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“Undetected, Unsuspected, and Unknown”: Should We Anticipate Problems for Scientific Innovation Following *Schering Corp. v. Geneva Pharmaceuticals*?

Jeffrey Coleman

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**“UNDETECTED, UNSUSPECTED, AND
UNKNOWN”:
SHOULD WE ANTICIPATE
PROBLEMS FOR SCIENTIFIC INNOVATION
FOLLOWING *SCHERING CORP. V. GENEVA
PHARMACEUTICALS*?**

*Jeffrey Coleman**

Once termed the “metaphysics” of patent law, the doctrine of inherent anticipation has befuddled courts and practitioners alike for decades. Inherent anticipation refers to the notion that a previously published reference can disclose each and every limitation of a later-patented invention without expressly delineating those limitations. These (un)disclosed limitations are necessarily present, or inherent, within the previously published reference. When a previously published reference discloses a later-claimed invention expressly or inherently, the patent covering the later-claimed invention is invalid because the invention lacks novelty. Thus, the doctrine of inherent anticipation allows invalidation of a patent in whole or in part upon a showing that a prior reference contained a patentee’s later-disclosed invention, even if the earlier reference did not expressly disclose what the patentee claimed as his invention.

Courts, including the Federal Circuit, have grappled with whether a person having ordinary skill in the relevant art must recognize inherent features in the prior art reference for the doctrine of inherent anticipation to apply. The resulting intracircuit split in Federal Circuit case law fostered two competing schools of thought on this issue. The Federal Circuit eventually held that recognition of inherent features is not required. Commentators, however, have called upon the court to revisit the doctrine due to its potential chilling effects on innovation. This Note suggests that the Federal Circuit should reexamine the doctrine, paying particular attention to considerations of whether or not a person having ordinary skill in the art was capable of identifying inherent features in the asserted prior art reference. Clarification, or even outright reformation, of the inherent anticipation doctrine grows more imperative as our technological capabilities quickly outpace our legal rules.

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INTRODUCTION

Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for “a method of making a fire by lighting a flame in the presence of oxygen.” Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires.¹

The doctrine of inherent anticipation has been described as “a puzzle that runs throughout patent law,”² a “troublesome area of U.S. patent law,”³ and

1. *EMI Grp. N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001).

2. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 372 (2005).

3. Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1102 (2008).

a “doctrinal morass.”⁴ The cases forming the underlying basis for the doctrine of inherent anticipation are confusing, at best, and the resulting opinions invoking the doctrine are confused, at worst.⁵

At its core, the doctrine of inherent anticipation functions to preclude patent protection for new inventions when a previously published reference discloses “each and every limitation”⁶ of the invention sought to be patented.⁷ U.S. patent laws prescribe that only new inventions may be patented.⁸ Obviously, an invention is not new (i.e., novel) when it already exists, and is therefore ineligible for patent protection.⁹ Similarly, an invention is not patentable if it has been expressly described in the prior art (such as in previously filed specifications in patent applications, journal articles, or other printed publications).¹⁰ However, “[t]echnologies may have qualities that are unappreciated or unidentified in a patent description, but which are nonetheless present. The law refers to these unknown attributes as ‘inherent’ in the product or process.”¹¹ The doctrine of inherency allows for invalidation of a patent, in whole or in part, when a prior art reference *does not* expressly disclose each and every limitation of the claimed invention.¹² A patent is not novel (or patentable) for inherency when a single prior art reference inherently describes a missing feature of the claimed invention, so long as the missing feature is a deliberate or a

4. *Id.* at 1103.

5. See Burk & Lemley, *supra* note 2, at 373 (“The cases appear to flatly contradict each other, are often accompanied by dissents, and in the last three years alone have triggered one abortive *en banc* rehearing and strong calls for a second.” (citation omitted)).

6. See *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891) (“[T]he object of the patent law in requiring the patentee to particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery, is not only to secure to him all to which he is entitled, but to apprise the public of what is still open to them.” (internal quotation marks omitted)).

7. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003), *reh’g denied*, 348 F.3d 992 (Fed. Cir. 2003) (*en banc*).

8. See 35 U.S.C. § 102 (2006). Further conditions for patentability are outlined in Title 35 of the U.S. Code. Briefly, an invention is eligible for patent protection when it is new, useful, nonobvious, and directed at statutorily acceptable subject matter. See *id.* §§ 101–03. The first paragraph of section 112 further demands that patent applicants set forth a written description sufficient to prove that they possessed the claimed invention at the time of the application filing, this description must be enough to enable one skilled in the art to make and use the invention. See *id.* § 112, para. 1; see also *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (*en banc*) (holding that the first paragraph of § 112 contains a written description requirement separate from enablement). Finally, the patent application must conclude with claims particularly delineating the bounds of the invention. See 35 U.S.C. § 112, para. 2.

9. See 35 U.S.C. § 102. An invention that is determined not to be novel is said to be “anticipated.” See *infra* Part I.A.

10. See 35 U.S.C. § 102. Specifically, section 102(b) states, “A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent.” Essentially, the prior art, or the current state of the art, sets forth the technological background against which the novelty and nonobviousness of an invention are examined. See C. Douglas Thomas, *Secret Prior Art—Get Your Priorities Straight!*, 9 HARV. J.L. & TECH. 147, 148 (1996).

11. Burk & Lemley, *supra* note 2, at 372.

12. See *Schering Corp.*, 339 F.3d at 1377.

necessary consequence of what was intended.¹³ The Federal Circuit has explained that the doctrine of inherent anticipation requires certainty of result.¹⁴ If the missing feature of the invention is determined to be present in a prior art reference as a result of an accident, the doctrine of inherent anticipation is not invoked and the patent covering the invention is not invalid for inherent anticipation.¹⁵

For decades, the case law invoking the doctrine suffered from conflicting opinions on one particular issue: must a person having ordinary skill in the art (commonly referred to as “PHOSITA”)¹⁶ recognize the existence of the missing (inherent) feature?¹⁷ Some cases explained that a PHOSITA must recognize the inherent feature before the doctrine may be used to defeat a patent or some of its claims;¹⁸ others held the exact opposite, explaining that inherent anticipation precludes patentability so long as the inherent feature is an inevitable consequence of practicing the prior art, whether or not PHOSITA recognizes the inherent feature.¹⁹ In its seminal—and controversial—2003 decision, *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,²⁰ the Federal Circuit explained that the doctrine of inherent anticipation does not require recognition of the inherent feature by a PHOSITA.²¹

In *Schering Corp.*, the Federal Circuit invalidated a patent claim to a metabolite²² as inherently anticipated in light of the prior art, in this case a patent for the parent drug.²³ The court explained that the patent for the parent drug precluded patentability of all of its future metabolites, presently known or unknown, since all metabolites would necessarily be formed when an individual ingests the parent drug.²⁴ The *Schering Corp.* decision

13. See 1 DONALD S. CHISUM, CHISUM ON PATENTS, § 3.03[2][c] (2013) (citing *Glaxo Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 877 (E.D.N.C. 1993), *aff'd*, 52 F.3d 1043 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 988 (1995) (finding that a method set forth an example in one patent did not inherently anticipate claims to a variant form of a compound claimed in a second patent because the “proper practice” of the example sometimes resulted in the claimed form and sometimes resulted in another form)).

14. See *Schering Corp.*, 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.” (emphasis added) (citing *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991))).

15. See *Tilghman v. Proctor*, 102 U.S. 707, 711–12 (1880).

16. For a more detailed description of the hypothetical person having ordinary skill in the art (PHOSITA), see *infra* Part I.

17. See *infra* Part II.

18. See *infra* Part II.A.

19. See *infra* Part II.B.

20. 339 F.3d 1373 (Fed. Cir. 2003).

21. See *id.* at 1377 (“At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art.”).

22. See *id.* at 1375 (“A metabolite is the compound formed in the patient’s body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound.”).

23. See *id.* at 1380.

24. See *id.* (“[T]he record shows that a patient ingesting [the parent drug] would necessarily metabolize that compound to [a metabolite]. That later act would thus [be an act

diverged from earlier precedent, however, in its holding vis-à-vis metabolites: all future metabolites of a patented parent drug—whether or not they are recognized by a PHOSITA at the time the parent drug is patented—are inherently anticipated²⁵ by the parent drug and are ineligible for patent protection.²⁶

Several commentators believe that the *Schering Corp.* decision represents a carefully considered balancing act by a Federal Circuit attempting to preserve the goals of the patent system²⁷—namely, to foster innovation by providing inventors with an exclusive time-limited monopoly to make their invention on the one hand, and ensuring that the public receives the benefit of the invention via full disclosure on the other.²⁸ The *Schering Corp.* decision may be explained in light of these public policy goals; perhaps the court was concerned with what it perceived to be patent “evergreening.”²⁹

of patent infringement]. Thus, a prior art reference showing administration of [the parent drug] to a patient anticipates claims [to the metabolite].”).

25. Essentially, they are not “novel,” and fail the novelty requirement for patentability under 35 U.S.C. § 102 (2006).

26. See *Schering Corp.*, 339 F.3d at 1380–81.

27. See Cynthia Chen, *Schering Corp. v. Geneva Pharmaceuticals, Inc.: Clarification of the Inherent Anticipation Doctrine and Its Implications*, 20 BERKELEY TECH. L.J. 95, 96 (2005) (“The *Schering* decision represents an effort by the Federal Circuit to balance two conflicting goals of the patent system: to stimulate inventive efforts by giving inventors exclusive rights for a limited period and to allow the public at large to derive benefits from the advances in technology.”); 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, 87 (2007) (“*Schering* attempted to prevent generic drug manufacturers from practicing the . . . patent, even after it had entered the public domain. The Federal Circuit was understandably troubled by this notion.”); Mueller & Chisum, *supra* note 3, at 1163 (“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.”).

28. See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63–64 (1998) (citing *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 533–34 (1870)). In *Seymour*, the Supreme Court explained:

Letters patent are . . . public franchises granted to the inventors of new and useful improvements for the purpose of securing to them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress.

78 U.S. (11 Wall.) at 533–34.

29. Patent evergreening is not a formal patent law concept, but rather a strategy by which a patentee obtains, or attempts to obtain, multiple patents that cover different aspects of the same invention in an effort to extend the term of the patent and the exclusivity privileges that come with it. See *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378 n.6 (Fed. Cir. 2002) (noting that new drug application (NDA) holders may evergreen their patents “by filing a series of applications for different patents covering the same basic drug”); see also Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD & DRUG L.J. 245, 250 (1999) (explaining that by filing and refiling “improvement” patents for the same basic drug—such as disectable tablets, special coatings, new formulations, crystalline forms of the same drug, and variations on drug delivery technologies—companies may essentially “evergreen their

Although the effect the opinion will have on scientific innovation is debatable,³⁰ the rule promulgated under *Schering Corp.* has effectively settled the argument for the time being about whether a PHOSITA must recognize the inherent feature, unless and until the Supreme Court weighs in.

In the *Schering Corp.* opinion, the Federal Circuit provided some guidance to future patent drafters about how to circumvent the inherent anticipation doctrine with respect to metabolites.³¹ In light of the rapid advancement of the study of metabolites, and an ever-expanding base of scientific knowledge in general, however, it behooves the Federal Circuit to reexamine the inherent anticipation doctrine. This Note focuses on the evolution and application of the inherent anticipation doctrine in the case law.

Part I of this Note begins by providing a brief introduction to U.S. patent law. Specifically, it focuses on the statutory provisions regarding novelty and anticipation. It also outlines the evolution of the inherent anticipation doctrine from early U.S. Supreme Court jurisprudence.

Part II examines the intracircuit split that developed within the Federal Circuit as the court struggled to determine whether PHOSITA recognition of the inherent feature was necessary for a finding of inherent anticipation. It then describes the Federal Circuit's seminal decision in *Schering Corp.* and predicts the future of metabolite research in the wake of the controversial rule that PHOSITA recognition is dispensable in an inherent anticipation analysis.

Finally, Part III examines proposals for changes to the inherent anticipation doctrine. This Note then argues for a new "capability" standard that would focus on what a PHOSITA was capable of discovering at the time the prior art was published. This Note concludes by arguing that much of the confusion in the inherent anticipation doctrine may be avoided by simply focusing on what an inventor was capable of identifying at the time of the prior art.

I. A PATENT LAW PRIMER

Mark Twain famously opined, "I knew that a country without a patent office and good patent laws was just a crab, and couldn't travel any way but sideways or backwards."³² The U.S. Constitution expressly mandates the patent system, which in turn provides to inventors a time-limited monopoly to make and practice their inventions, and to exclude others from doing the

drug patents"). One such evergreening example relevant to this Note could be the attempted patenting of a derivative of an existing drug.

30. Compare Chen, *supra* note 27 (arguing that the necessary and inevitable consequence test promulgated under *Schering Corp.* will not harm future metabolite research), with De La Rosa, *supra* note 27 (arguing that the inherent anticipation doctrine will endanger pharmaceutical innovation and encourage recourse to trade secrets).

31. See *Schering Corp.*, 339 F.3d at 1381; see also *infra* Part II.C.

32. MARK TWAIN, A CONNECTICUT YANKEE IN KING ARTHUR'S COURT 72 (Bernard L. Stein ed., Univ. of Cal. Press 3d ed. 1979) (1889).

same.³³ To be eligible for patent protection, however, an invention must satisfy the basic requirements for patentability;³⁴ specifically, the invention must be new (i.e., novel), useful, and nonobvious. The requirement that an invention be novel, prescribed by 35 U.S.C. § 102, is the cornerstone of the patent system.³⁵ Novelty is defeated, however, when the invention already exists.³⁶

To examine novelty, courts scrutinize the claimed invention in light of the “prior art,”³⁷ which represents the entirety of the “preexisting knowledge and technology already available to the public.”³⁸ The public policy behind the novelty provision is to promote efficient research—to put “libraries before laboratories, investigation before investment.”³⁹ A previously published document asserted against a claimed invention to defeat its novelty is commonly referred to as a “prior art reference.”⁴⁰ A prior art reference defeats novelty when (1) it predates the applicant’s invention, (2) it discloses each and every limitation⁴¹ of the claimed invention (either expressly or inherently), and (3) it is enabling (the reference teaches a person having ordinary skill in the art how to make and use the invention without undue experimentation).⁴² When a prior art

33. See U.S. CONST. art. 1, § 8, cl. 8 (“The Congress shall have Power . . . To 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.”). An applicant whose invention satisfies the requirements of novelty, nonobviousness, and utility, and who discloses his invention to the public is granted “the right to exclude others from using, offering for sale, or selling the invention throughout the United States” for a period of 20 years. 35 U.S.C. § 154 (2006).

34. See *id.* §§ 101–03.

35. See *id.* § 102; see also MARTIN J. ADELMAN ET AL., PATENT LAW IN A NUTSHELL 75 (2008) (“Novelty, the most fundamental characteristic of patentability, ensures that an inventor has truly created something new.”).

36. See ADELMAN ET AL., *supra* note 35, at 75.

37. See 35 U.S.C. § 102. “Prior art” may refer to any printed publication, issued patent, or other document asserted against the claimed invention to defeat its novelty.

38. Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 922 (2011); see also *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (“[T]he real reason for the denial of patent rights . . . is 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))).

39. ADELMAN ET AL., *supra* note 35, at 75.

40. Seymore, *supra* note 38, at 922.

41. Claim limitations stake out the limits of the patentee’s property right. See *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1248–49 (Fed. Cir. 1998) (“[T]he claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.”). Thus, claim limitations are the words of the claim detailing the specific elements of the invention. See ADELMAN ET AL., *supra* note 35 at 218–19 (explaining that claims must describe complex subject matter in terms broad enough to foresee and capture future related technology and narrow, or limited, enough to distinguish all past related technology).

42. Seymore, *supra* note 38, at 922–23. The PHOSITA is a legal fiction of patent law, considered to possess the normal skills and knowledge of a person in the field, without being a genius. See *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566 (Fed. Cir. 1987) (explaining that a PHOSITA is “not unlike the ‘reasonable man’ and other ghosts in the law”). The PHOSITA is similar to the reasonably prudent person in tort law, and his

reference successfully defeats the novelty of a claimed invention, that invention is said to be “anticipated.”⁴³ A finding of anticipation thus renders the invention unpatentable as a result of the technology already being within the public domain.⁴⁴ Part I.A first describes anticipation generally. Part I.B then traces the evolution of the inherent anticipation doctrine, as it grew out of an earlier doctrine termed “accidental anticipation.”

A. Anticipation Generally

A famous patent law adage recites, “That which infringes, if later, would anticipate, if earlier.”⁴⁵ A patent cannot issue on an invention or technology already within the public domain; to allow a patentee an exclusive monopoly over public technology is injurious to society as a whole and does not incentivize innovation.⁴⁶ The novelty provision guarantees to the public the right to make and use that which it already possesses.⁴⁷

An invention that is anticipated by the prior art is not novel.⁴⁸ Anticipation is a pure question of fact.⁴⁹ Courts assess anticipation using a two-step analysis: (1) by analyzing the current state of public knowledge as indicated by the prior art, and (2) by examining each prior art reference individually to determine if a single reference discloses each and every limitation of the claimed invention.⁵⁰ Assessing the novelty of a simple

hypothetical construction can change depending on several factors, such as “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

43. *See Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”).

44. *See ADELMAN ET AL.*, *supra* note 35, at 75–76.

45. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889).

46. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (stating that to allow a patentee a patent on an anticipated invention “would in fact injure the public by removing existing knowledge from public use”); *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966) (holding that it would be unconstitutional for Congress to authorize the issuance of patents that would remove existing knowledge from the public domain).

47. *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453–54 (Fed. Cir. 1984). The Federal Circuit stated:

That is the real meaning of ‘prior art’ in legal theory—it 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. Society, speaking through Congress and the courts, has said “thou shalt not take it away.”

Id.

48. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1367 (Fed. Cir. 1991) (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1574 (Fed. Cir. 1985)).

49. *See id.* (“[A]nticipation is a factual determination.”).

50. *See ADELMAN ET AL.*, *supra* note 35, at 76. The limitations of the claimed invention are defined by the claims in the patent application. *See id.* at 218. The claims are “the fence around the inventor’s property right,” defining the boundaries of the patentee’s right to

invention might be a relatively trivial task.⁵¹ Determining the novelty of an invention directed at more complex subject matter, however, proves an increasingly difficult endeavor.⁵² For example, consider the interesting case of *Titanium Metals Corp. v. Banner*.⁵³ In *Titanium Metals Corp.*, the patent at issue was directed at a titanium-nickel-molybdenum alloy that resisted corrosion in hot brine environments.⁵⁴ The patent recited three claims for a base titanium-nickel-molybdenum alloy consisting of 0.2 percent to 0.4 percent molybdenum and 0.6 percent to 0.9 percent nickel that could also contain iron.⁵⁵

The relevant prior art reference asserted against the patent to defeat its novelty was a highly technical three-page Russian article in the Russian language.⁵⁶ The article displayed graphical data generated by various titanium-nickel-molybdenum alloys, including one alloy having 0.25 percent molybdenum and 0.75 percent nickel by weight.⁵⁷ Although the Russian article did not disclose resistance to corrosion in hot brine environments, the court held that the Russian article anticipated Claims 1 and 2 because the alloy was not new; the Russian alloy clearly fell within the recited ranges of the claimed invention.⁵⁸

exclude others from making, using, selling, offering to sell, and importing inventive technology. *See id.* at 218.

51. *See* Seymore, *supra* note 38, at 923–25 (posing the example of a paper clip made from an alloy of titanium and nickel; thus, an anticipating prior art reference must disclose a paper clip made from titanium and nickel).

52. *See id.* For example, consider a patent directed at the chemical and biological arts that discloses a specific drug X. Patents directed at drug molecules are typically broad in scope, even though they disclose specific molecular structures, because the claims are drafted in such a manner as to ensnare every compound using the basic molecular backbone of the patented molecule. For example, U.S. Patent No. 5,422,351 is directed at “Bis-benzo or benzopyrido cyclohepta piperidene, piperidylidene and piperazine compounds” and their pharmaceutically acceptable salts having a particular structural formula, the claims of which encompass at least one novemdecillion (10^{60} , or one followed by sixty zeroes) separate compounds. *See* Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 1028 n.225 (2012); *see also* U.S. Patent No. 5,422,351 (filed June 21, 1991).

53. 778 F.2d 775 (Fed. Cir. 1985).

54. *See id.* at 776.

55. *See id.* The claims at issue recited:

1. A titanium base alloy consisting essentially by weight of about 0.6% to 0.9% nickel, 0.2% to 0.4% molybdenum, up to 0.2% maximum iron, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments.
2. A titanium base alloy as set forth in Claim 1 having up to 0.1% iron, balance titanium.
3. A titanium base alloy as set forth in Claim 1 having 0.8% nickel, 0.3% molybdenum, up to 0.1% maximum iron, balance titanium.

Id.

56. *See id.*

57. *See id.* at 776–77. This composition clearly falls within the claimed percentages recited within claims 1 and 2 of the patent.

58. *See id.* at 782 (“[C]laims 1 and 2 . . . properly construed . . . are anticipated under § 102 by the Russian article which admittedly discloses an alloy on which these claims read.”).

Biotechnology inventions⁵⁹ pose their own special problems when it comes to anticipation.⁶⁰ Notwithstanding the fact that laws of nature, physical phenomena, and abstract ideas are not patentable,⁶¹ a patentee must differentiate the claimed invention from any previously existing, naturally occurring compounds to satisfy the novelty requirement.⁶² This can be a daunting challenge, as much of life science research involves “the elucidation of biological mechanisms already long present in nature.”⁶³ A patentee can successfully differentiate his invention from a naturally occurring compound by isolating the compound in its purified form.⁶⁴ This challenge is especially difficult when the invention concerns metabolites.⁶⁵ For example, secondary metabolites, which are derived from primary metabolites, tend to be biologically synthesized in specialized cell types and at distinct developmental stages, limiting their existence in time and quantity.⁶⁶

A patentee that manages to extract, purify, and isolate a useful metabolite also faces a potential inherency problem.⁶⁷ The nature of biological research typically proceeds with some observable experimental finding only to be understood long after the discovery, if at all.⁶⁸ Thus, publication of an

59. This term refers to inventions in the biological, chemical and pharmaceutical arts.

60. See Paul G. Alloway, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 SUFFOLK U. L. REV. 73, 75 (2004) (“One problem with biotechnology inventions is that they often relate to discoveries of already-existing natural biological compositions or mechanisms.”).

61. See 35 U.S.C. § 101 (2006) (describing the statutory requirements for patentable subject matter). Section 101 states, “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.” *Id.* The Supreme Court held that section 101 is not so broad as to encompass naturally occurring biological or chemical products. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

62. See Alloway, *supra* note 60, at 75 (noting that inherency is “particularly problematic” for biotechnology inventions because they often relate to discoveries of already-existing natural biological compositions or mechanisms).

63. Jeffery M. Duncan, *The Court Is Listening*, LEGAL TIMES, Nov. 4, 2002, at 2.

64. See *In re Bergstrom*, 427 F.2d 1394, 1401–02 (C.C.P.A. 1970) (“[B]y definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference . . . perforce the ‘pure’ materials are ‘new’ with respect to them.”).

65. See Manuel F. Balandrin et al., *Natural Plant Chemicals: Sources of Industrial and Medicinal Materials*, 228 SCIENCE 1154, 1154 (1985) (noting the problems in extracting, isolating, and purifying primary and secondary metabolites); Gregory S. Walker et al., *Validation of Isolated Metabolites from Drug Metabolism Studies As Analytical Standards by Quantitative NMR*, 39 DRUG METABOLISM & DISPOSITION 433, 433 (2011) (stating that many metabolites are difficult and expensive to synthesize chemically).

66. See Balandrin, *supra* note 65, at 1154 (explaining that secondary metabolites are frequently accumulated by organisms in smaller quantities than primary metabolites).

67. See Alloway, *supra* note 60, at 75 (“Inherency is particularly problematic for modern biotechnology inventions. . . . [This is because] they often relate to discoveries of already-existing natural biological compositions.”).

68. See *id.* at 76 (“A second problem that biotechnology inventions often encounter is that particular observed biological results and underlying mechanisms of biological action are often not understood until well after publication of initial experimental findings.”).

initial finding can effectively preclude patent protection for a later understanding via the doctrine of inherent anticipation.⁶⁹

*B. From Unwitting Result to Necessary Consequence:
The Evolution of the Inherent Anticipation Doctrine*

Inherent anticipation grew out of an earlier doctrine referred to as accidental anticipation,⁷⁰ which was first discussed in the 1880 Supreme Court case *Tilghman v. Proctor*.⁷¹ The Supreme Court held in *Tilghman* that accidental production of a product, “unwittingly produced,” was not anticipatory over Tilghman’s invention.⁷² Tilghman’s patent was directed at a method of treating fats and oils by separating them into their respective component parts “by the action of water at a high temperature and pressure.”⁷³ The Court eventually found Tilghman’s patent not invalid for anticipation, noting that the process used by the accused infringer, following instructions in the prior art, was never fully understood or appreciated.⁷⁴ As the Court rather bluntly stated, “[They] certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids.”⁷⁵ Although some commentators would later disagree about the implications of the inherent anticipation doctrine, they agree that the Court seemed to emphasize a PHOSITA’s subjective appreciation in determining whether a prior art reference triggers accidental or inherent anticipation.⁷⁶

Tilghman, therefore, is a case of accidental anticipation, distinguished from inherent anticipation by several factors.⁷⁷ Although courts treat

69. *See id.* (noting that patenting biological and chemical entities is challenging in light of both the doctrine of inherent anticipation and technological limitations that often delay understanding).

70. *See* Anne Brown & Mark Polyakov, *The Accidental and Inherent Anticipation Doctrines: Where Do We Stand and Where Are We Going?*, 4 J. MARSHALL REV. INTELL. PROP. L. 63, 63–65 (2004). The phrase “accidental anticipation” is misleading; pursuant to this doctrine prior art does not anticipate under 35 U.S.C. § 102. *See id.*

71. *See generally* *Tilghman v. Proctor*, 102 U.S. 707 (1880).

72. *Id.* at 711. The Supreme Court continued:

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.

73. *Id.* at 709.

74. *See id.* at 711.

75. *Id.*

76. *See* Chen, *supra* note 27, at 98 (“The Court emphasized the importance of subjective appreciation in the anticipation analysis”); *see also* De La Rosa, *supra* note 27, at 45 (“The Court’s determination in *Tilghman* centers on the previous producer’s failure to appreciate what had occurred through its actions.”).

77. Paul G. Alloway lists several factors that the Federal Circuit considers in determining whether an accidental or inherent analysis is prudent, including:

whether the prior art intended the claimed composition or process; whether the prior art includes knowledge of the claimed composition or process; whether the prior art includes knowledge of the newly discovered result of the claimed process or knowledge of the newly discovered function of the claimed composition;

accidental and inherent anticipation as being separate legal theories,⁷⁸ pinpointing which factor or set of factors a court will emphasize in determining the type of anticipation is difficult.⁷⁹ As previously mentioned, a finding of inherent anticipation means that the patent-defeating result inevitably and logically follows from an analysis of the cited prior art.⁸⁰ The Federal Circuit's predecessor, the Court of Customs and Patent Appeals (CCPA), explained in *In re Oerlich*,

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.⁸¹

Allowing an applicant to possess intellectual property rights to a claimed feature or invention that is inherent in the prior art "is not the law"; such a policy would effectively "remove from the public that which is in the public domain by virtue of its inclusion in . . . the prior art."⁸² Although the boundary between accidental and inherent anticipation is unclear, courts are reluctant to provide patent protection for claimed inventions already available to the public.⁸³

*Eibel Process Co. v. Minnesota & Ontario Paper Co.*⁸⁴ is another case of accidental anticipation. In *Eibel Process Co.*, the Supreme Court considered a challenge to Eibel's patent, which was directed at an improved paper-making machine that elevated the pitch of paper-making wire.⁸⁵ The

whether the prior art includes knowledge of a claimed component in the claimed composition; whether the prior art includes knowledge of the function of a component in a prior art process or composition; whether the prior art performs the claimed process or makes or uses the claimed composition for a different purpose; whether the claimed composition is useful in the prior art; whether the claimed process is useful to achieve the claimed result in the prior art; and whether the claimed process performs occasionally or under unusual conditions in the prior art or the claimed composition is formed occasionally or under unusual conditions.

Alloway, *supra* note 60, at 91.

78. *See* *Am. Original Corp. v. Jenkins Food Corp.*, 696 F.2d 1053, 1059 (4th Cir. 1982) (holding that a patent directed to the hydraulic evisceration of mollusks was valid in light of accidental occurrences of incidental shearing in the prior art). *But see* *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375 (5th Cir. 1978) (finding a patent covering a method of processing and packaging of pork sausage invalid for inherent anticipation under the prior art, because "the discovery of the process' shelf life implications involved nothing that was new in its use or method of application").

79. *See* Alloway, *supra* note 60, at 91-93.

80. *See In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

81. *Id.* (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)).

82. *In re Wiseman*, 596 F.2d 1019, 1023 (C.C.P.A. 1979).

83. *See, e.g., Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1949) ("It is not invention to perceive that the product which others had discovered had qualities they failed to detect."); *In re Wiseman*, 596 F.2d at 1023; *In re Finsterwalder*, 436 F.2d 1028, 1033 (C.C.P.A. 1971) (affirming the rejections of claims in a patent application as obvious in view of the prior art).

84. 261 U.S. 45 (1923).

85. *See id.* at 52.

challengers cited prior art references that described machines that used a similar pitch solely for drainage purposes.⁸⁶ The Court found no evidence that any pitch of the wire, before Eibel, had produced Eibel's results, and that the challenger's results were produced under unusual conditions, "not intended and not appreciated."⁸⁷ While the Court did not find inherent anticipation, it did provide guidance for future courts, explaining that if the alleged discovery or invention advanced the art substantially, "then the court is liberal in its construction of the patent, to secure to the inventor the reward he deserves."⁸⁸

The circumstances giving rise to *Tilghman* and *Eibel Process Co.* are quite rare and, as a result, these cases continue to be good law.⁸⁹ Nevertheless, the accidental anticipation doctrine, received further clarification from the Supreme Court in 1949. In *General Electric Co. v. Jewel Incandescent Lamp Co.*,⁹⁰ the Court stated that simply finding latent qualities in an old discovery and adapting them to a useful end did not meet the exacting standards of the U.S. patent system.⁹¹ Discovery of an *existing* quality did not "advance the frontiers of science."⁹² The court's decision in *General Electric Co.* did, however, allow for the possibility of patent protection for the discovery of a *new* quality within an old invention, so long as it advanced the public's scientific knowledge.⁹³

Thus, *Tilghman*, *Eibel Process Co.*, and several lower court decisions that followed generally stand for the proposition that accidental achievements do not anticipate later inventions.⁹⁴ For example, the Second Circuit held that anticipation was not established when a prior user did not appreciate or have knowledge of the results, stating that "novelty is not negated by a prior accidental production of the same thing when the operator does not recognize the means by which the accidental result is accomplished, and no knowledge of them, or of the method of their employment, is derived from the prior use by any one."⁹⁵ The Third Circuit similarly held that prior production of an alloy, when unknown by its producers and unappreciated as a new product, was "without value as an anticipation."⁹⁶ Finally, the Sixth Circuit held that the prior accidental

86. *See id.* at 58.

87. *Id.* at 66 (citing *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880)).

88. *Id.* at 63.

89. *See De La Rosa, supra* note 27, at 45–46.

90. 326 U.S. 242 (1945).

91. *See id.* at 248–49.

92. *Id.* at 249.

93. *See id.* at 248–49.

94. *See, e.g., Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 66 (1923); *Tilghman v. Proctor*, 102 U.S. 707, 711–12 (1880); *Pittsburgh Iron & Steel Foundries Co. v. Seaman-Sleeth Co.*, 248 F. 705, 709 (3d Cir. 1918); *Toch v. Zibell Damp Resisting Paint Co.*, 233 F. 993, 997 (2d Cir. 1916); *Munising Paper Co. v. Am. Sulphite Pulp Co.*, 228 F. 700, 703–04 (6th Cir. 1915).

95. *Toch*, 233 F. at 995.

96. *Pittsburgh Iron & Steel*, 248 F. at 709.

production of the same invention with characteristics not recognized until the later patent issued did not constitute anticipation.⁹⁷

As this Note next describes, when the doctrine of accidental anticipation evolved into inherent anticipation, however, the Federal Circuit vacillated on the issue of whether or not PHOSITA recognition of the inherent characteristic was required for a finding of inherent anticipation.⁹⁸ Until the *Schering Corp.* decision essentially ended the debate in 2003, two schools of thought had emerged in an intracircuit split within the Federal Circuit regarding this issue.⁹⁹

II. A PERSON HAVING ORDINARY SKILL IN THE ART MUST (SOMETIMES) RECOGNIZE THE INHERENT FEATURE: AN INTRACIRCUIT SPLIT

Whether or not a prior art reference anticipates an invention is a factual determination.¹⁰⁰ When a single prior art reference expressly discloses each and every limitation of the claimed invention, an anticipation analysis is straightforward and the invention is unpatentable for failure to satisfy the novelty requirement under 35 U.S.C. § 102.¹⁰¹ But does a prior art reference anticipate an invention when it does not expressly disclose each and every limitation of the claimed invention?¹⁰² If it does anticipate, must a PHOSITA recognize the missing limitations of the claimed invention for that reference to preclude patentability?¹⁰³ As this section will describe, the Federal Circuit has not always provided clear guidance on these issues. Part II.A explores the beginnings of the intracircuit split within Federal Circuit case law, holding essentially that a prior art reference anticipates an invention when it inherently¹⁰⁴ discloses each and every limitation of that invention *and* a PHOSITA recognizes the inherent feature. Part II.B outlines recent Federal Circuit case law in which the inherent anticipation doctrine is upheld but a PHOSITA *need not* recognize the inherent feature. Part II.C describes in detail the interesting case of *Schering Corp. v. Geneva*

97. See *Munising Paper Co.*, 228 F. at 703.

98. See Chisum, *supra* note 13, § 3.03[2][c].

99. See De La Rosa, *supra* note 27, at 44–52.

100. See *supra* notes 46–48.

101. See 35 U.S.C. § 102 (2006).

102. The simple answer to this question is yes. See *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (“Patent law nonetheless establishes that a prior art reference which expressly *or inherently* contains each and every limitation of the claimed subject matter anticipates and invalidates.” (emphasis added) (citing *EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001))).

103. As of the publication date of this Note, the short answer to this question is no. See *id.* at 1377.

104. The Federal Circuit explained in *Schering Corp.*:

In this court’s . . . inherency cases, a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency supplied the missing aspect of the description. Upon proof that the missing description is inherent in the prior art, that single prior art reference placed the claimed subject matter in the public domain.

Id. at 1378–79.

Pharmaceuticals, Inc., the seminal Federal Circuit case on this issue. Finally, Part II.D examines predictions about the state of metabolite research in the wake of the *Schering Corp.* decision.

A. PHOSITA Recognition Required

The *Tilghman* case, although largely considered a case of accidental anticipation,¹⁰⁵ was one of the first cases to state that PHOSITA appreciation of the inherent characteristics in the prior art was necessary for a finding of inherent anticipation.¹⁰⁶ The threshold inquiry for similar cases now also categorized as accidental anticipation was whether a PHOSITA recognized and appreciated the value of the invention.¹⁰⁷

The 1964 case *In re Seaborg* supports the proposition that PHOSITA recognition is required for inherent anticipation.¹⁰⁸ Although the CCPA decided the case, the Federal Courts Improvement Act of 1982 merged the CCPA with the appellate branch of the Court of Claims,¹⁰⁹ establishing this case as Federal Circuit precedent. The patent in question was directed at Americium (element 95, hereinafter Am), its isotopes, and the methods of isolating and purifying it.¹¹⁰ The patent application was initially rejected in light of the prior art, specifically that Am had already been produced in the Fermi reactor.¹¹¹ The applicant responded that the Am produced could only have been one billionth of a gram “distributed throughout forty tons of intensely radioactive uranium reactor fuel,” and that such an amount would surely be undetectable if it was present at all.¹¹² The court examined the prior art in light of the present technology, and concluded that a prediction “with any degree of definiteness” about the formation of Am would require an “exercise of more than the ordinary skill of the art.”¹¹³ Because a PHOSITA could not possibly recognize or produce Am from the prior art, the patent was granted.¹¹⁴

When the CCPA decided the case *In re Shetty* a little over a decade later, PHOSITA recognition as a prerequisite for inherent anticipation seemed all but a bright-line rule.¹¹⁵ The invention claimed was “a method . . . of curbing appetite in animals by administering certain adamantane compounds,” and also pertained to the unit dosage form of a composition for curbing appetite comprising such adamantane compounds along with a

105. See CHISUM, *supra* note 13, § 3.03[1][a]; Chen, *supra* note 27, at 97–98; De La Rosa, *supra* note 27 at 45–46.

106. See *Tilghman v. Proctor*, 102 U.S. 707, 711–12 (1880).

107. See, e.g., *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923); *Edison Elec. Light Co. v. Novelty Incandescent Light Co.*, 167 F. 977 (3d Cir. 1909).

108. See *In re Seaborg*, 328 F.2d 996, 998–99 (C.C.P.A. 1964).

109. See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.).

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

111. See *id.*

112. *Id.* at 997.

113. *Id.* at 999.

114. See *id.*

115. See *In re Shetty*, 566 F.2d 81, 85 (C.C.P.A. 1977).

pharmaceutically acceptable carrier.¹¹⁶ The Patent and Trademark Board of Appeals had originally rejected the claims as obvious or anticipated in light of the prior art.¹¹⁷ The CCPA affirmed the Board's decision as to one claim being invalid for obviousness, but reversed it on the other five.¹¹⁸ The court stated, "[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result."¹¹⁹

The Federal Circuit again held that PHOSITA appreciation of the inherent feature was required for a finding of inherent anticipation in *Glaxo Inc. v. Novopharm, Ltd.*¹²⁰ That case concerned ranitidine hydrochloride, a "potent histamine blocker" that "inhibit[s] the secretion of stomach acid."¹²¹ Glaxo Inc. received a patent (U.S. Patent No. 4,128,658 or the '658 patent) for ranitidine hydrochloride in 1978.¹²² In 1980, Glaxo ceased development of ranitidine using the method claimed in the '658 patent, and instead used a more efficient method that "yielded ranitidine hydrochloride identical in all respects to that originally produced" under the old method.¹²³ The new method, however, produced a crystalline version of the drug that was "visibly different from all previous batches of the salt."¹²⁴ This new crystalline version, a polymorph, was better suited for commercial applications, and was subsequently patented as U.S. Patent No. 4,521,431 (the '431 patent).¹²⁵ In 1991, Novopharm Ltd., one of Glaxo's competitors, filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), seeking approval to manufacture and sell a generic version of the '431 patent material in December of 1995, when the '658 patent was set to expire.¹²⁶ Glaxo then sued Novopharm for patent infringement under 35 U.S.C. § 271(e)(2).¹²⁷ Novopharm admitted

116. *Id.* at 82.

117. *See id.*

118. *See id.* at 86–87.

119. *Id.* at 86 (quoting *In re Naylor*, 369 F.2d 765, 788 (C.C.P.A. 1966)).

120. 52 F.3d 1043, 1046 (Fed. Cir. 1995).

121. *Id.*

122. *See id.*

123. *See id.*

124. *Id.*

125. *See id.* at 1045.

126. *See id.* at 1046–47. December 1995 was still, however, long before the expiration date of the '431 patent, which was set to expire in 2002. *See id.*

127. *See id.* at 1047. 35 U.S.C. § 271(e)(2) provides in part,

It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . .

. . . .

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

infringement of the claims, but countered that that '431 patent was invalid for anticipation by the '658 patent.¹²⁸

The Federal Circuit stated that a claim is only anticipated if a single prior art reference expressly or inherently encompasses all the limitations of that claim.¹²⁹ For a finding of inherent anticipation, it was necessary that a PHOSITA appreciate the inherently missing characteristics.¹³⁰ The district court below found the '431 patent valid and infringed because the '658 patent did not always produce the '431 polymorph of ranitidine hydrochloride, and in so doing expressly rejected the anticipation argument.¹³¹ The Federal Circuit affirmed because the district court's ruling was not clearly erroneous.¹³²

The first open conflict between the two schools of thought on inherent anticipation occurred in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*.¹³³ The patent at issue was directed toward a method of generating transgenic mice.¹³⁴ The district court below held Elan's patents (U.S. Patent Nos. 5,612,486 and 5,850,003 or the '486 and '003 patents, respectively) invalid for anticipation by the Mullan patent (U.S. Patent No. 5,455,169 or the '169 patent).¹³⁵ The majority opinion authored by Judge Newman reversed the district court's finding, holding that the legal requirements were not met to establish anticipation.¹³⁶ The Federal Circuit panel found no inherent anticipation, stating, "The single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art *and that its existence was recognized by persons of ordinary skill in the field of the invention.*"¹³⁷ Judge Newman's opinion pointed out that "[a]lthough Mullan described known procedures for making a transgenic animal, he neither described

35 U.S.C. § 271(e)(2) (2006). Thus, the act of filing an ANDA is deemed to be an act of infringement, enabling the patent holder (Glaxo Inc.) to bring a lawsuit prior to FDA approval, if the purpose of such ANDA is to obtain FDA approval prior to the expiration of a patent that claims the use of the drug.

128. *Glaxo Inc.*, 52 F.3d at 1047.

129. *See id.* at 1047.

130. *Id.*

131. *See id.* at 1047.

132. *See id.* at 1047–48.

133. 304 F.3d 1221 (Fed. Cir. 2002), *vacated*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc), *aff'd on other grounds*, 346 F.3d 1051 (Fed. Cir. 2003).

134. *See id.* at 1221. These transgenic mice were genetically altered to contain, in addition to their normal mouse genome, a mutated human gene called the "Swedish mutation," because the gene was isolated from the cells of a Swedish family having an unusually high incidence of early-onset Alzheimer's disease. *Id.* at 1223–24. These transgenic mice would produce a detectable amount of amyloid precursor protein (APP), which is common in brains of people with Alzheimer's disease. *See id.*

135. *See id.* at 1223.

136. *See id.* The '169 patent issued after Dr. Mullan located a Swedish family susceptible to Alzheimer's disease, isolated the mutated gene and its protein, and expressed the mutation. *See id.* at 1224. He did not, however, make a transgenic mouse. *See id.* at 1226. By contrast, the '486 and '003 patents encompassed the limitations of transgenic mice and the unpredictability of their production. *See id.* at 1226–27.

137. *Id.* at 1227–28 (emphasis added).

every element of the claims, nor taught, in terms other than by trial and error and *hope*, production of a transgenic mouse.”¹³⁸ In support of this holding, Judge Newman recited Elan’s argument that successful transgenic mice production was unpredictable, so much so that the transgenic mouse was produced by Mayo’s technology on the 2,576th attempt.¹³⁹

The first *Elan* decision prompted a strong dissent from Judge Dyk, who was concerned that the panel’s decision allowed for patenting “existing inventions” while at the same time contradicting recent Federal Circuit case law.¹⁴⁰ As to the issue of inherency, Judge Dyk stated, “It matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics.”¹⁴¹

After reconsideration en banc, the first *Elan* decision was vacated and the case was remanded to the panel for further consideration. In the second panel decision, Judge Newman stated that the patent was not invalid for inherent anticipation because the prior art reference was nonenabling.¹⁴² Judge Newman did make it clear that, in her opinion, an enabling prior art reference alone was insufficient to find inherent anticipation.¹⁴³ The Federal Circuit then remanded the case for a determination of whether the ‘169 patent enabled a PHOSITA to make and use the invention without undue experimentation.¹⁴⁴

Although there seems ample precedent in the case law that a finding of inherent anticipation requires that a PHOSITA recognize and appreciate the inherent characteristics, the opposite—namely that a PHOSITA *need not* recognize the inherent feature—also enjoyed substantial support in the case law.

B. PHOSITA Recognition Not Required

The second school of thought regarding inherent anticipation has been championed primarily by Judge Rader, and expressly disregards PHOSITA recognition as necessary to establish a finding of inherent anticipation.¹⁴⁵ In *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*,¹⁴⁶ for example, recognition of inherent characteristics was irrelevant for patentability.¹⁴⁷ The patent at issue in *Abbott Laboratories* concerned Abbott’s “Form IV” anhydrous terazosin hydrochloride, a drug to treat hypertension and “benign prostatic hyperplasia,” and was issued as U.S. Patent No. 5,504,207 (the

138. *Id.* at 1228 (emphasis added).

139. *See id.* at 1228 n.4.

140. *Id.* at 1231 (Dyk, J., dissenting).

141. *Id.* (citing *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1350 (Fed. Cir. 2002)).

142. *See Elan Pharms. Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (“We conclude that Elan’s arguments are more properly characterized as enablement arguments rather than inherency arguments.”).

143. *See id.* at 1055.

144. *See id.* at 1057.

145. *See, e.g., Chen, supra* note 27, at 101–02; De La Rosa, *supra* note 27, at 71–83.

146. 182 F.3d 1315 (Fed. Cir. 1999).

147. *See id.* at 1319.

'207 patent).¹⁴⁸ Between 1989 and 1992, Byron Chemical Company, who was not a party to the lawsuit, sold three lots of anhydrous terazosin hydrochloride: two to Geneva Pharmaceuticals and one to Warner Chilcott Laboratories.¹⁴⁹ Abbott developed the Warner Chilcott lot into its "Form IV" product and filed its patent application in 1994.¹⁵⁰

Three of Abbott's competitors—Novopharm Ltd.; Invamed, Inc.; and Geneva Pharmaceuticals—filed ANDAs seeking approval to make and distribute generic versions of the '207 material containing the Form IV anhydrate.¹⁵¹ Abbott sued for infringement pursuant to 35 U.S.C. § 271(e)(2)(A).¹⁵² The competitors countered that the '207 patent was invalid, and therefore not infringed, because the claimed material violated the § 102(b) on-sale statutory bar, "asserting that Form IV was anticipated because it was sold in the United States more than one year before the '207 patent's filing date, October 18, 1994."¹⁵³ Abbott tried to argue that neither Byron Chemical nor the defendants knew that the "invention" (Form IV anhydrate) was "on sale" because "the parties must 'conceive,' or *know* precisely, the nature of the subject matter with which they are dealing."¹⁵⁴

The Federal Circuit was not persuaded.¹⁵⁵ Instead, the court focused its inquiry on the three commercial sales that occurred before the critical filing date of October 18, 1994, noting that the subjective knowledge of the parties to the sale was irrelevant.¹⁵⁶ The court, rejecting Abbott's argument, stated, "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."¹⁵⁷ Thus, an inquiry into whether the parties—both PHOSITAS—knew (recognized or appreciated) at the time that they were dealing with Form IV anhydrate or not was immaterial to the analysis of inherent properties and their effect on patentability.¹⁵⁸

*Atlas Powder Co. v. IRECO Inc.*¹⁵⁹ follows similar reasoning. Judge Rader authored the opinion in *Atlas Powder Co.*, explicitly holding, "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art."¹⁶⁰ The court explained, "Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation."¹⁶¹ In *Atlas Powder Co.*, the Federal

148. *Id.* at 1316–17.

149. *See id.* at 1317.

150. *See id.* at 1318.

151. *See id.* at 1317.

152. *See id.* at 1317 n.1.

153. *Id.* at 1317; *see* 35 U.S.C. § 102(b) (2006).

154. *Abbott Labs.*, 182 F.3d at 1318.

155. *See id.*

156. *See id.* at 1319.

157. *Id.*

158. *See id.*

159. 190 F.3d 1342 (Fed. Cir. 1999).

160. *Id.* at 1347.

161. *Id.* at 1349.

Circuit considered two patents—the Clay patent (U.S. Patent No. 4,111,727), and its reissue patent (U.S. Patent No. RE 33,788). The district court held both the Clay patent and its reissue patent invalid for anticipation by either the Egly patent (U.S. Patent No. 3,161,551) or by the Butterworth patent (U.K. Patent No. 1,306,546).¹⁶² Both the Clay patent and its reissue patent claimed explosive compositions composed of ammonium nitrate and fuel oil (ANFO) as well as an unsensitized water-in-oil emulsion.¹⁶³ Although the anticipating prior art references did not encompass the exact chemical compositions as the Clay and reissue patents, they did disclose blasting compositions containing a water-in-oil emulsion and ANFO with ingredients identical to those of the Clay patents in overlapping amounts.¹⁶⁴ The Egly and Butterworth patents did not explicitly disclose a “sufficient aeration” limitation, however, which was explicitly included in the Clay patent disclosure.¹⁶⁵ The Federal Circuit found that the aeration limitation was “inevitably and inherently” present in the prior art, thus rendering the claims of the Clay and reissue patents unpatentable.¹⁶⁶ Judge Rader, in affirming the district court’s holding, stated, “this court detects no error in the district court’s conclusion that ‘sufficient aeration . . . to enhance sensitivity’ is understood by those of ordinary skill in the art.”¹⁶⁷ Because “sufficient aeration” was inherently present in the prior art, “it is irrelevant that the prior art did not recognize the key aspect of [the Clay patent’s] alleged invention.”¹⁶⁸

*Titanium Metals Corp. of America v. Banner*¹⁶⁹ further supports the idea that insufficient understanding or appreciation by those of ordinary skill in the art should not defeat a finding of anticipation. In that case, the Federal Circuit held a patent invalid for inherent anticipation even though a critical property of the claimed alloy was not expressly disclosed in the prior art reference.¹⁷⁰ In reversing the district court, the Federal Circuit held that inherent anticipation was established even though a PHOSITA did not appreciate the inherent property of “good corrosion resistance in hot brine environments,” despite the fact that such a property was a newly discovered characteristic.¹⁷¹ Thus, *Titanium Metals Corp.* and *Atlas Powder Co.* seem to stand for the proposition that inherent anticipation may be established whether or not a PHOSITA knows or appreciates the inherent feature or characteristic.

Cases following similar reasoning are *MEHL/Biophile International Corp. v. Milgraum*¹⁷² and *In re Cruciferous Sprout Litigation*.¹⁷³ In

162. *See id.* at 1343.

163. *See id.* at 1344.

164. *See id.* at 1345.

165. *Id.* at 1344–45.

166. *Id.* at 1348.

167. *Id.* at 1347.

168. *Id.* at 1348.

169. 778 F.2d 775 (Fed. Cir. 1985).

170. *See id.* at 780–81.

171. *Id.* at 782.

172. 192 F.3d 1362 (Fed. Cir. 1999).

Cruciferous Sprout, several patents directed at the production and consumption of the sprouts of certain types of cruciferous seeds (such as broccoli and cauliflower) were held invalid for anticipation.¹⁷⁴ The patented sprouts are rich in glucosinolates, which have high Phase 2 enzyme-inducing potential and therefore make them potent anticancer agents.¹⁷⁵ The defendants claimed that the patents were invalid for anticipation in light of the prior art, which disclosed methods for germinating and harvesting cruciferous seeds without explicitly disclosing the importance of glucosinolates.¹⁷⁶ The district court below granted the defendants' motion for summary judgment, stating that "plant[s] (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature."¹⁷⁷ The Federal Circuit affirmed, holding that the patents were anticipated in light of the prior art, stating that, "the glucosinolate content and Phase 2 enzyme-inducing potential of these sprouts are inherent properties of the sprouts put there by nature, not by [the patentee]."¹⁷⁸ The discovery of inherent, unappreciated properties of previously patented products was not the discovery of something new, and thus, was not worthy of patent protection.

In *MEHL/Biophile*, the Federal Circuit held that a patent claiming a method of hair removal using lasers was invalid for anticipation in light of a prior art article teaching the "alignment of the laser light over a hair follicle."¹⁷⁹ Judge Rader again wrote the opinion, stating that it was "of no import[ance]" that the prior art reference's authors did not appreciate the necessary consequence of what was deliberately intended.¹⁸⁰

C. *Settling the Debate, for Now: Schering Corp. v. Geneva Pharmaceuticals, Inc.*

The Federal Circuit issued its landmark ruling on the subject of inherent anticipation in the case of *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,¹⁸¹ holding that recognition of the inherent feature in a prior art reference by a PHOSITA was not necessary to sustain a finding of inherent anticipation.¹⁸² Part II.C.1 will outline the procedural history of *Schering Corp.* Part II.C.2 will discuss the case on appeal to the Federal Circuit. Part II.C.3 then concludes by highlighting the Federal Circuit's denial of en banc review.

173. 301 F.3d 1343 (Fed. Cir. 2002).

174. *See id.* at 1352.

175. *See id.* at 1345.

176. *See id.* at 1346.

177. *Id.*

178. *Id.* at 1352.

179. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999).

180. *Id.*

181. 339 F.3d 1373 (Fed. Cir. 2003).

182. *See id.* at 1377.

1. The Procedural History

The District of New Jersey granted summary judgment invalidating claims in Schering Corporation's patent (U.S. Patent No. 4,659,716 or the '716 patent) directed at antihistamines.¹⁸³ Schering also owned U.S. Patent No. 4,282,233 (the '233 patent), likewise directed at antihistamines, specifically loratadine, the pharmacologically active ingredient in Claritin.¹⁸⁴ The '716 patent covered descarboethoxyloratadine (DCL), a metabolically formed byproduct of loratadine.¹⁸⁵ Structurally, loratadine and DCL differ only in that loratadine has a carboethoxy group on a ring nitrogen, while DCL has a hydrogen atom on that ring nitrogen.¹⁸⁶ The Federal Circuit affirmed the district court's ruling, finding that the '233 patent inherently anticipates the '716 patent.¹⁸⁷

The defendant pharmaceutical companies sought to manufacture generic versions of Claritin upon the expiration of the '233 patent, with each appellee submitting applications to the FDA.¹⁸⁸ The applications contained a certification denying the validity of the '716 patent, which was listed in the Orange Book for loratadine.¹⁸⁹ Upon receiving notice of the FDA filings, Schering filed suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A).¹⁹⁰ Cross motions for summary judgment were filed by both parties.¹⁹¹

The claims as construed by the district court covered DCL in all of its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form."¹⁹² Both parties agreed to that claim construction, and further stipulated that, at the time the '716 application was filed, a PHOSITA would not recognize that administration of loratadine produced the metabolite DCL in the human body.¹⁹³ The district court then found that the '233 patent did not expressly disclose DCL, but that DCL was necessarily formed as a result of practicing the '233 patent.¹⁹⁴ By 1985, Schering and its scientists "consistently

183. *See id.* at 1374. "Antihistamines inhibit the histamines that cause allergic symptoms." *Id.* at 1375.

184. *See id.* at 1374–75.

185. *See id.* at 1375.

186. *See id.*

187. *See id.* at 1374.

188. *See id.* at 1376.

189. *See id.* The FDA publishes the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book, which identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 355(j)(7)(A)(iii), (b)(1) (2006). The book is known popularly as the "Orange Book" because of its orange-colored cover. *See Applications for FDA Approval to Market a New Drug*, 68 Fed. Reg. 36676 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314).

190. *Schering Corp.*, 339 F.3d at 1376.

191. *See id.*

192. *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 539 (D.N.J. 2002), *aff'd*, 339 F.3d 1373, 1374 (Fed. Cir. 2003).

193. *See id.* at 537.

194. *See id.* at 541.

characterized DCL as the ‘active 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.”¹⁹⁵

The district court invalidated several claims of the ‘716 patent as inherently anticipated, noting that, “there [was] no genuine issue that the consumption of loratadine by humans, with a wide variety of health statuses, necessarily results in the natural production in the human body of the DCL metabolite.”¹⁹⁶ The court explained that, “the natural, inevitable production of metabolic DCL upon human ingestion of loratadine, although not fully appreciated by persons of ordinary skill in that field until more recently than 1984, demonstrates that this process is an ‘inherent characteristic or functioning’ of the use of loratadine.”¹⁹⁷ Thus, the defendants’ motion for summary judgment was granted invalidating Schering’s patent, and Schering appealed to the Federal Circuit.

2. The Appeal to the Federal Circuit

The Federal Circuit affirmed the district court’s ruling of summary judgment, holding the ‘716 patent invalid for inherent anticipation in light of the prior art.¹⁹⁸ The court used this case to explain the proper interpretation of previous case law—a prior art reference may anticipate without disclosing a feature of the claimed invention if: (1) that missing characteristic is necessarily present, or inherent, in the single anticipating reference, and (2) that inherency was a “natural result” that flowed with certainty from the disclosure in the prior art.¹⁹⁹ Cases like *Tilghman* and *Eibel Process Co.* were distinguished as cases dealing “with ‘accidental, unwitting, and unappreciated’ anticipation,” standing for the proposition that inherency did not require recognition by a PHOSITA.²⁰⁰ When the result in question is deemed born out of accidental conditions, such results do not run afoul of the novelty provision for patentability.²⁰¹

The Federal Circuit stated frankly, in an opinion authored by Judge Rader, “At the outset, this court *rejects* the contention that inherent anticipation requires recognition in the prior art.”²⁰² Thus, the *Schering Corp.* decision resolved the long standing intracircuit split,²⁰³ making it quite clear a prior art reference anticipates even when it fails to disclose a feature of the claimed invention, so long as the missing characteristic is “necessarily present, or inherent” in that reference.²⁰⁴ Judge Rader used

195. *Id.* at 538.

196. *Id.* at 541.

197. *Id.* at 542.

198. *See Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1374 (Fed. Cir. 2003).

199. *Id.* at 1378–79.

200. *Id.* at 1378.

201. *See id.*

202. *Id.* at 1377 (emphasis added).

203. *See supra* Part II.A–B and accompanying text.

204. *Schering Corp.*, 339 F.3d at 1377.

this opportunity to clarify prior Federal Circuit cases that were previously viewed as holding that a PHOSITA must recognize the missing (inherent) characteristic to support a finding of inherent anticipation.²⁰⁵ For instance, the court remarked that *Continental Can Co. v. Monsanto Co.*, stood “for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art.”²⁰⁶ Therefore, the Federal Circuit did not require PHOSITA recognition. Rather, it merely attempted to view the scope of the relevant prior art through the eyes of a PHOSITA, and thus resolve any factual questions about the subject matter expressly and inherently within the references under examination.²⁰⁷ In other words, the court observed that *Continental Can Co.* merely requires that the Federal Circuit resort to the opinions of “skilled artisans” to determine if the inherent feature exists in the prior art at all.²⁰⁸ Moreover, according to Judge Rader, summary judgment on inherent anticipation in *Continental Can Co.* was vacated due to conflicting expert testimonies on the existence of the inherent feature.²⁰⁹

After dispensing with the argument that inherent anticipation requires PHOSITA recognition of the inherent feature, the court described the issue in *Schering Corp.* as being one “of first impression.”²¹⁰ The court noted that the prior art references put forward by the defendants “supplie[d] no express description of any part of the claimed subject matter.”²¹¹ Previous Federal Circuit case law contained examples of prior art references having an “incomplete description of the anticipatory subject matter,” with the inherency doctrine supplying the missing feature.²¹² By contrast, the defendants in *Schering Corp.* were not seeking to use the inherent anticipation doctrine to plug gaps in the prior art. They were, instead, “ask[ing] [the] court to find anticipation when the *entire* structure of the claimed subject matter is inherent in the prior art.”²¹³ Judge Rader found no reason why the doctrine of inherent anticipation should be limited to situations involving an undisclosed feature.²¹⁴ Judge Rader’s opinion in *Schering Corp.* has made it clear that the doctrine of inherent anticipation may well be used to invalidate entire inventions.²¹⁵

205. *See id.* (“*Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date.”).

206. *Id.*

207. *See id.* at 1377–78.

208. *Id.* at 1378.

209. *See id.*; *see also* *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268–69 (Fed. Cir. 1991).

210. *Schering Corp.*, 339 F.3d at 1378.

211. *Id.* (noting that the prior art ‘233 patent did not expressly disclose any compound identifiable as DCL).

212. *Id.* at 1378–79.

213. *Id.* at 1379 (emphasis added). The “new” structure claimed, DCL, was not at all described by the prior ‘233 patent. *Id.* at 1379.

214. *See id.*

215. *See id.*

The *Schering Corp.* decision also clarified that an anticipatory reference “need only enable subject matter that falls within the scope of the claims at issue, nothing more.”²¹⁶ Actual creation or reduction to practice of the prior art subject matter are not required for the purposes of an anticipation inquiry.²¹⁷ Applying this rule to the facts in *Schering Corp.*, the court found that the ‘233 patent qualified as an enabling anticipatory reference if it “describe[d] how to make DCL in any form encompassed by a compound claim covering DCL”²¹⁸ This, then, would include DCL as a metabolite in a patient’s body. Since the ‘716 patent covers DCL in any form, the ‘233 patent would then inherently anticipate its claims so long as it enables a PHOSITA to make DCL. Because a PHOSITA could practice the ‘233 patent without undue experimentation, the ‘233 patent enables and is an anticipatory reference under the Federal Circuit’s doctrine of anticipation.²¹⁹

Judge Rader explained that patent protection could still be available for metabolites of pharmaceutical compounds so long as they were properly claimed, and provided guidance for future drafters seeking such protection.²²⁰ The metabolite could be claimed in its pure and isolated form;²²¹ or it might be claimed as a pharmaceutical composition (bonded to an acceptable pharmaceutical carrier).²²² In the alternative, the “drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition.”²²³ Thus, according to Judge Rader, proper claiming avoids the inherent anticipation doctrine promulgated under *Schering Corp.*

3. Denial of En Banc Review

Did Judge Rader’s opinion in *Schering Corp.* violate the Federal Circuit’s local rules by overruling a binding precedent via panel decision?²²⁴ It appeared that way to Judges Newman and Lourie, who dissented from the denial of en banc review.²²⁵

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation *or the entire invention* is inherent and in the public domain if it is the “natural result flowing from” the explicit disclosure of the prior art.

Id. (emphasis added).

216. *Id.* at 1380–81.

217. *See id.* at 1380.

218. *Id.* at 1381.

219. *See id.*

220. *See id.* (“With proper claiming, patent protection is available for metabolites of known drugs.”).

221. *See id.*

222. *See id.*

223. *Id.*

224. *See* FED. CIR. R. 35(a)(1) (“*Arguing to a Panel to Overrule a Precedent.* Although only the court en banc may overrule a binding precedent, a party may argue, in its brief and oral argument, to overrule a binding precedent without petitioning for hearing en banc. The

Judge Newman was concerned that, by finding anticipation of an entire compound not known in the prior art and that did not previously exist, the *Schering Corp.* decision departed from the “established law of anticipation.”²²⁶ Judge Newman objected to what she viewed as “panel disruption” of existing precedent, stating that if the law were to be changed in this manner it required “*en banc* action.”²²⁷ Judge Newman argued that the court’s precedent was entirely contradictory to the panel’s holding in *Schering Corp.* that DCL was unpatentable simply because it existed, even if no one knew that it existed.²²⁸ Most troubling for Judge Newman was the fact that no prior art reference disclosed the claimed DCL, and that a PHOSITA would not have known that DCL was formed upon ingestion of loratadine by patients.²²⁹ Judge Newman was uncertain as to the implications of the panel’s holding for the patenting of products that had not yet been discovered, but desired that the court “speak with one voice on this important question.”²³⁰

Judge Lourie also dissented, going so far as to call the court’s “extraordinary decision” preclusive to “virtually all patents on human metabolites of drugs.”²³¹ This fact alone, in the eyes of Judge Lourie, mandated *en banc* review of the *Schering Corp.* decision.²³²

Judge Lourie’s dissent also addressed the practical implications of the *Schering Corp.* decision on the patentability of pharmaceutical compounds and their metabolites.²³³ He was concerned that the *Schering Corp.* decision would effectively preclude patent protection for these metabolites, arguing that the court had essentially endorsed the holding that existing patents may be effective prior art references to the metabolites they generate.²³⁴ Judge Lourie did not question the notion that a pharmaceutical product is unpatentable when it is “*in actual public use*” prior to the filing of a patent application.²³⁵ Rather, he took issue with a decision “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.”²³⁶

panel will decide whether to ask the regular active judges to consider hearing the case *en banc*.”); *see also* *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (denying rehearing *en banc*).

225. *See Schering Corp.*, 348 F.3d at 994–95 (Newman, J., dissenting); *see also id.* at 996 (Lourie, J., dissenting).

226. *Id.* at 993 (Newman, J., dissenting).

227. *Id.* at 995.

228. *See id.*

229. *See id.*

230. *Id.*

231. *Id.* (Lourie, J., dissenting).

232. *See id.*

233. *See id.* at 995–96.

234. *See id.*

235. *Id.* at 996.

236. *Id.* Judge Lourie noted, however, that he would have ruled differently if the ‘233 really taught how to make metabolites. “However, that patent simply included a minimal, boilerplate statement of how to use the claimed products, sufficient to satisfy the requirements of 35 U.S.C. § 112, but far from the careful and thorough prescribing information required by the FDA.” *Id.*

Whether a pharmaceutical product patent owner would desire or require a patent on a metabolite should not be the issue, Judge Lourie stated.²³⁷ The holding “that a patent on a product, with a minimal disclosure of administering it to a human or other subject, anticipates a later application on a metabolite, of which no mention appears whatsoever in the patent, cannot be correct.”²³⁸

The Federal Circuit’s subsequent decision in the *SmithKline* case, however, indicates that the court has formally accepted the rule established by *Schering Corp.*, despite the panel’s detractors.²³⁹

4. Formal Acceptance of *Schering Corp.*: The Case of *SmithKline Beecham Corp. v. Apotex Corp.*

SmithKline Beecham Corp. v. Apotex Corp. endorsed the idea that PHOSITA recognition of inherent properties was unnecessary to sustain a finding of inherent anticipation.²⁴⁰ Judge Posner, sitting by designation, authored the opinion dismissing SmithKline’s suit for patent infringement.²⁴¹ The patent at issue covered paroxetine (U.S. Patent No. 4,721,723 or the ‘723 patent), an antidepressant drug that SmithKline sold under the brand name Paxil.²⁴² Originally, paroxetine was patented by a British company called Ferrosan (the ‘196 patent).²⁴³ Ferrosan was not a manufacturer of pharmaceutical drugs, so it licensed the ‘196 materials, an anhydrous form of paroxetine, to SmithKline.²⁴⁴ Anhydrous materials are difficult to manufacture and maintain due to their tendency to become “soggy” with moisture, thus requiring special measures to control humidity.²⁴⁵ A pseudopolymorph of paroxetine, called a hemihydrate, was subsequently discovered by SmithKline in 1985.²⁴⁶ The hemihydrate was more stable and was more amenable to manufacturing than the original anhydrous material.²⁴⁷ SmithKline patented paroxetine hydrochloride hemihydrate, in which there is one water molecule for every two of the other molecules constituting the unit crystal cell, as the ‘723 patent, marketed as Paxil, in 1993.²⁴⁸

237. *See id.*

238. *Id.*

239. *See SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1320–21 (Fed. Cir. 2004), *vacated*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (en banc), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

240. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1025–26 (N.D. Ill. 2003), *vacated*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (en banc), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

241. *See id.* at 1052.

242. *See id.* at 1015.

243. *See id.* at 1015–16.

244. *See id.*

245. *Id.* at 1017.

246. *Id.* at 1016–17, 1022.

247. *See id.* at 1017.

248. *See id.*

In 1998, six years after the expiration of the '196 patent, Apotex filed an ANDA seeking FDA approval to manufacture anhydrous paroxetine hydrochloride.²⁴⁹ SmithKline commenced suit against Apotex for infringement, claiming that any version of the '196 materials would necessarily contain the '723 materials, which was not set to expire until 2006.²⁵⁰ In the alternative, SmithKline argued that the likelihood of producing the '723 hemihydrate was high even if Apotex was attempting to produce the '196 anhydrate because of a phenomenon known as "seeding."²⁵¹ Seeding would occur, SmithKline said, anytime the anhydrate was improperly handled, producing the hemihydrate from the anhydrate by way of conversion induced by "seeds," which could be a single tiny crystal or a grain of dust.²⁵² The '723 material would then multiply within the '196 material, "leveling off at a few percentage points" of the whole.²⁵³ Finally, SmithKline argued that even if Apotex was able to prevent the conversion of the '196 anhydrate into the '723 hemihydrate and avoid seeding altogether,²⁵⁴ Apotex would still infringe the '723 patent when patients ingested the '196 anhydrate and the human metabolism converted it into the stable hemihydrate in the warm, fluid human stomach.²⁵⁵

Judge Posner ultimately ruled the '723 patent valid but not infringed.²⁵⁶ Regarding the natural conversion of the '196 material to the '723 material, Judge Posner construed the relevant claim "to cover crystalline paroxetine hydrochloride hemihydrate in any commercially significant quantity, and so construed[,] the claim [was] valid against the various attacks on it made by Apotex but clearly [would] not be infringed by Apotex's anhydrate product."²⁵⁷ If the claim was valid and infringed by a single crystal of hemihydrate produced by Apotex, Judge Posner would allow Apotex a complete affirmative defense that SmithKline was the cause of the infringement.²⁵⁸ To allow any greater protection would be contrary to established laws of patent and equity.²⁵⁹ Judge Posner was also unconvinced that the '196 materials inherently contained the '723 materials, stating, "I am not persuaded that Apotex will produce an anhydrate that has

249. *See id.* at 1023.

250. *See id.* at 1023–24.

251. *Id.* at 1020–21.

252. *See id.*

253. *Id.* at 1023.

254. *See id.* at 1020–21. One witness, testifying for SmithKline, proposed an interesting scenario for Apotex if they wished to avoid "seeding" and infringement of the '723 patent: Apotex could, theoretically, build a plant in Antarctica, where no hemihydrate had ever been manufactured. However, a "depressed worker" could still possibly drop Paxil on the floor, thus providing a "seed" and making it impossible for them to produce pure anhydrate and thus, avoid infringement. *See id.*

255. *See id.* at 1014.

256. *See id.* at 1052.

257. *Id.*

258. *See id.*

259. *See id.* at 1046.

sufficient hemihydrate to be detectable by the methods in use in 1985.”²⁶⁰ Thus, the ‘723 patent was valid and immune from an inherent anticipation attack.

The case went to the Federal Circuit on appeal, where Judge Rader dispensed of Judge Posner’s conclusions, holding the patent invalid for being in public use in violation of 35 U.S.C. § 102(b).²⁶¹ Initially, Judge Rader’s panel did not use the inherent anticipation doctrine to invalidate the patent. Instead, the panel reasoned that it ran afoul of the public use bar because the drug was administered to patients without any apparent confidentiality restrictions on the patients or the administering physicians during the clinical trials.²⁶² Addressing “miscellaneous issues,” Judge Rader opined that if SmithKline proved that Apotex committed contributory infringement by showing that the anhydrate necessarily converts to the hemihydrate upon ingestion, SmithKline would have also clearly shown that the ‘723 patent was invalid for inherent anticipation in light of the ‘196 patent.²⁶³ This point is dictum, however, because the appeal by SmithKline for contributory infringement was moot as it ran afoul of the prior use bar.²⁶⁴

Pursuant to an order en banc, Judge Rader’s panel again considered the *SmithKline* case on remand, affirming the previous panel’s decision invalidating the ‘723 patent, this time via the doctrine of inherent anticipation.²⁶⁵ Judge Rader explained that the ‘196 patent suffices as an anticipatory reference if it discloses in an enabling manner the production of the hemihydrate.²⁶⁶ Because the ‘196 patent, when practiced, enabled a PHOSITA to naturally produce the hemihydrate claimed by the ‘723 patent, the ‘723 patent was invalid for anticipation.²⁶⁷ Judge Rader explicitly stated that a finding of inherent 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.”²⁶⁸ The record contained clear and convincing evidence that production of paroxetine anhydrate as per the ‘196 patent inherently results in at least trace amounts of the hemihydrate, and the “court’s law does not require Apotex to take extraordinary measures to practice the prior art without infringing [the ‘723 patent].”²⁶⁹ Judge Rader did note, however, that SmithKline could obtain a patent for an inherently

260. *Id.* at 1036.

261. *See* *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1320–21 (Fed. Cir. 2004), *vacated*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (en banc), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

262. *See id.* at 1317.

263. *Id.* at 1320.

264. *See id.*

265. *See SmithKline*, 403 F.3d at 1334.

266. *See id.* at 1344.

267. *See id.*

268. *Id.* at 1343 (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

269. *Id.* at 1345. One such extraordinary measure would be the requirement that Apotex build a plant not “seeded” with the hemihydrates.

anticipated compound using the proper claims, and that the holding merely prevented SmithKline from obtaining patent protection for the “bare compound” claimed in the ‘723 patent.²⁷⁰

Judge Newman dissented from the denial of a rehearing en banc, expressly stating her concern that the court “has preserved the opinion’s enlargement of the ground of invalidity called ‘inherent anticipation.’”²⁷¹ Noting that the hemihydrate was first discovered in 1985 and *may have existed* in 1984, Judge Newman wondered, “how then can it have been ‘inherently disclosed,’ in a patent application filed in 1975?”²⁷² Comparing the court’s decision to precedent, Judge Newman pointed out that there was “no evidence whatsoever that the hemihydrate existed at the time the anhydrate patent application was filed, and no evidence that such existence would have been recognized [by a PHOSITA].”²⁷³ Judge Newman endorsed the view that the inherent anticipation doctrine should be limited to “situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention.”²⁷⁴ To Judge Newman, inherent anticipation required that a PHOSITA knew, or should have known, of the presence of the inherent characteristics, “not that it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown.”²⁷⁵ In Judge Newman’s opinion, the expansion of the doctrine of inherent anticipation to a product that may exist in trace amounts calls the patentability of antibiotics, hormones, antibodies, and other products into question.²⁷⁶ According to Judge Newman, this results in uncertainty regarding existing patents, and the loss of incentives to search for the beneficial components of existing materials.²⁷⁷ If a product’s existence is not known to a PHOSITA, Judge Newman argued, it cannot later be retrospectively “inherently anticipated.”²⁷⁸

Although *SmithKline* was decided later, it was the Federal Circuit’s decision in *Schering Corp.* that settled the debate about whether PHOSITA recognition was required to sustain a finding of inherent anticipation. The court held that inherent anticipation is not dependent on whether PHOSITA recognizes or appreciates the missing properties of the invention.²⁷⁹ The proper inquiry, rather, is whether the result was “accidental,” obtained

270. *Id.* at 1346.

271. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (Newman, J., dissenting).

272. *Id.* at 1329 (citations omitted).

273. *Id.*

274. *Id.* at 1330 (quoting *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991)) (internal quotation marks omitted).

275. *Id.* (citing *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)).

276. *See id.*

277. *See id.*

278. *Id.*

279. *See Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1382 (Fed. Cir. 2003).

“under unusual conditions,” or a “natural result flowing from the explicit disclosure of the prior art.”²⁸⁰

D. Predictions for the Future of Metabolite Research

Until the Supreme Court provides further guidance, the controversial rule promulgated under *Schering Corp.* remains the final word on PHOSITA recognition in an inherent anticipation analysis. Will the Federal Circuit’s expansion of the inherent anticipation doctrine stifle future metabolite research? Commentators are as divided as the case law.

One commentator argues that the Federal Circuit’s decision in *Schering Corp.* seems harsh on its face, but its future impact is limited because subsequent cases have strictly applied the “necessary and inevitable consequence” test.²⁸¹ Another commentator argues that the Federal Circuit has created “a substantial danger to innovation” through its expansion of the inherent anticipation doctrine.²⁸² By removing the recognition requirement, the Federal Circuit has expanded the doctrine and has created “a dangerous weapon against innovation,” even though its public policy goals may be admirable.²⁸³ Other commentators posit that excessive application of the inherent anticipation doctrine chills the stated policy goals of the patent system, goals like encouraging investment, innovation, and full public disclosure of new inventions.²⁸⁴ Yet another commentator believes that the clarification of the inherent anticipation doctrine by *Schering Corp.* may actually undermine the doctrine itself by creating a burden that litigants are unable to overcome.²⁸⁵ Could this doctrine be overtly problematic to some inventors, yet still be kept in check? At least one commentator believes so. Inherent anticipation is particularly problematic as applied against chemical compounds, but the effect is tempered by the court’s requirement that the chemical compound at issue must form in readily detectable amounts upon ingestion for the doctrine to be triggered.²⁸⁶

280. *Id.* at 1378–79.

281. See Chen, *supra* note 27, at 119–20 (citing *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004); *Glaxo Grp. Ltd. v. Teva Pharms. USA, Inc.*, No. 02-219, 2004 WL 1875017, at *19 (D. Del. Aug. 20, 2004); *AstraZeneca AB v. Mut. Pharm. Co.*, 278 F. Supp. 2d 491, 515 (E.D. Pa. 2003), *aff’d in part, rev’d in part*, 384 F.3d 1333 (Fed. Cir. 2004)).

282. De La Rosa, *supra* note 27, at 89 (arguing that pharmaceutical companies will likely be dissuaded from investing in the research and development of metabolites as a result of *Schering Corp.*, because they will not be able to patent their discoveries and recoup their investment, ultimately resulting in recourse to trade secrets).

283. Peter D. Smith, *Anticipating Too Much: Why the Court Should Avoid Expanding the Doctrine of Inherent Anticipation*, 61 N.Y.U. ANN. SURV. AM. L. 823, 864 (2006) (arguing that preventing drug companies from extending their patents beyond the limited monopoly granted by Congress is admirable, but alternative means to accomplish this goal exist).

284. See Mueller & Chisum, *supra* note 3, at 1105.

285. See Alloway, *supra* note 60, at 93 (arguing that the limited understanding of many biotechnology inventions may render impossible an accurate determination of whether an inherent characteristic or result is necessary and inevitable at the time that such a determination must be made).

286. See A. Meaghin Burke, Comment, *New Approaches to Pharmaceutical Patent Law: Why Current Patent Jurisprudence Is Inappropriate As Applied to the Unique*

Indeed, the predictions about the effects of the inherent anticipation doctrine on metabolite research are wide ranging, due largely in part to the rule promulgated under *Schering Corp.* and its progeny that a PHOSITA need not recognize the inherent feature. Whether or not the doctrine will actually stifle pharmaceutical research into metabolites remains to be seen. This uncertainty has not, however, quelled the calls for a reformation of the doctrine by commentators and patent practitioners alike, especially as it is applied against the unpredictable biological, chemical, and pharmaceutical arts.

III. TECHNOLOGICAL ADVANCEMENT IN THE TIME OF *SCHERING CORP.*: REEXAMINING THE DOCTRINE IN LIGHT OF OUR RAPIDLY EXPANDING BASE OF SCIENTIFIC KNOWLEDGE

The utterly confusing nature of the inherent anticipation doctrine has not only prompted calls for its reform, but also its outright abolishment.²⁸⁷ Part III.A will examine several proposed changes to the doctrine of inherent anticipation to make it less difficult to apply in future cases. Part III.B will propose a new “capability” standard for courts grappling with issues of inherency in patent law. This standard would focus primarily on what a PHOSITA was *capable* of discovering, and would require a factual determination as to the nature of scientific technology at the date of the potentially anticipating reference.

A. Proposed Changes to the Doctrine

One commentator has proposed that the doctrine should be applied strictly and narrowly in future cases to avoid the potential chilling effects on innovation.²⁸⁸ This is not a proposed solution to the doctrine itself but only to its application in biological and chemical patent cases. If the inherency analysis is strictly applied in biological and chemical cases where an absolute certainty of result exists, the chilling effects of the inherent anticipation doctrine should be limited.²⁸⁹ Under this proposal, the doctrine “would only invalidate claims that merely recite scientific explanations of preexisting subject matters.”²⁹⁰ Another commentator proposes a seemingly opposite solution: inventions directed at the biological and chemical arts pose their own special problems²⁹¹—namely,

Characteristics of Chemical Compounds, 75 *Miss. L.J.* 1143, 1163 (2006) (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)).

287. See Mueller & Chisum, *supra* note 3, at 1107, 1163–64 (proposing cabining the doctrine altogether in favor of more robust tools for policing patent validity, such as the nonobviousness requirement).

288. See Chen, *supra* note 27, at 119–21.

289. See *id.*

290. *Id.* at 121.

291. See Alloway, *supra* note 60, at 93 (“Given the limited understanding of many biotechnology inventions, it may not be possible for the courts to accurately determine whether an inherent characteristic or result is necessary and inevitable at the time that such a determination must be made. Scientific understanding of the mechanisms of biological

unpredictability—which is precisely why the inherent anticipation doctrine needs to be relaxed, not tightened, when applied against such inventions.²⁹² The very nature of biological and chemical patents should make courts pause when considering whether “poorly-understood biotechnological inventions” are inherently anticipated.²⁹³

Other commentators have suggested that inherency is best understood from a public benefit perspective.²⁹⁴ The doctrine does not require substantial change; a proper inherency analysis simply seeks to determine whether or not the public already benefits from the invention.²⁹⁵ The authors argue that this “public benefit” analysis makes sense from a public policy perspective.²⁹⁶ If a court determines that the public already benefits from an invention, the discovery of that benefit (or the causes for it) does not justify withdrawing it from the public domain by granting it patent protection.²⁹⁷ Conversely, if the public does not yet benefit from the discovery, then a “discovery or modification that gives the world a new benefit is precisely the sort of improvement that we want to encourage through patent protection.”²⁹⁸

Substantive changes to the doctrine via the patent statute have also been proposed. In patent cases where the inherent anticipation doctrine is applied, some commentators argue that prior art relied upon to establish that an invention is inherently anticipated should satisfy a heightened enablement standard.²⁹⁹ Patent law already requires that an anticipating reference enable a PHOSITA to make and use the invention described.³⁰⁰ The Federal Circuit explained that the patent statute requires an individual to be able to replicate an invention without “undue experimentation.”³⁰¹ In

action underlying an invention, which may be required to determine the necessity and inevitability of the inherent characteristic or result, may only occur years later.”).

292. *See id.* at 77 (“[G]iven the particular problems associated with biotechnology inventions, and other inventions for which technological understanding is limited . . . courts should apply less stringent requirements for holding patent claims to such inventions inherently anticipated.”).

293. *Id.* at 77 n.33.

294. *See* Burk & Lemley, *supra* note 2, at 374 (“[T]he inherency cases are all ultimately about whether the public already gets the *benefit* of the claimed element or invention.”).

295. *See id.* (“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.”).

296. *See id.* at 407.

297. *See id.* (arguing that such a discovery “adds only a modest amount to our technological capabilities and does not justify withdrawing from the public the benefit they already receive”).

298. *Id.*

299. *See* Mueller & Chisum, *supra* note 3, at 1108.

300. *See* 35 U.S.C. § 112 (2006) (“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”); *see also supra* Part I and accompanying text.

301. *See In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (“[E]xperimentation needed to practice the invention must not be undue experimentation.”). In determining whether experimentation is “undue,” the court weighs the following factors: (1) the quantity of

cases where the doctrine of inherent anticipation is invoked to defeat patentability, however, “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.”³⁰² The authors argue that the inherent anticipation doctrine should be used sparingly to defeat patentability, and posit that, under a heightened enablement theory, *Schering Corp.* might have been decided differently.³⁰³

The need to balance the public’s desire for low-cost generic drugs with the need to incentivize pharmaceutical research into useful compounds has prompted calls for other kinds of reform. At least one commentator has called for changes to the patent statute itself, allowing for a short patent term extension to an existing patent to protect newly discovered metabolites provided that the science is “sufficiently advanced.”³⁰⁴ This change, however, should be limited in scope to allow an individual to avoid liability for infringement if he unknowingly practices the metabolite or the prior art.³⁰⁵

B. Towards a New “Capability” Standard for Inherent Anticipation Analyses in Patent Cases

Scientific advancement is proceeding rapidly. Consider the following examples. The storage capacity of computing hardware doubles every eighteen months but new biological data are doubling every nine months.³⁰⁶ Researchers recently developed the most powerful brain simulation ever—the Sequoia supercomputer at Lawrence Livermore National Laboratory—with a simulated 10 billion neurons and 100 trillion connections among them.³⁰⁷ When the Human Genome Project launched in 1990, the scientific

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. *Id.* at 737.

302. Mueller & Chisum, *supra* note 3, at 1145–46 (arguing that experimentation should be limited to trivial choices and not the conventional trial-and-error testing expected of those who want to replicate a patented invention by following the patentee’s teachings).

303. *See id.* at 1153–54 (arguing that the ‘233 patent’s disclosure could not satisfy the author’s proposed heightened enablement standard, leaving the court to “forc[e] the square peg of *Schering* into the round hole of anticipation by inherency”).

304. De La Rosa, *supra* note 27, at 89–90 (arguing for a middle ground for patenting metabolites wherein additional patent protection is appropriate so long as a PHOSITA did not recognize the inherent feature and the discovery sufficiently advanced the public’s scientific knowledge).

305. *See id.* at 90.

306. *See Quick Facts and Figures About Biological Data*, ELIXIR, <http://www.elixir-europe.org/news/quick-facts-and-figures-about-biological-data> (last visited Sept. 20, 2013).

307. *See* Rebecca Boyle, *Simulated Brain Ramps up To Include 100 Trillion Synapses*, POPULAR SCIENCE (Nov. 19, 2012, 4:02 PM), <http://www.popsci.com/technology/article/2012-11/world’s-fastest-supercomputer-simulates-100-trillion-synapses-many-human-brain> (noting the “unprecedented 2.084 billion neurosynaptic cores, which are an IBM-designed computer architecture that is designed to work like a [human] brain” (emphasis added)).

community was deeply skeptical about whether the project's audacious goals could be achieved. In April 2003, the International Human Genome Sequencing Consortium announced the successful completion of the project, mapping the genome to within 99.99% accuracy, more than two years ahead of schedule.³⁰⁸ Moore's Law, simply stated, holds that the number of transistors that can be successfully placed on a processor will double approximately every eighteen months. Although Moore's Law held true for many decades, some believed that the end of Moore's Law was near.³⁰⁹ But, in February 2012, researchers announced the successful production of a single-atom transistor that would effectively allow computer manufacturers to beat the physical limits of Moore's law.³¹⁰ At least one commentator believes that the rate of technological growth is exponential, rather than linear, and, at today's rate, progress achieved in the next 100 years will actually resemble 20,000 years of progress, attributable mainly to synergistic feedback among the various fields of scientific research, including genetics, nanotechnology, and robotics.³¹¹ Metabolomics (research concerned with the comprehensive characterization of the small molecule metabolites in biological systems) currently benefits from the "rapid pace" at which metabolite detection and elucidation techniques are evolving, with data reporting in this area having increased over 600 percent in recent years.³¹² As science uncovers more about the world, all we know with certainty is that we do not know much.³¹³

308. See *International Consortium Completes Human Genome Project*, NAT'L HUM. GENOME RES. INST. (Apr. 14, 2003), <http://www.genome.gov/11006929>.

309. See Brooke Crothers, *Report: IBM Researcher Says Moore's Law at End*, CNET NEWS (Apr. 9, 2009, 9:00 PM), http://news.cnet.com/8301-13924_3-10216733-64.html.

310. See *One and Done: Single-Atom Transistor Is End of Moore's Law; May Be Beginning of Quantum Computing*, PURDUE U. NEWS SERVICE (Feb. 19, 2012), <http://www.purdue.edu/newsroom/research/2012/120219KlimeckAtom.html>.

311. See Ray Kurzweil, *The Law of Accelerating Returns*, KURZWEIL ACCELERATING INTELLIGENCE (Mar. 7, 2001), <http://www.kurzweilai.net/the-law-of-accelerating-returns> (arguing that technological growth is exponential, not linear, and, at today's rate, 100 years of scientific advancement in the twenty-first century will actually resemble around 20,000 years of progress by century's end).

312. See Thomas A. Baillie, *Metabolism and Toxicity of Drugs. Two Decades of Progress in Industrial Drug Metabolism*, 21 CHEMICAL RES. TOXICOLOGY 129, 135 (2008); see also David S. Wishart et al., *HMDB 3.0—The Human Metabolome Database in 2013*, 41 NUCLEIC ACIDS RES. 801 (2012) ("[T]he number of annotated metabolite entries has grown from 6500 to more than 40,000 (a 600% increase). This enormous expansion is a result of the inclusion of both 'detected' metabolites (those with measured concentrations or experimental confirmation of their existence) and 'expected' metabolites (those for which biochemical pathways are known or human intake/exposure is frequent *but the compound has yet to be detected in the body*).") (emphasis added).

313. See Adam Hadhazy, *Science's 8 Greatest Unsolved Mysteries: Progress Report*, POPULAR MECHANICS, <http://www.popularmechanics.com/science/sciences-greatest-unsolved-mysteries-progress-report#slide-1> (last visited Sept. 20, 2013).

We've split the atom and gone to the moon, spliced open the genome and saved countless lives with medicines. Yet as far as we've come, we have a long way to go. We continue to grapple with realities beyond our understanding, from the inner workings of our bodies to the intrinsic mechanics of the universe.

Id.

The point of the previous paragraphs is not to trumpet the advancement of scientific progress, but merely to emphasize that the public's analytical knowledge of the world advances at a rapidly increasing rate. Metabolite research in particular has progressed exponentially, yet it remains in its infancy.³¹⁴ In fact, the Metabolomics Society, whose goal is to promote the growth, use, and understanding of metabolomics in the life sciences, was only founded in 2004.³¹⁵ Recent estimates hold that many chemical metabolites are currently unknown, but likely “play vital and *previously unappreciated* roles in human health and disease.”³¹⁶ In fact, researchers have already successfully identified metabolites associated with chronic pain when found in higher than normal levels, a discovery that might lead to new treatment options for chronic pain sufferers.³¹⁷ The notion that metabolism inactivates pharmaceutically active drugs seems antiquated in the face of increasing evidence that metabolites are just as efficacious, if not more so, than the parent drug they were derived from.³¹⁸ In fact, their increased safety profile has led to the use of metabolites as a source for new drug candidates.³¹⁹ Moreover, advanced technologies such as deep-learning artificial intelligence programs and supercomputers are providing new means by which to identify promising new molecules for drug design.³²⁰

Commentators who disagree about the scope or application of the inherent anticipation doctrine seem to agree, however, on the usefulness and beneficial aspects of metabolites.³²¹ This Note agrees with previous scholarship that labels the discovery of metabolites as a “substantial discovery that advances science.”³²² Unfortunately, pharmaceutical drug

314. See Cory Abate-Shen & Michael M. Shen, *Diagnostics: The Prostate-Cancer Metabolome*, 457 NATURE 799, 799 (2009) (noting that until now cancer metabolomics has remained in its infancy).

315. See *Society History and Objectives*, METABOLOMICS SOC'Y, <http://www.metabolomicsociety.org/history> (last visited Sept. 20, 2013).

316. *Expanding Database Enables Discoveries in Emerging Field of Metabolomics*, SCRIPPS RES. INST. (Sept. 10, 2012), <http://www.scripps.edu/news/press/2012/20120910suizdak.html> (emphasis added).

317. See *id.* (stating that researchers are already identifying metabolites involved in cancer progression, aging, and drug addiction, and that these and further discoveries are likely to provide promising targets for new therapies).

318. See Jiunn H. Lin & Anthony Y. H. Lu, *Role of Pharmacokinetics and Metabolism in Drug Discovery and Development*, 49 PHARMACOLOGICAL REV. 403, 407 (1997).

319. See *id.* (describing that acetaminophen demonstrates greater analgesic activity when compared to its parent compound phenacetin, and does not cause methemoglobinemia (a blood disorder that produces an abnormal amount of a form of hemoglobin) or hemolytic anemia (a condition in which the body does not have enough healthy red blood cells)).

320. See John Markoff, *Learning Curve: No Longer Just a Human Trait*, N.Y. TIMES, Nov. 24, 2012, at A1.

321. See Chen, *supra* note 27, at 112–13 (arguing that branded pharmaceutical companies will continue metabolite research in spite of the inherent anticipation doctrine because it remains possible under *Schering Corp.* to gain patent protection for useful metabolites); De La Rosa, *supra* note 27, at 83 (“The Hatch-Waxman Act acknowledges that pharmaceuticals play a special role in our society.”); Smith, *supra* note 283, at 856 (“[M]etabolites . . . help explain the scientific process behind drugs.”).

322. De La Rosa, *supra* note 27, at 90.

research and design is a costly proposition.³²³ The average cost of bringing a new pharmaceutical entity to market is \$500 million over a period of approximately twelve to fifteen years,³²⁴ with much of that time spent seeking FDA approval that the entity is safe for public use.³²⁵ Completely recouping the costs of developing a new drug can take manufacturers as long as twelve to nineteen years.³²⁶ Over recent years, branded pharmaceutical companies have seen a marked increase in competition from generic competitors, resulting in a shorter time frame where they may recoup their investment.³²⁷ Patent protection—the time-limited monopoly during which they may make the drug, and exclude others from making the same—is the primary manner by which branded pharmaceutical companies can protect their investments. The expansion of the inherent anticipation doctrine under *Schering Corp.* is likely to dissuade pharmaceutical companies from fully disclosing their discoveries to the public via patent specifications,³²⁸ encouraging them instead to seek to protect their discoveries as trade secrets. The Federal Circuit’s Judge Newman expressed a similar concern, stating that, “no newly discovered product found in an organism [could] be patented” under *Schering Corp.*³²⁹

From a public policy perspective, recourse to trade secrets would hinder,³³⁰ rather than promote, the policy goal of full public disclosure that underlies U.S. patent law.³³¹

323. See PHARM. RESEARCH & MFRS. OF AM., WHY DO PRESCRIPTION DRUGS COST SO MUCH? . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINES 2–3 (2000), available at <http://web.whittier.edu/chemistry/newdrug/PhRMA.pdf>.

324. See *id.* at 2 (noting that much of the time is spent obtaining the requisite approval that the drug is safe).

325. See Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 96–98 (2001) (noting that patents are typically obtained before manufacturers go through the approval process, and this FDA regulation causes time—approximately seven years—to be lost on the patent).

326. See *id.* at 98.

327. See PHARM. RESEARCH & MFRS. OF AM., *supra* note 323, at 2.

328. See De La Rosa, *supra* note 27, at 87 (“[I]f discoveries such as [metabolites] are denied patent protection, it is likely that companies like Schering will choose in the future to maintain these unpatentable advancements as trade secrets, lest a competitor be handed a starting point to reverse engineer a competing product before the expiration of the original patent.”).

329. *Schering Corp. v. Geneva Pharm., Inc.*, 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting).

330. See Unif. Trade Secrets Act § 1(4) (amended 1985), 14 U.L.A. 538 (2005) (A “trade secret” is defined as “information, including a formula, pattern, compilation, program, device, method, technique, or process, that . . . derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and . . . is the subject of efforts that are reasonable under the circumstances to maintain its secrecy”). The Prefatory Note to the Uniform Trade Secrets Act indicates why a company would choose to maintain information as a trade secret as opposed to seeking patent protection:

A valid patent provides a legal monopoly for seventeen years in exchange for public disclosure of an invention. If, however, the courts ultimately decide that the Patent Office improperly issued a patent, an invention will have been disclosed to

Thus, in light of the importance of metabolite research to society, the public policy goals of the patent laws, and our rapidly expanding base of scientific knowledge, this Note suggests reforming the inherent anticipation doctrine. The decision in *Schering Corp.* is notable for the establishment of a bright-line rule,³³² but this rule will ultimately fail to keep pace with scientific advancement.³³³ The nature of scientific discovery necessitates a new standard for inherent anticipation analyses, which this Note terms a “capability” standard. This proposed standard is a two-part inquiry that focuses on the state of the relevant art when the potentially anticipating prior art was disclosed. Under this standard, a court dealing with inherency should ask two questions: (1) Would the state of the relevant art at the time of the anticipating prior art reference permit a PHOSITA to detect the inherent feature? (2) If it would, would a PHOSITA have been reasonably expected to detect it?

The first prong of this analysis asks the court to make a factual determination about the state of the relevant art (e.g., biological, chemical, or pharmaceutical) at the time that the anticipating prior art reference was published.³³⁴ Such an inquiry would involve factual determinations about the state of scientific computing and analysis, technological capabilities, and scientific instrumentation during the relevant time period.

For instance, consider a hypothetical drug A, patented in 1980. Drug A has a useful metabolite, metabolite B, discovered in 2012. Under this Note’s suggested “capability” standard, evidence could be presented either asserting or rebutting the notion that the technological capabilities of a PHOSITA living in the year 1980 made it possible for him to detect the inherent feature (metabolite B) which necessarily and inevitably follows from the administration of drug A to patients. If metabolite B was

competitors with no corresponding benefit. In view of the substantial number of patents that are invalidated by the courts, many businesses now elect to protect commercially valuable information through reliance upon the state law of trade secret protection. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974), which establishes that neither the Patent Clause of the United States Constitution nor the federal patent laws pre-empt state trade secret protection for patentable or unpatentable information, may well have increased the extent of this reliance. *Id.* prefatory n., 14 U.L.A. at 530. The patent term length has since expanded from seventeen years to twenty years. 35 U.S.C. § 154(a)(2) (2006).

331. See De La Rosa, *supra* note 27 at 87–88 (“If *Schering* encourages recourse to trade secrets, then the policy goals of patent law have not been served because scientific advancement will not become readily accessible to the public.”).

332. See *supra* Part II.C.

333. A similar view has been expressed elsewhere in the scholarship on this topic. See Burke, *supra* note 286, at 1163 (“The term ‘readily detectable,’ however, produces special problems in the pharmaceutical context. As scientific equipment and methodology continue to improve, the Federal Circuit will have to return to the ‘readily detectable’ standard and clarify the requirement.”).

334. In cases involving drug metabolites, the anticipating prior art reference would likely be the patent issued on the parent drug. See Mueller & Chisum, *supra* note 3, at 1148 (describing the argument of the generic drug company Geneva Pharmaceuticals, Inc., in *Schering Corp.* that the patent on the parent drug loratadine rendered the patent on its metabolites invalid as anticipated under a theory of inherency).

completely undetectable in 1980, but new scientific instruments and methodologies permitted its detection in 2012, the doctrine of inherent anticipation should not be invoked to defeat the novelty of metabolite B.

If sufficient evidence demonstrates that a PHOSITA was capable of detecting the inherent feature as of the date of the potentially anticipatory prior art reference using 1980s technology, the second prong of this analysis would ask the court to consider whether or not a PHOSITA reasonably should have been expected to detect it. Perhaps metabolite B is a pharmaceutically active metabolite responsible for the beneficial effects of drug A, or perhaps it is the dominant metabolic product of the body's metabolism of drug A, or perhaps it is easily detectable in high concentrations in the blood. In these cases, it is likely that a PHOSITA would have discovered the metabolite during the course of obtaining FDA approval, drug development, and other clinical studies. If both of these prongs were satisfied, the patent on drug A would inherently anticipate metabolite B.

But, perhaps metabolite B produces unforeseen side effects wholly unrelated to drug A's intended use. It is not uncommon for drugs to produce side effects that researchers had no reason to expect.³³⁵ Under the second prong of this Note's proposed analysis, patent protection for metabolite B should not be precluded via inherent anticipation, even if the technology of the day permitted its detection. The complex nature of the human body's biological system produces strange, surprising, and often unforeseeable results when it encounters foreign agents such as active pharmaceutical entities.

Under the inherent anticipation doctrine promulgated by *Schering Corp.* and reinforced by *SmithKline*, however, any undiscovered metabolites of drug A, including metabolite B, would be inherently anticipated and thus not patentable because they are a necessary and inevitable consequence of the administration of drug A. *Schering Corp.* holds that it makes no difference if a PHOSITA knew about the metabolite in 1980, or if he was even capable of detecting its presence using the technology of the era. Due to the costly nature of drug discovery and design, and the valuable nature of metabolite research to society in general, it behooves the Federal Circuit to reexamine the doctrine of inherent anticipation.

CONCLUSION

To date, the patent law doctrine of inherent anticipation remains mired in confusion, both in its present interpretation and its future application. Much of this uncertainty stems from confusing precedent and a recent

335. See *Viagra Touted As Life-Saving Heart Treatment—After Scientists Find It Makes Heart Muscles Less Stiff*, DAILY MAIL (Dec. 23, 2011, 12:39 PM), <http://www.dailymail.co.uk/sciencetech/article-2078139/Viagra-touted-life-saving-heart-treatment--scientists-makes-heart-muscles-LESS-stiff.html> ("The drug [Viagra] was first developed as a heart disease treatment—it's more well-known use was simply a lucky side-effect.").

controversial decision in *Schering Corp.* that seemingly bucks that precedent in favor of the rule that PHOSITA recognition of the inherent feature is not required for inherent anticipation. Calls for doctrinal reform, and even outright dispensation of the doctrine itself, abound. In the absence of reform, however, inherency challenges against patent applicants seeking to protect their technological inventions are only likely to grow as society's scientific knowledge increases. With its decision in *Schering Corp.*, the court has placed upon itself the daunting challenge of determining whether or not a feature is inherent within the prior art. Such a determination is typically problematic for the scientists and inventors behind these discoveries, given the vast complexities associated with technological inventions. It will be nearly impossible for the court to accurately assess whether or not a feature is truly inherent in the prior art as our technological capabilities quickly outpace the patent laws. The Federal Circuit should reexamine, and strongly consider reforming, the doctrine of inherent anticipation in light of these advancements. This Note suggests one possible method of reform that focuses an inherent anticipation analysis on the state of the relevant art at the time an asserted prior art reference was published to determine whether or not a PHOSITA was even capable of determining the presence of the inherent feature, and if he was, whether or not he should have reasonably been expected to find it. By focusing its analysis on facts that are readily ascertainable (such as the state of the relevant art at the time the anticipating prior art reference was published), as opposed to those facts which may only come to light years after a technological invention is disclosed (such as an inherent feature which is a necessary and inevitable consequence of practicing the prior art), the court could alleviate much of the confusion plaguing the doctrine of inherent anticipation.