE study to demonstrate ramipril increased the risk of stroke by 43 percent).

104. See The HOPE Study Investigators, *Effects of an Angiotensin–Converting–Enzyme Inhibitor, Ramipril, on Cardiovascular Events in High–Risk Patients*, 342 NEW ENG. J. MED. 145, 148 tbl.3 (2000) [hereinafter HOPE II].

105. *In re Montgomery*, 677 F.3d at 1378 (majority opinion); *id.* at 1385 (Lourie, J., dissenting).

106. *Id.* at 1383 (majority opinion).

107. See *id.* (Lourie, J., dissenting).

108. Compare *id.* at 1381–83 (majority opinion), with *id.* at 1383–85 (Lourie, J., dissenting).

claims.<sup>109</sup> Invoking strong language from *Schering*, the court reminded the dissent that “anticipation ‘requires only an enabling disclosure,’ not ‘actual creation or reduction to practice,’ so that ‘actual administration of [ramipril] to patients [in the prior art] is irrelevant.’”<sup>110</sup> The majority concluded by dismissing Judge Lourie’s characterization of HOPE as a mere “invitation to investigate” that was not enabling.<sup>111</sup> To the majority, HOPE was “an advanced stage of testing designed to secure regulatory approval.”<sup>112</sup>

Judge Lourie began his dissent by clearly delineating his side of the inherency debate.<sup>113</sup> He critiqued the Federal Circuit’s decision in *Schering* and argued that, when properly understood, inherency is “much more limited.”<sup>114</sup> His dissent emphasized that HOPE described no more than a design for a study that, at least to him, had not actually been carried out, and thus could not have disclosed any results whatsoever—let alone *inevitable* results. Additionally, because it disclosed no results on efficacy, it also failed to enable a PHOSITA to treat or prevent stroke.<sup>115</sup> Judge Lourie argued that HOPE was simply too indeterminate to be deemed inevitable. Regardless of whether HOPE was an advanced stage of testing, it was no more than the description of a study that required four years of testing to produce data sufficient to demonstrate efficacy. In other words, it was anything but inevitable.<sup>116</sup> To that end, in order to find inevitability, Judge Lourie argued that the majority reached outside the scope of HOPE (and of the record in general) and relied on the second HOPE disclosure, published years after Montgomery’s priority date, to find inherency.<sup>117</sup>

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109. *Id.* at 1381–82 (majority opinion).

110. *Id.* at 1382 (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003)).

111. *Id.* (quoting *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004)).

112. *Id.*

113. *Id.* at 1383 (Lourie, J., dissenting).

114. *See id.* 1383–84 (citing *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880)). Judge Lourie also dissented from the denial of rehearing en banc in *Schering*, along with Judge Newman. *See Schering Corp. v. Geneva Pharm.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (Newman, J., dissenting from denial of petition for rehearing en banc); *id.* at 995–96 (Lourie, J., dissenting from denial of petition for rehearing en banc).

115. *In re Montgomery*, 677 F.3d at 1384 (Lourie, J., dissenting).

116. *Id.*

117. *See id.* at 1385.

## III. INHERENCY, PREDICTABILITY, AND BRIGHT-LINE RULES

The importance of uniformity and predictability applies *a fortiori* in industries where development costs are high, such as the pharmaceutical industry.<sup>118</sup> Taking into account the cost of failures, one study suggests that the “average drug developed by a major pharmaceutical company costs at least \$4 billion, and it can be as much as \$11 billion.”<sup>119</sup> Given that successful drugs can generate billions of dollars in profits for their manufacturers, such costs can be justifiable.<sup>120</sup> Of course, this presupposes that manufacturers are afforded a sufficiently uniform system of patent law from which to predict whether their drug or medical device will be worthy of patent protection.<sup>121</sup> At the same time, the importance of encouraging pharmaceutical research through ensuring predictable patent protection must be balanced with the manifest interest of society in receiving new and useful pharmaceuticals at cost-effective prices.<sup>122</sup>

Congress has already recognized the unique nature of pharmaceutical patent protection.<sup>123</sup> The Hatch-Waxman Act, passed in 1984, allows pharmaceutical patents to be extended when delays in obtaining FDA approval significantly reduce the amount of time the patentee can exclusively market the patented pharmaceutical.<sup>124</sup> This clearly promotes pharmaceutical research and development. The Hatch-Waxman Act also allows generic drug manufacturers to begin testing the patented pharmaceutical technology during the extended time frame, which permits cost-effective generics to be marketed to the public as soon as the patent term expires.<sup>125</sup> Despite Congress’s response to the unique nature of pharmaceutical patents, the Federal Circuit’s inherency decisions treat complex pharmaceutical processes

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118. *Id.* at 1384.

119. See Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES.COM (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>.

120. See *id.*

121. See De La Rosa, *supra* note 49.

122. See, e.g., 35 U.S.C. §§ 156, 271 (2011).

123. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); see also 35 U.S.C. §§ 156, 271 (2011) (codifying Hatch-Waxman Act).

124. 35 U.S.C. § 156.

125. *Id.*; 21 U.S.C. § 355. For further reading on the intricacies of the Hatch-Waxman Act, see Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417 (2011).

as if they involve the same kind of technology as any other invention.

### *A. Predictability in Inherency*

The last decade of precedent on inherent anticipation is anything but predictable.<sup>126</sup> *Schering* prompted significant dissent within the Federal Circuit and the patent bar at large.<sup>127</sup> In the decade since *Schering* was decided, the intra-circuit battle over recognition remains largely unsettled.<sup>128</sup> The Federal Circuit has had the ability to clarify the law of inherent anticipation in various cases, but it has instead rejected opportunities to hear the cases en banc.<sup>129</sup> Indeed, in at least one instance, instead of clarifying the state of the law, the Federal Circuit simply vacated a panel opinion requiring recognition and remanded the underlying matter to the district court.<sup>130</sup> Given that this posture has more or less forced application of the *Schering* articulation of the law, it is fair to say that *Continental Can* has been rejected.<sup>131</sup> However, some unpublished Federal Circuit opinions continue to cite directly to *Continental Can* for the proposition that inherency does require recognition, while the published opinions continue to assert that recognition is not required, though not without prompting dissents.<sup>132</sup> Everyone deserves uniform protection, but the

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126. See, e.g., *Haberman v. Gerber Prod. Co.*, 236 F. App'x 592, 598 (Fed. Cir. 2007) (citing *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)) (not designated for publication). See also *In re Montgomery*, 677 F.3d 1375, 1383 (Fed. Cir. 2012) (Lourie, J., dissenting) (critiquing the inherency rule announced in *Schering*).

127. See *Schering Corp. v. Geneva Pharm.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (Newman, J., dissenting from denial of petition for rehearing en banc); *id.* at 995–96 (Lourie, J., dissenting from denial of petition for rehearing en banc); Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1132 (2008); De La Rosa, *supra* note 49, at 87.

128. See, e.g., *Haberman*, 236 F. App'x at 598 (citing *Cont'l Can Co.*, 948 F.2d at 1268) (not designated for publication). See also *In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting) (critiquing the inherency rule announced in *Schering*).

129. See, e.g., *Schering*, 348 F.3d at 992 (majority opinion) (denying petition for rehearing en banc); *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 314 F.3d 1299 (Fed. Cir. 2002) (denying petition for rehearing en banc).

130. See *Elan Pharm.*, 314 F.3d at 1299 (granting rehearing en banc, but declining to address the issue in an en banc decision and instead simply vacating the panel opinion and remanding to district court).

131. See *In re Montgomery*, 677 F.3d at 1375 (rejecting recognition); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (rejecting recognition).

132. Compare *Haberman*, 236 F. App'x at 598 (requiring recognition), with *SmithKline Beecham Corp.*, 403 F.3d at 1343 (rejecting recognition); *Schering Corp. v. Geneva Pharm.*, 339

Federal Circuit's internal conflict concerning the nature of inherency denies uniform, predictable patent protection—at least where the dispute concerns recognition in an inherency analysis. Despite the uncertainty and turmoil surrounding the post-*Continental Can* cases rejecting recognition, at least one aspect of inherency law seemed clear: inevitability is the touchstone of inherency.<sup>133</sup>

Before, and even after *Schering*, the Federal Circuit required that the undisclosed, i.e., inherent, result flow with something tantamount to statistical necessity from the operation as taught in the prior art.<sup>134</sup> For example, in the 1995 case *Glaxo Inc. v. Novopharm Ltd.*,<sup>135</sup> the Federal Circuit refused to find that a prior art process inherently anticipated a later claim directed at crystals—even though the defendant's experts reproduced the crystals using a prior art process each of thirteen times—because the plaintiffs twice produced different crystals using the same process.<sup>136</sup> *Schering* was consistent with *Glaxo*, insofar as the court found DCL formed naturally upon human consumption of the prior art loratadine.<sup>137</sup>

In *SmithKline Beecham Corp. v. Apotex*,<sup>138</sup> the Federal Circuit arguably began to loosen the strict necessity requirement. However, the holding is best understood as addressing the burden on the party seeking to invalidate an issued patent.<sup>139</sup> There, the district court found in favor of SmithKline Beecham, the plaintiff-patentee suing for infringement, because the defendant “did not prove by clear and convincing evidence that it was *impossible* to make [a pure version of the prior art compound with no trace elements of the allegedly

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F.3d 1373, 1373 (Fed. Cir. 2003) (rejecting recognition). Cf. *In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting) (critiquing the inherency rule announced in *Schering*).

133. No inherency case questions the inevitability requirement. See generally *Schering*, 339 F.3d at 1377 (“[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.”); *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (requiring, in addition to recognition, that the pertinent evidence “make clear that the missing descriptive matter is necessarily present in the thing described”).

134. See *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995).

135. *Id.*

136. See *id.*; *In re Seaborg*, 328 F.2d 996, 998–99 (C.C.P.A. 1964) (holding that the prior art process did not anticipate the claims because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material).

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

138. 403 F.3d 1331 (Fed. Cir. 2005).

139. *Id.*

anticipated compound] in the United States before the critical date” of the plaintiff’s patent.<sup>140</sup> The Federal Circuit reversed, holding that “[t]he district court erred in requiring Apotex to meet [that] standard of proof, which [was] too exacting.”<sup>141</sup> Instead, the court held that a reference “suffices as an anticipatory prior art reference if it discloses in an enabling manner” the production of the later-claimed invention.<sup>142</sup> Thus, because the prior art “disclose[d] a method . . . that naturally results in the production of [the claimed compound],” the court found the claimed compound was inherently anticipated by the prior art.<sup>143</sup> *SmithKline Beecham* is thus consistent with pre-*Schering* cases requiring strict necessity.<sup>144</sup> However, in their 2012 decision in *In re Montgomery*, the Federal Circuit calls even inevitability into question.<sup>145</sup>

Reading *Continental Can*, then *Schering*, followed by *In re Montgomery*, would likely lead to confusion. This confusion is not only because the recognition requirement from *Continental Can* was rejected in *Schering* and would have foreclosed a finding of inherent anticipation in *In re Montgomery*,<sup>146</sup> but also because it is difficult to square *In re Montgomery* with any prior cases on inherent anticipation—it effectively eviscerated the requirement that the inherent characteristics be “necessarily” present in the prior art disclosure.<sup>147</sup> Judge Lourie was correct when he said that nothing properly before the court indicated that stroke treatment or prevention was a necessary result of the process described in HOPE.<sup>148</sup> Prior to the fallout from *Schering*, and indeed even in *Schering*, the Federal Circuit pointed to actual record evidence establishing that the undisclosed result necessarily resulted from the process in question with something resembling statistical

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140. *Id.* at 1343 (emphasis added).

141. *Id.*

142. *Id.* at 1344 (citing *Schering*, 339 F.3d at 1380).

143. *Id.*

144. *See id.*; *Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (requiring, in addition to recognition, that the pertinent evidence “make clear that the missing descriptive matter is necessarily present in the thing described”).

145. *See In re Montgomery*, 677 F.3d 1375, 1384 (Fed. Cir. 2012).

146. *See In re Montgomery*, 677 F.3d at 1375; *Schering*, 339 F.3d at 1381; *Cont’l Can Co.*, 948 F.2d at 1268.

147. *See In re Montgomery*, 677 F.3d at 1383 (Lourie, J., dissenting).

148. *Id.* at 1385.

necessity.<sup>149</sup> In *In re Montgomery*, the Federal Circuit found necessity by pointing to the mere description of a proposed study that said absolutely nothing about whether ramipril would treat stroke.<sup>150</sup> In essence, the majority found it sufficient to say that HOPE *could* have been carried out, and if carried out it *would* have—or at least *should* have—shown that ramipril possesses stroke-prevention qualities.<sup>151</sup> However, despite the majority’s belief, “could have, would have, should have” is not the law: strict necessity is.<sup>152</sup>

The counterargument is that what Judge Lourie argues for in *In re Montgomery* is no more than a disguised recognition requirement. After all, the first step Judge Lourie took in his dissenting opinion was to critique *Schering* for the overly broad conception of inherency it produced.<sup>153</sup> In other words, to require inevitability be shown contemporaneously requires record evidence that would independently satisfy the recognition requirement.<sup>154</sup> But Judge Lourie did not demand something tantamount to recognition without having a reasonable basis for doing so.<sup>155</sup> Indeed, even ignoring *Schering* and *Continental Can*, there is an argument that Supreme Court precedent from *Tilghman* and *Eibel* requires something resembling recognition—at least in certain instances. The Supreme Court rested its holdings in both *Tilghman* and *Eibel*, at least in part, on the fact that the records lacked evidence establishing that the prior art actually employed the newly patented techniques.<sup>156</sup> That is, the records did not establish that the prior art necessarily contained the

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149. See, e.g., *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995).

150. *In re Montgomery*, 677 F.3d at 1378; see also *id.* at 1384 (Lourie, J., dissenting) (“As the majority acknowledges, the references do not expressly disclose this claimed method. Nor is the claimed method an inherent result of carrying out what the references describe.”).

151. Compare *id.* at 1382–83 (majority opinion) (arguing “even if HOPE merely proposed the administration of Ramipril for treatment or prevention of stroke (without actually doing so), it would still anticipate”), with *id.* at 1385 (Lourie, J. dissenting) (“[A] mere description of a process that, if it had been carried out, might yield a particular undisclosed result is not an inherent anticipation of that result.”) (emphasis omitted).

152. See *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939) (“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.”).

153. *In re Montgomery*, 677 F.3d at 1383–84 (Lourie, J., dissenting).

154. See *id.* at 1382–83 (majority opinion).

155. See *id.* at 1383–85 (Lourie, J., dissenting) (citing *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880)).

156. *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45 (1923); *Tilghman*, 102 U.S. 707.

later claimed invention.<sup>157</sup> However, the Court did state, as a second ground, that “accidental results” which are “not intended and not *appreciated*” cannot constitute anticipation.<sup>158</sup> Whether the Court meant to include a “per se” requirement that a PHOSITA appreciate—i.e., recognize—the undisclosed characteristic is open to debate. Indeed, as cases like *Atlas Powder* and *Schering* make clear, the Federal Circuit continues to vigorously debate the meaning and significance of the Court’s holdings in *Tilghman* and *Eibel*; the judges are not in agreement.<sup>159</sup>

Disagreement over “per se” recognition notwithstanding, in a situation like the one presented in *In re Montgomery*, there is a significantly large gap between requiring contemporaneous recognition and demanding a showing of inevitability that adequately protects the investment of the patent applicant.<sup>160</sup>

HOPE described a massive, complicated, long-term study of the efficacy of ramipril in treating or preventing a number of cardiovascular diseases.<sup>161</sup> The fact that it took the HOPE authors roughly four years to publish the results of their proposed study is informative: the outcome of the study was anything but preordained.<sup>162</sup> In fact, the exact study described in the HOPE publication never happened.<sup>163</sup> The authors had to alter the study to account for lag time, meaning the study used by the majority to invalidate *Montgomery*’s claims was never carried out.<sup>164</sup> Consequently, HOPE, as described before *Montgomery*’s priority date, was no more than an aspiration; it was, as its name suggests, only a “hope.”

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157. *Eibel*, 261 U.S. at 45.

158. *Id.* at 66 (emphasis added) (citing *Tilghman*, 102 U.S. at 711).

159. Compare *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003) (distinguishing *Tilghman* and *Eibel* as “accidental” anticipation cases involving a lack of evidence establishing inevitability), with *In re Montgomery*, 677 F.3d at 1383–84 (Lourie, J., dissenting) (citing *Tilghman*, 102 U.S. at 711) (“Properly understood [under *Tilghman*], anticipation by inherency is far more limited.”).

160. While requiring contemporaneous evidence of inevitability is essentially the same as requiring that a PHOSITA would have, or should have, recognized the undisclosed characteristics in the prior art, to require a sufficiently “definite” showing of inevitability *based on* the prior art disclosure is not at all tantamount to recognition.

161. *In re Montgomery*, 677 F.3d at 1378 (majority opinion).

162. *Id.* at 1385 (Lourie, J., dissenting).

163. *Id.*

164. *Id.*



Moreover, though the appellate record in *In re Montgomery* was silent on the results of the HOPE study, the record contained evidence from the AIRE study indicating that ramipril could actually increase the likelihood of stroke, or at the very least, had no relevant effect on stroke.<sup>165</sup> The PTO examiner, the Board, and the majority of the Federal Circuit dismissed this data as irrelevant by arguing that evidence of “teaching away” is limited to an obviousness analysis under § 103.<sup>166</sup> Teaching away is, no doubt, an obviousness consideration.<sup>167</sup> But how does a process “necessarily” produce a given result if multiple results are possible? Logically, prior precedent in cases such as *Glaxo* held that it could not.<sup>168</sup> In *In re Montgomery*, the prior art is no more than the description of a study that disclosed absolutely nothing regarding efficacy, included specific criteria for early termination, and—insofar as it was modified after publication—was never realized.<sup>169</sup> “Inherency follows from the carrying out of an activity that inherently produces what is claimed; [it] does not arise from a plan whose description does not indicate its realization.”<sup>170</sup>

*In re Montgomery* thus departs from prior cases on inherency, not only by finding necessity despite evidence that the undisclosed characteristics were not always produced by the prior art but also by finding necessity through the mere design of a study that was never carried out.<sup>171</sup> If inherency can be established through prior art as indeterminate as a description of a proposed study, the scope of inherent anticipation is dangerously boundless.<sup>172</sup> Indeed, “every

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165. See Brief for Appellant, *supra* note 102, at 2–4 (reproducing the results of the AIRE study to demonstrate ramipril increased the risk of stroke by 43 percent, or at minimum had no effect on stroke prevention).

166. *In re Montgomery*, 677 F.3d at 1381 n.11 (majority opinion).

167. See *United States v. Adams*, 383 U.S. 39, 52 (1966) (“[K]nown disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.”); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550–51 (Fed. Cir. 1983) (the totality of a reference’s teachings must be considered in an obviousness analysis). See also *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (discussing the relationship between a prima facie face of obviousness and teaching away as a secondary consideration capable of rebutting a prima facie showing of obviousness).

168. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995).

169. See *In re Montgomery*, 677 F.3d at 1378; *id.* at 1385 (Lourie, J., dissenting).

170. *Id.* at 1385 (Lourie, J., dissenting).

171. *Id.*

172. *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 976 (Fed. Cir. 2001) (Newman, J., dissenting from denial of petition for rehearing en banc).

biological property is the natural and inherent result of the chemical structure from which it arises.”<sup>173</sup> Thus, under the law of inherency as announced in *In re Montgomery*, the mere recitation of a process involving a prior art compound, with essentially no enabling disclosure, is sufficient to negate a later patent directed at that process, regardless of whether the prior art disclosed efficacy or was intended to cure the ailment at issue.<sup>174</sup>

Predictability is always important in law, but uncertainty is particularly problematic in the pharmaceutical context.<sup>175</sup> Given the staggering cost of pharmaceutical research and development, pharmaceutical companies need to have a clear understanding of what will anticipate and what will not, so as to invest prudently.<sup>176</sup> Moreover, while there are various types of litigation insurance a company can take out to protect against unanticipated changes in the law, there is no insurance that can ameliorate the negative consequences of a patent being invalidated due to shifting articulation of the law.<sup>177</sup>

### *B. Bright-Line Rules are Often Inadequate at Protecting the Policy Interests at Stake in Patent Law*

The purpose of § 102 is to ensure that a claimed invention does not take something away from the public that was already in their possession.<sup>178</sup> To that end, it is consistent with the public policy behind patent law for a prior art publication to anticipate without expressly disclosing all limiting characteristics of the later claimed

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173. *Id.*

174. *See id.*; *see also In re Montgomery*, 677 F.3d at 1378–83 (invalidating patent as inherently anticipated even where prior art did not disclose efficacy).

175. *E.g., Montgomery*, 677 F.3d at 1383–84 (Lourie, J. dissenting).

176. *See supra* Part II.

177. *See generally Insurance Coverage*, A.B.A. (Jan. 17, 2003), <http://apps.americanbar.org/litigation/committees/insurance/> (discussing litigation insurance coverage). Intellectual property insurance generally comes in two forms: (1) “defensive” insurance that allows companies to insure their assets against future infringement claims, and (2) “offensive” insurance—known as abatement insurance—for companies seeking to bolster their ability to enforce their intellectual property rights. Ian McClure, *Intellectual Property Insurance: Transforming the Economic Model for IP Litigation*, 57 *FED. LAW.* 18, 18 (2010). Of course, these forms of insurance cover the costs of litigating patent infringement; they do not indemnify a patent holder against future losses that stem from an inability to enforce patent rights subsequent to a finding of patent invalidity. *Id.*

178. *See Montgomery*, 677 F.3d at 1385 (Lourie, J., dissenting); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

invention, even where no one recognizes the undisclosed result.<sup>179</sup> Indeed, there is no language in § 102 that discusses recognition or even inevitability.<sup>180</sup> Rather, both are judicial creations that seek an appropriate balance—ensuring that subject matter already within the public domain is not later taken away from the public on the one hand, and fostering scientific research and development through patent grants on the other.<sup>181</sup>

In the early shift away from *Continental Can's* bright-line recognition requirement in *Atlas Power*, Judge Rader's assertion that inherency and recognition are not necessarily coterminous accurately summarizes the relationship between public disclosure and the patent policy of promoting scientific progress.<sup>182</sup> Judge Rader's opinion in *Atlas Powder* acknowledges that there are times when recognition is not relevant to an anticipation analysis, such as patents involving compositions of matter.<sup>183</sup> These patents are different because a patent on a composition of matter provides the patentee with the exclusive right to exclude all uses of the composition.<sup>184</sup> This holds true in *Schering*, where DCL, the metabolite of loratadine, formed upon human metabolization of loratadine.<sup>185</sup> DCL is a composition of matter; thus, a patent on DCL carries with it the right to exclude the public from using DCL in any form, including the use of loratadine, given that DCL necessarily forms upon consumption of loratadine.<sup>186</sup>

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179. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373 (Fed. Cir. 2003); *Atlas Powder*, 190 F.3d at 1347.

180. 35 U.S.C. § 102(b) (2000).

181. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005).

182. *See Atlas Powder*, 190 F.3d at 1347.

183. *Id.*

184. *See* 35 U.S.C. § 101 (listing composition of matter as patentable subject matter); § 271(a) (providing remedy for infringement).

185. *Schering*, 339 F.3d at 1375–76 (Fed. Cir. 2003).

186. This was the very premise of Schering's infringement action against Geneva, i.e., that use of loratadine necessarily leads to production of the metabolite DCL. *Id.* Indeed, Judge Newman's dissent from the denial of rehearing en banc in *Schering* implies that the majority was overly concerned with the issue of infringement and whether it would be equitable to permit infringement in the situation presented in *Schering*. *See Schering Corp. v. Geneva Pharm., Inc.*, 348 F.3d 992, 993–94 (Fed. Cir. 2003). Newman believes the panel reached the appropriate result—that is, a finding of no liability—but that they took the wrong steps and muddled the law of inherency to arrive there. *Id.* Instead of deciding the case on infringement grounds, which may or may not have required the crafting of an exception of some sort, Newman argues the panel misapplied inherency law to invalidate the patent. *See id.* (“[I]nstead of simply ruling that

Conversely, a method of use patent, such as the one at issue in *In re Montgomery*, applies only to a particularized, i.e., problem specific, process; that process must be carried out in full for infringement liability to attach.<sup>187</sup> The claims at issue in *In re Montgomery* only involved application of ramipril for stroke treatment, and would not remove ramipril from the public domain in the same manner that Schering's DCL patent did. Even if Montgomery's patent issued, ramipril could be used to treat hypertension, as it had been used before Montgomery's patent application or the HOPE study.<sup>188</sup>

At least with respect to method of use patents in the pharmaceutical context, recognition seems to play some indirect role in deciding whether the public actually possessed the inherent characteristic of efficacy, whether the disclosure was enabling, and whether the undisclosed result was inevitable based on the prior art.<sup>189</sup> There is little question that ramipril does effectively treat stroke,<sup>190</sup> but the primary concern in *In re Montgomery* was whether HOPE inherently disclosed that effective treatment before Montgomery's patent application. If no one—including the HOPE authors—recognized the stroke-preventing characteristics of ramipril, can the public really be said to “possess” this knowledge in the same way they possessed the DCL compound? A PHOSITA was not put on notice that ramipril treats stroke based on the HOPE disclosure's description of a proposed research study.<sup>191</sup> Therefore, although a per se recognition requirement is unnecessary, the concept

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Schering cannot prevent the practice of the expired patent in accordance with its teachings, the panel strains to hold that this newly discovered, previously unknown product cannot be validly patented. That is not the law. [Newman] also point[ed] out that the issue here is validity, not infringement.”).

187. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378–79 (“Direct infringement requires a party to perform or use each and every step or element of a claimed method or product.”); *see also id.* at 1379 (citing *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993)) (“For process patent or method patent claims, infringement occurs when a party performs all of the steps of the process.”).

188. Montgomery's claims only involved a method of administering ramipril to stroke prone patients. *In re Montgomery*, 677 F.3d 1375, 1376–77 (Fed. Cir. 2012); *see also* U.S. Patent No. 20,050,192,326 (filed Apr. 29, 2005) (Montgomery's patent application). He did not, and could not have, claimed exclusive rights in the compound ramipril.

189. *Montgomery*, 677 F.3d at 1383–85 (Lourie, J., dissenting).

190. *Id.* at 1378 n.8 (majority opinion); *see also* HOPE II, *supra* note 104, at 148 tbl.3 (publishing results of the HOPE study).

191. *See Montgomery*, 677 F.3d at 1385 (Lourie, J., dissenting).

of recognition should play some role in informing the otherwise relevant inherency inquiries,<sup>192</sup> at least in pharmaceutical patent cases.<sup>193</sup> Yet the majority of the Federal Circuit's categorical rejection of recognition, and anything that resembles recognition, forecloses the ability to pursue this seemingly inescapable overlap.<sup>194</sup>

Inherency is further obfuscated by the *In re Montgomery* majority's rejection of the argument that the AIRE study foreclosed a finding of inevitability. AIRE was published just before HOPE and found that ramipril either increased stroke risk or had no meaningful effect on stroke prevention.<sup>195</sup> This seems to indicate that the natural result of the operation as taught was not necessarily treatment or prevention of stroke.<sup>196</sup> The majority in *In re Montgomery* was so quick to resort to a bright line rejection of "teaching away" as a consideration limited to obviousness that it failed to consider the implications on the question of inevitability.<sup>197</sup> It seems questionable that an undisclosed result can be said to "necessarily" flow from a publication describing a proposed study that took no position on its outcome, was modified after publication, and did not produce results for nearly a half decade.<sup>198</sup> But it is entirely implausible that an undisclosed result necessarily flows from such a disclosure when a similar process, carried out beforehand, produced contradictory results.<sup>199</sup> Despite these shortcomings, the majority of the Federal Circuit panel in *In re Montgomery* found inherency.<sup>200</sup>

If the Federal Circuit's precedent on inherent anticipation teaches us anything, it is that rigid, bright-line rules fail to adequately address the public policy goals of patent law.<sup>201</sup> By focusing the inherency analysis on bright-line definitions of inevitability and enablement and by categorically rejecting recognition, the Federal Circuit's recent inherency cases produce results that are not only

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192. *E.g.*, inevitability, enablement, and the policy germane to inherency.

193. *See, e.g.*, *Montgomery*, 677 F.3d at 1385–86 (Lourie, J., dissenting).

194. *See id.* at 1381–83 (majority opinion).

195. *Id.* at 1381 n.11.

196. *Cf.* *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995).

197. *Montgomery*, 677 F.3d at 1381.

198. *See id.* at 1385 (Lourie, J., dissenting).

199. *Id.*

200. *Id.* at 1383 (majority opinion).

201. *See id.* at 1383–84 (Lourie, J., dissenting).

unpredictable but also questionable in light of the patent policy at issue.<sup>202</sup>

The Supreme Court has previously highlighted the ineffectiveness of bright-line rules in another area of patent law.<sup>203</sup> In *KSR International Co. v. Teleflex Inc.*,<sup>204</sup> the Court rejected the Federal Circuit's bright-line test for obviousness finding "[r]igid preventative rules that deny factfinders recourse to common sense . . . [are] neither necessary under . . . nor consistent with" the Court's precedent.<sup>205</sup> Instead of supporting a bright-line rule, the Supreme Court instructed the Federal Circuit to apply an "expansive and flexible approach" to the question of obviousness.<sup>206</sup> Despite announcing this "common sense" approach to obviousness, the Court was sure to underscore the fact that its precedent "recognized the need for 'uniformity and definiteness'" in patent law matters.<sup>207</sup> However, because obviousness—like inherency—applies to the entire gambit of patentable subject matter, the Court found that a "functional approach" to obviousness was the appropriate choice.<sup>208</sup> An expansive and flexible approach to the question of inherency is equally necessary, especially in the context of pharmaceutical patents, given Congress's unique treatment of pharmaceuticals under Hatch-Waxman.<sup>209</sup>

#### IV. A FLEXIBLE, COMMON SENSE APPROACH TO INHERENCY

To resolve the lack of predictability in inherent anticipation once and for all, the Federal Circuit needs to do what it could have done decades ago after *Continental Can* was decided: take an inherent anticipation case en banc and set forth a clear standard for inherent

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202. *See id.*

203. *See* *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

204. *Id.*

205. *Id.* at 421.

206. *Id.* at 415–16.

207. *Id.* (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966)).

208. *Id.* (citing *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850)).

209. *See* 35 U.S.C. §§ 156, 271 (2004) (Hatch-Waxman patent term restoration). *See also* De La Rosa, *supra* note 49, at 83 (arguing Hatch-Waxman demonstrates that Congress recognizes the uniqueness of pharmaceutical patents and consequently that Congress should address the troubling consequences of inherency cases like *Schering* and *SmithKline Beecham* in order to allow pharmaceutical companies to maximize the value of their research and development).

anticipation so as to dispel confusion and properly bind the court.<sup>210</sup> Presently, given that a three-judge Federal Circuit panel cannot overrule any other panel's decision, earlier inherency decisions technically remain good law alongside the conflicting opinions in cases such as *In re Montgomery*.<sup>211</sup> The need for clarification and establishment of a solid foundation en banc thus cannot be overstated.<sup>212</sup> In announcing its definitive inherency decision en banc, the Federal Circuit need not adopt a "new" rule.<sup>213</sup> Instead, the Federal Circuit should align the inherency test with the obviousness analysis mandated by the Supreme Court in *KRS International Co.*<sup>214</sup> By taking an "expansive and flexible" approach to inherent anticipation, more complicated technology will not fall prey to bright-line rules, which might be appropriately applied to less

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210. In addition to calling for en banc consideration of the issue, there is a possibility that the scope of inherency could be made clear through a grant of certiorari from the United States Supreme Court. *See, e.g.,* Eibel Process Co. v. Minn. & Ontario Paper Co., 261 U.S. 45 (1923); Tilghman v. Proctor, 102 U.S. 707 (1880). In fact, *Montgomery* filed a petition for certiorari on August 6, 2012. *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012), *petition for cert. filed*, 2012 WL 3229399 (U.S. Aug. 6, 2012) (No. 12-182). However, the Court denied the petition for certiorari on December 10, 2012, foreclosing any chance for additional review in *In re Montgomery*. 677 F.3d 1375 (Fed. Cir. 2012) *cert. denied*, 133 S. Ct. 788 (2012).

211. Only en banc consideration of an issue permits the Federal Circuit to repudiate prior panel decisions. In the Federal Circuit's first case, *South Corp. v. United States*, the court, sitting en banc, adopted all the prior precedent of the Court of Claims and the CCPA. 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc). The court noted it had the right to overrule any prior CCPA precedents, as well as any panel decisions that were later deemed improper, through en banc consideration. *Id.* at 1370 n.2.

212. The Federal Circuit has recognized the importance of en banc hearings. A recent en banc decision cites Justice Scalia, who in a 1998 letter to the Commission on Structural Alternatives for the Federal Courts of Appeals, wrote: "[T]he function of en banc hearings . . . is not only to eliminate intra-circuit conflicts, but also to correct and deter panel opinions that are pretty clearly wrong . . . . The disproportionate segment of [the Supreme Court's] discretionary docket that is consistently devoted to reviewing [a regional court of appeals'] judgments, and to reversing them by lopsided margins, suggests that this error-reduction function is not being performed effectively. *Pfizer, Inc. v. Apotex, Inc.*, 488 F.3d 1377, 1381 (Fed. Cir. 2007) (en banc) (citing *Hearing Before the S. Subcomm. on Admin. Oversight and the Courts of the S. Comm. on the Judiciary*, 106th Cong. 72 (1999) (letter dated Aug. 21, 1998)).

213. The Federal Circuit may well disagree with the proposal set forth herein, but that does not change the need for reconsideration en banc or the fact that their present case law is questionable in light of the patent policy inherency is meant to foster. Though this Note takes the position that some post-*Schering* cases have been decided contrary to the patent policy behind inherency, another critical issue is that of inadequate guidance, i.e., predictability. The Federal Circuit can still rectify the inconsistencies of prior panel decisions, and properly bind the minority of the circuit that continues to adhere to pre-*Schering* cases, by taking a case en banc and announcing a rule of law consistent with the holding in *Schering*.

214. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

complex inventions. A “common sense” approach also has the added benefit of allowing for constant adaptation to the current state of science and the arts. Finally, by avoiding a bright-line requirement that inherency cannot ever be *X*, or that it must always involve *Y*, the court is better equipped to focus on the proper goal of inherency—protecting that which is already in the public domain from being wrenched away from the public by a patent.<sup>215</sup>

Under the “common sense” approach to inherency, the court would still ask whether the undisclosed result is inevitably present, or inherent, in the prior art and whether the prior art enabled a PHOSITA to practice the later claimed invention.<sup>216</sup> But in answering the question of inevitability, the court should be mindful of the purpose of § 102 and the system of patent protection generally.<sup>217</sup> Approached from this angle, the need for recourse to common-sense concepts such as recognition would not be denied when necessary to determine the extent to which the prior art inherently discloses, and therefore anticipates, later patent claims. There is no language in § 102 requiring either inevitability or enablement.<sup>218</sup> Rather, inevitability and enablement are judicial creations that seek to ensure that subject matter previously disclosed is not later removed from the public domain through a patent grant.<sup>219</sup> Thus, the common-sense approach to inherency in no way upsets the intent of Congress; to the contrary, it advances it by promoting the policy underlying the Patent Act, instead of focusing exclusively on judicially created concepts not expressly set forth in the statute.<sup>220</sup>

If the common-sense approach were applied to the facts of *Schering*, the outcome would be the same. The compound DCL was placed within the public domain by Schering’s loratadine patent because it formed naturally upon human metabolism.<sup>221</sup> DCL

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215. See *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *In re Montgomery*, 677 F.3d at 1385 (Lourie, J., dissenting).

216. See, e.g., *In re Montgomery*, 677 F.3d at 1379–80 (majority opinion) (discussing the facts necessary to establish anticipation through inherency).

217. See 35 U.S.C. § 102 (2012).

218. *Id.*

219. See *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005).

220. Compare *id.* (discussing purpose of inherency), with 35 U.S.C. § 102(b) (discussing the novelty requirement and setting forth the statutory basis for anticipation).

221. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003).



exists as a necessary part of loratadine, and even more importantly, Schering's prior art patent on loratadine disclosed the efficacy of administration of loratadine and administration to humans.<sup>222</sup>

Conversely, if the common sense test for inherency were applied in *In re Montgomery*, it would be clear that the majority erred in finding that HOPE anticipated Montgomery's claims. HOPE did not inform the public that ramipril administration to stroke-prone patients decreased the risk of stroke.<sup>223</sup> No cardiologist could have prescribed ramipril to treat stroke based on HOPE's proposed tests of ramipril, nor would a PHOSITA have been placed on notice of the fact that ramipril treats or prevents stroke. For that, the HOPE authors asked the public to wait another four years.<sup>224</sup> Meanwhile, when Montgomery filed his patent application, he disclosed that ramipril does, in fact, treat or prevent stroke,<sup>225</sup> and he bestowed upon the public something heretofore unknown—something novel. It follows that Montgomery's claims would not have been found invalid by inherency under the common-sense approach.

The common-sense approach to inherency is, by definition, not a strict, bright-line rule that can be readily applied with minimal effort. Rather, the utility of this approach is its ability to take into account the multifaceted nature of the technology covered by U.S. patent law so as to ensure "uniformity and definiteness"<sup>226</sup> without sacrificing the balance in patent policy concerning novelty, public disclosure, and inventorship.

## V. CONCLUSION

Predictability is among the most essential criterion of U.S. patent law. However, recent Federal Circuit decisions on inherent anticipation lack uniformity and predictability and, therefore, undermine the predictability of our patent system.<sup>227</sup> The need to

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222. *Id.*

223. *In re Montgomery*, 677 F.3d 1375, 1385 (Fed. Cir. 2012) (Lourie, J., dissenting).

224. *Id.*

225. As discussed *supra*, Montgomery's patent specification disclosed effective treatment or prevention of stroke by administering ramipril to stroke-prone patients. *See id.* at 1377 (majority opinion).

226. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966)).

227. *Compare Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991) (requiring recognition), *and Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995)

clarify the law of inherency en banc is thus of critical importance. While any clarification would help return patent law to some level of stability, the “common sense” approach proposed in this Note is specifically designed to maximize predictability while also promoting patent policy.

As it stands, the Federal Circuit’s conception of inherency is so vast that applications of drugs for purposes that were never before envisioned are patent ineligible, simply because the drug was later discovered to effectively treat that ailment.<sup>228</sup> The purpose of patent law is to promote the advancement of science and the useful arts,<sup>229</sup> but the current law of inherency encourages only new growth, not improvements.<sup>230</sup> Indeed, if claims like Montgomery’s, which build off of and improve previously patented subject matter, are invalid under the doctrine of inherency, the pharmaceutical industry is given little incentive to continue researching and developing the effectiveness of previously patented pharmaceuticals.<sup>231</sup> When pharmaceuticals like ramipril can help prevent stroke-related death, but such characteristics were unknown at the time of patenting, it makes little sense to say that the person who discovered the previously unknown quality is less deserving of patent protection than the initial inventor, who knew nothing of the additional characteristics.<sup>232</sup> Moreover, given the recent “bad drug” mass tort

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(demanding that the prior art produce the later claimed invention each and every time it is performed to find inherent anticipation), *with* Schering Corp. v. Geneva Pharm., 339 F.3d 1373 (Fed. Cir. 2003) (rejecting recognition), *and In re Montgomery*, 677 F.3d 1375 (finding inherency despite evidence that the claimed method produced contradictory results).

228. *See, e.g., In re Montgomery*, 677 F.3d at 1377–83.

229. *See* U.S. CONST. art. I, § 8, cl. 8.

230. *Cf.* 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

231. For example, Montgomery was seeking to expand our knowledge of the efficacy of ramipril, yet, under the current doctrine of inherency, his patent was invalidated, providing him—and the rest of the industry—no incentive to engage in similar conduct in the future. *See In re Montgomery*, 677 F.3d at 1377–83 (invalidating method of use patent involving administration of previously patented compound as inherently anticipated).

232. *See id.* at 1383–85 (Lourie, J., dissenting); *see generally* Eibel Process Co. v. Minn. & Ontario Paper Co., 261 U.S. 45, 66 (1923) (citing *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880)) (“[I]f [the prior art] had [brought about the result sought by the patent applicant] under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.”).

cases, public policy clearly favors encouraging additional research and development on patented pharmaceuticals.<sup>233</sup>

The common-sense approach to inherency seeks to promote patent policy and protect both inventors and the public. At the same time, by requiring the court to focus on the purpose of § 102, instead of simply allowing discussion of the words long ago imposed to address that same purpose, the common-sense approach seeks to restore uniformity and predictability to the doctrine of inherency, and to patent law as a whole.

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233. One such example is the Vioxx litigation. *See, e.g.*, Duff Wilson, *Merck to Pay \$950 Million Over Vioxx*, N.Y. TIMES, Nov. 22, 2011, [http://www.nytimes.com/2011/11/23/business/merck-agrees-to-pay-950-million-in-vioxx-case.html?\\_r=0](http://www.nytimes.com/2011/11/23/business/merck-agrees-to-pay-950-million-in-vioxx-case.html?_r=0). This is not to imply that Merck did not continue testing Vioxx, but in light of the fact that even drugs that receive FDA approval can turn out to be dangerous, public policy certainly favors laws encouraging additional research on previously patented drugs that are already being marketed for other purposes. *Cf. In re Montgomery*, 677 F.3d at 1377–85 (invalidating method of use patent involving administration of previously patented compound to treat or prevent stroke as inherently anticipated, even where no prior art reference indicated the method of use effectively treated or prevented stroke).