ANTICIPATING TOO MUCH: WHY THE COURT SHOULD AVOID EXPANDING THE DOCTRINE OF INHERENT ANTICIPATION

*PETER D. SMITH**

CONTENTS

* Articles Editor, *NYU Annual Survey of American Law*, 2005–06. J.D. candidate, New York University School of Law, 2006; B.S., Duke University, 2000. I would like to thank my friends and family for their continued support, Herbert Schwartz who provided helpful comments and in whose class I learned patent law, and the entire editorial board and staff of the NYU Annual Survey of American Law, especially Scott Elengold for his valuable feedback on initial drafts and Jeremy Stein for preparing this Note for publication.

Schreiber's patent application claims a device for dispensing popped popcorn. That device is conically shaped with a large opening that fits on a container and a smaller opening at the opposite end that allows popped popcorn to pass through when the device is attached to a popcorn container and turned upside down . . . . There is no dispute that the structural limitations recited in Schreiber's application are all found in the Harz reference . . . . Schreiber . . . argues that the functional limitations of his claim distinguish it from Harz. In particular, Schreiber points to the recitation that the claimed top 'allows several kernels of popped popcorn to pass through at the same time,' and that the taper of the top is such 'as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.' . . . [T]he opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to 'allow[ ] several kernels of popped popcorn to pass through at the same time' and . . . the taper of Harz's conically shaped top is inherently of such a shape 'as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container.' . . . [T]herefore . . . Harz established a prima facie case of [inherent] anticipation.[1]

1. *In re* Schrieber, 128 F.3d 1473, 1474, 1477–78 (Fed. Cir. 1997). This excerpt serves as an example of the doctrine of inherent anticipation, a doctrine which will be explored in more depth throughout this Note.

I.
INTRODUCTION

The U.S. Constitution grants Congress the 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."[2] It is important to understand that the "ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."[3] The government offers exclusive monopolies to inventors as incentives to discover new things, and in exchange, the inventor must disclose, or describe, the details of the invention to the public.[4] The patent monopoly allows the inventor to exclude all others from the practice of the invention for a specified period of time.[5] The scope of a patent, or the bounds from which the inventor may exclude others, is measured by its claims, a list of each element involved in the invention.

This Note examines a complex area of patent law known as inherent anticipation. Before understanding inherent anticipation, one must first understand regular anticipation. The general rule of anticipation is that one cannot patent an invention which exists in prior art, e.g., previous patents, inventions, written descriptions, or public uses or sales.[6] In other words, to be patentable an invention must be new, which it would not be if it were completely disclosed in a prior art reference. Inherent anticipation is an extension of this notion; it allows one to look not only at what is expressly mentioned in a prior art reference, but at what is actually occurring in that reference.[7] For example, if the prior art claimed an invention involving two objects tied together by a piece of string, a later inven-

2. U.S. CONST. art. I, § 8, cl. 8.

3. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

4. *See, e.g.*, Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 (Fed. Cir. 1995) ("The inventor is required to make full disclosure of his invention to the Patent and Trademark Office (PTO) and to the public in his patent specification, which he is otherwise not obligated to do. In return, the law allows the government to confer a property right to exclude anyone else from making, using, or selling the invention covered by the claims for seventeen years, which it is otherwise not obligated to do."), *aff'd*, 517 U.S. 370 (1996).

5. "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2000).

6. The various forms of prior art are detailed in 35 U.S.C. § 102 (2000).

7. *See, e.g.*, P.N. Makrogiannis, *Review of the 1999 Patent Law Decisions of the United States Court of Appeals for the Federal Circuit*, 49 AM. U. L. REV. 1381, 1396 (2000) ("The doctrine of inherent anticipation expands the scope of a prior art

tion which claimed the exact same thing but added the requirement that there be a knot involved would be inherently anticipated by the earlier art. Although the earlier art made no express mention of the use of knots, it is inherent in the process of tying objects together.

This Note will address whether the United States Court of Appeals for the Federal Circuit ("Federal Circuit"), the court with appellate jurisdiction over all patent cases, should liberally expand the use of the doctrine of inherent anticipation to invalidate patents, or whether, as I will argue, this doctrine should be used sparingly, only when necessary to fill in a true gap in the prior art. A finding of anticipation means an invention is not new because it exists completely in the prior art; such a strong finding removes the incentives necessary for discovery of things that would otherwise remain unknown to the public. For this reason, inherent anticipation should only be used to invalidate patents when the invention is truly not novel, i.e. when the later invention adds no new knowledge to the public domain.

To fully express this argument, I will focus on the use of inherent anticipation in biotechnology, where the inventor has discovered a new chemical structure; particular attention will be paid to the Federal Circuit decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*[8] as an example of the mistake of expanding this doctrine. The reader should bear in mind, however, that inherent anticipation and the arguments involved in this Note apply to all types of inventions, not just to biotechnology. After reviewing the facets and policies of inherent anticipation in Part II, I will examine some of the Federal Circuit's previous decisions in this realm in Part III. Then I will take a close look at *Schering* in Part IV and will discuss a benefit of, and possible motivation behind, the *Schering* court's decision, namely to curb pharmaceutical companies' unfair extension of their drug patents through the patenting of metabolites. I will contrast the court's application of the doctrine of inherent anticipation in *Schering* with the precedent and show that the court broadened the scope of the doctrine beyond the dictates of the precedent by both removing the requirement of recognition and extending inherent anticipation to encompass situations in which there is absolutely no express disclosure. I will then suggest alternatives to the court's expansion of inherent anticipation in Part V, showing this was not the only way the court could have protected

reference to anticipate more than what is explicitly taught in that prior art reference.").

8. 339 F.3d 1373 (Fed. Cir. 2003).

the public from the unfair use of metabolite patents. This Note will conclude with an analysis of the extension of the doctrine of inherent anticipation and an argument that it is poor policy and should be avoided.

II.
OVERVIEW OF INHERENT ANTICIPATION

A. Anticipation

In this section, I will describe anticipation, which is a determination that a patent is invalid because it fails the test of novelty. I will then discuss the two main qualifications which must be met before a finding of anticipation can be made, namely that every element must be found in a single piece of prior art and that that piece of prior art must give sufficient instructions so as to enable the public to practice the invention. This section will conclude with an examination of the main purpose behind anticipation, to stop patentees from taking inventions already available to the public away from them.

As codified at 35 U.S.C. § 102(a), an invention must be novel in order to be patentable.[9] "An invention that is not novel is said to be 'anticipated.'"[10] References that anticipate a claimed invention render those claims invalid.[11] Anticipation requires that the identical invention be previously disclosed or known to others.[12] In order for prior art to anticipate and thereby invalidate a patent, every element or limitation of the patented claim must be disclosed in a

9. 35 U.S.C. § 102(a) (2000) ("[A] person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . . ."); *see, e.g.*, Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991) ("The statutory requirement that a patented invention be 'new' is tested in accordance with 35 U.S.C. § 102(a) . . . ."); Steven C. Carlson, *Inherent Anticipation*, 40 IDEA 297, 298 (2000) ("Inventions have to be novel to qualify for patent protection. This common sense notion . . . bars patentability of inventions that have been anticipated by prior art.").

10. Todd R. Miller, *Patented Compounds Inherently Coproduced as Trace Impurities: Issues of Inherent Anticipation and Literal Infringement*, 32 AIPLA Q.J. 425, 437 (2004); *see, e.g.*, Brown v. 3M, 265 F.3d 1349, 1351 (Fed. Cir. 2001); Irving N. Feit & Christina L. Warrick, *Inherency in Patent Law*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 5, 5 (2003).

11. *See, e.g.*, Robert A. Matthews, Jr. & Louis M. Troilo, Schering Corp. v. Geneva Pharmaceuticals, Inc.: Just How Far Can Inherent Anticipation Extend?, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 779, 779 (2004) ("References that anticipate a claimed invention show that the invention lacks novelty and renders invalid any claim to that described invention.").

12. *See, e.g.*, *Cont'l Can*, 948 F.2d at 1267; *Brown*, 265 F.3d at 1351.

single prior art reference.[13] Judge Learned Hand explained that "[n]o doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated."[14] The reason for this requirement is that a finding of anticipation means that a later invention is not new; this only occurs if the identical invention has been found and disclosed at an earlier point in time. If the later invention cannot be found in a single piece of prior art, it must be considered new because no one else has combined all the same elements together before.

One additional requirement of anticipation was alluded to in Hand's explanation of anticipation when he discussed "adequate directions for the practice of the patent invalidated."[15] To anticipate, the prior art must enable the newly claimed invention, i.e. it "must place the . . . subject matter [of the claimed invention] in the possession of the public."[16] This means that the prior art must give instructions sufficient for the public to be able to practice the claimed invention. Before the public has the ability to practice the invention, it cannot be said that the prior art has revealed the invention to the public and thus the later invention is still considered novel. This requirement for anticipation was made distinctly clear in the Federal Circuit's recent opinion in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*.[17] In this case, the challenged patent claimed a transgenic rodent whose genetic makeup was modified to include a mutation to assist in Alzheimer's research.[18] The prior art described the same mutation and stated

13. *See, e.g.*, *Brown*, 265 F.3d at 1351; Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim."); Studiengesellschaft Kohle, M.B.H. v. Dart Indus., Inc., 726 F.2d 724, 726–27 (Fed. Cir. 1984) ("It is hornbook law that anticipation must be found in a single reference . . . ."); Feit & Warrick, *supra* note 10, at 5; Miller, *supra* note 10, at 437.

14. Dewey & Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 989 (2d Cir. 1942).

15. *Id.*

16. Miller, *supra* note 10, at 437. The concept of enablement is derived from the specification requirement. 35 U.S.C. § 112 (2000) ("[T]he specification shall . . . enable any person skilled in the art . . . to make and use the [invention]."). "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (citations omitted).

17. 346 F.3d 1051 (Fed. Cir. 2003).

18. *See id.* at 1053. A representative claim recites:

> A transgenic rodent comprising a diploid genome comprising a transgene encoding a heterologous APP polypeptide having the Swedish mutation wherein

that "the invention provides a transgenic animal whose cells contain the mutated gene."[19] On appeal from a finding of anticipation by the district court, the Federal Circuit remanded the case for determination of whether the prior art enabled the production of the transgenic mouse.[20] The court thought the relevant issue in this case was whether the prior art, which disclosed the same invention, gave sufficient instructions such that the public could actually practice the invention and create the transgenic rodent. It stressed that "invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation."[21]

The main purpose of anticipation is to protect inventions already in the public domain from being patented.[22] The entire patent system is designed around encouraging innovation by giving incentives to inventors to develop or discover new ideas and inventions and disclose them to the public.[23] This quid pro quo system operates by giving temporary monopolies to inventors as inducement to add to the body of public knowledge; the government trades a grant of limited exclusivity in exchange for development

---

> the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively, wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation, and wherein said polypeptide is processed to ATF-betaAPP in a sufficient amount to be detectable in a brain homogenate of said transgenic rodent.

Id.

19. *Id.* at 1055–56.

20. *Id.* at 1057. In an earlier decision which was later vacated en banc, the Federal Circuit reversed the finding of anticipation after determining that the requirements of inherent anticipation were not met because the transgenic mouse did not previously exist and therefore its properties were not known to persons of ordinary skill in the art. *See* Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 304 F.3d 1221 (Fed. Cir. 2002), *vacated en banc*, 314 F.3d 1299 (Fed. Cir. 2002).

21. *Elan Pharm.*, 346 F.3d at 1052.

22. *See, e.g.*, Matthews & Troilo, *supra* note 11, at 782 ("The validity requirement of novelty and the corresponding doctrine of anticipation provide one means of protecting subject matter already in the public domain.").

23. This "bargain theory starts with the premise that people will be encouraged to produce new inventions if there is some reward as an incentive." ARTHUR R. MILLER & MICHAEL H. DAVIS, INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL 16 (3d ed. 2000). "Commentators have amassed data seeming to support the proposition that the American patent system has been extremely successful in furnishing the incentive to develop more and greater inventions . . . [and] that disclosure has enabled later inventors to build upon the base developed by earlier patents." *Id.* at 17–18.

and disclosure of new products and processes.[24] However, there is no reason to grant a monopoly when the public was previously aware of the invention because this incentive would serve no purpose but to take an invention already available to the public away from it. The use of anticipation to invalidate patents ensures that new patents do not grant monopolies on inventions "already within the public's store of knowledge."[25]

B. Inherent Anticipation

The doctrine of inherent anticipation is a variation on the purely express form of anticipation discussed above. This section will explain the differences between inherent anticipation and express anticipation and then look at the main purpose of inherency, to allow flexibility in the rigid rules of anticipation such that patentees are prevented from taking away from the public inventions which would be anticipated but for a gap in the prior art.

Prior art can anticipate elements of a claim either expressly or inherently.[26] To find express anticipation, the reference must expressly disclose the entire claim; each and every element of the invention is expressly stated in the prior art.[27] When not every limitation of a claim is expressly disclosed in the prior art, the doctrine of inherency can be used to allow an implicit disclosure to stand in for the missing express disclosure.[28] In other words, the "anticipatory reference . . . need not duplicate word for word what

24. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989) ("The federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of . . . advances in technology and design in return for the exclusive right to practice the invention for a period of years."); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 621 (Fed. Cir. 2000) (en banc) (Linn, J., concurring in part and dissenting in part) ("An exclusive right granted by the government for one's invention has value to an inventor as a guarantee of protection, and, thus, stimulates inventors to add to the sum of human knowledge."), *vacated*, 535 U.S. 722 (2002); Miller, *supra* note 10, at 438 ("The patent system . . . encourages inventors to add to the already available body of knowledge by conferring upon the patentee a right to temporarily exclude others from that which he contributed.").

25. Miller, *supra* note 10, at 439.

26. *See, e.g.*, Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999); In re Schrieber, 128 F.3d 1473, 1477 (Fed. Cir. 1997); Feit & Warrick, *supra* note 10, at 5.

27. *See, e.g.*, Carlson, *supra* note 9, at 299.

28. *See, e.g.*, *Atlas Powder Co.*, 190 F.3d at 1347 ("[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it."); Matthews & Troilo, *supra* note 11, at 781.

is in the claims."[29] "Where the combination of the expressly disclosed subject matter and the inherently disclosed subject matter meets each claim limitation of a later-claimed invention, the reference inherently anticipates the later-claimed invention."[30] "The doctrine of inherent anticipation expands the scope of a prior art reference to anticipate more than what is explicitly taught in that prior art reference."[31]

The doctrine of inherent anticipation can be viewed as "modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference."[32] It serves to account for common knowledge that judges might not know but those with skill in the art would.[33] For example, revisiting the aforementioned hypothetical of two objects tied together by string,[34] inherent anticipation allows a judge who might not know that tying objects with string necessarily involves the implicit element of a knot to use this information known by those skilled in the art of tying string. The doctrine recognizes that a newly claimed invention is not truly "novel" if all that is missing from a prior art reference is an implicit element of the claim, such as the knot in the string example. Only by examining both the express and implicit disclosures of the prior art can a true determination of anticipation be made such that inventions previously available to the public are not removed from its grasp. However, by limiting the use of implicit disclosures to that which is recognized and present in the prior art, the necessary incentives for innovation and discovery of previously unknown inventions remain intact in the patent system.

29. Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369 (Fed. Cir. 1991).

30. Matthews & Troilo, *supra* note 11, at 781; *see* Miller, *supra* note 10, at 439–40 ("Inherent anticipation occurs when the prior art reference does not expressly disclose at least one element of the claim, but each missing element is nonetheless inherent in the disclosure of the reference.").

31. Makrogiannis, *supra* note 7, at 1396.

32. Cont'l Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991).

33. *See id.*; Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 304 F.3d 1221, 1229 (Fed. Cir. 2002), *vacated en banc*, 314 F.3d 1229 (Fed. Cir. 2002).

34. See discussion *supra* Part I.

C. Inherent Anticipation is Different Than Obviousness

In addition to being novel, an invention must also be non-obvious.[35] As outlined in 35 U.S.C. § 103, a patent is invalid for obviousness if a hypothetical person of ordinary skill in the relevant art would think to make the invention by combining elements of prior art.[36] Some have confused inherent anticipation with obviousness analyses because both permit one to look at more than what is expressly disclosed in a piece of prior art; however, these are distinct concepts with distinct analyses, and it is important to understand the differences between the two. This becomes clear by first comparing explicit anticipation to obviousness, and then comparing inherent anticipation to obviousness in a similar manner.

An explicit anticipation analysis differs from an obviousness analysis. As discussed, prior art references cannot be combined to invalidate a patent for anticipation.[37] However, a reference can be combined with other prior art to show that each limitation of the claim is obvious and invalid under 35 U.S.C. § 103(a); though invalid for obviousness, the later invention is not said to be anticipated.[38] Such an invention is still considered novel so long as no *single* prior art reference discloses all of its limitations, because this exact invention has never been disclosed before.

While the doctrine of inherent anticipation allows for examination of the implicit disclosures of the prior art reference—i.e. that which exists in the prior art but which is not expressly disclosed—it does not permit one to fill in missing elements with material known from another source.[39] Anticipation always requires the entire invention to exist in a single prior art reference; this rule does not change even when the doctrine of inherency is used. Inherent anticipation is still a measure of novelty and must therefore be derived from the mixture of express and implicit disclosures within one reference. For example, in *Trintec Industries, Inc. v. Top-U.S.A. Corp.*,

35. *See, e.g.*, U.S. v. Adams, 383 U.S. 39, 48 (1966) ("[N]ovelty and nonobviousness—as well as utility—are separate tests of patentability and all must be satisfied in a valid patent.").

36. 35 U.S.C. § 103(a) (2000) ("A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.").

37. *See, e.g.*, Miller, *supra* note 10, at 437–38 ("It is impermissible to combine prior art references to build an anticipation rejection.").

38. *See, e.g.*, Matthews & Troilo, *supra* note 11, at 780.

39. *See, e.g.*, *id.* at 785.

the Federal Circuit held that a prior art reference related to a color photocopier did not anticipate a later invention involving a color printer.[40] The court explained that while the "difference between a printer and a photocopier may be minimal and obvious to those of skill in this art . . . obviousness is not inherent anticipation."[41] Only if the exact invention exists in a single prior art reference can an invention be anticipated because only then is it truly not a novel invention.

III. AN EXAMINATION OF THE PRECEDENT REVEALS A TWO PART TEST FOR INHERENT ANTICIPATION WITH SPECIFIC EXCEPTIONS

A. Before Schering, Continental Can*'s Test was Used to Determine Inherency*

In 1991, the Federal Circuit decided the seminal case relating to inherent anticipation, *Continental Can Co. USA v. Monsanto Co.*[42] This case involved a patent, the '324 patent, entitled "Ribbed Bottom Structure for Plastic Container," an invention for a "plastic bottle whose bottom structure has sufficient flexibility to impart improved impact resistance, combined with sufficient rigidity to resist deformation under internal pressure."[43] One claimed feature of the '324 patent was that its ribs were hollow.[44]

40. 295 F.3d 1292 (Fed. Cir. 2002).

41. *Id.* at 1296. "The Federal Circuit . . . rejected attempts to expand the applicability of inherent anticipation, noting that inherent anticipation is not a substitute for a well-reasoned obviousness analysis." Kristin L. Yohannan et al., *2002 Patent Law Decisions of the Federal Circuit*, 52 AM. U. L. REV. 891, 908–09 (2003).

42. 948 F.2d 1264 (Fed. Cir. 1991).

43. *Id.* at 1266. The broadest claim of the '324 patent recites:

> A container having a sidewall and a bottom structure closing the container at an end portion of the sidewall, the outer surface of the bottom structure comprising a central concavity, a convex heel surrounding the concavity and merging therewith and with the sidewall end portion, the lowermost points of the heel lying in a common plane, and a plurality if ribs interrupting the outer surface if the concavity and distributed in a symmetrical array, each rib extending longitudinally in the direction of the heel and downwardly from an inner portion of the concavity, whereby the outer end portion of each rib is lower than the inner end portion thereof, characterized by the feature that the ribs are hollow.

Id.

44. *Id.*

Continental brought an infringement suit against Monsanto, which filed for summary judgment on the issue of validity of the '324 patent.[45] Monsanto argued that a piece of prior art, the Marcus patent, anticipated the '324 patent.[46] Although the Marcus patent did not explicitly mention *hollow* ribs, Monsanto argued that the ribs in the Marcus patent were inherently hollow because they were formed by injection blow molding, the same process used to produce the ribs in the '324 patent.[47]

The Federal Circuit stated:

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.[48]

The court found that the determination of whether the ribs in the Marcus patent were "necessarily" hollow was improper for summary judgment because it was a disputed issue of material fact and required trial.[49]

Thus, *Continental Can* set forth a two-prong formula for determining inherent anticipation.[50] First, the undisclosed element must be a necessary technological fact of the prior art.[51] It is inadequate to show that the prior art *might* produce the undisclosed element; rather, it *must* produce the undisclosed element.[52] "The undisclosed element has to flow as a natural consequence from the technological constraints of the prior art."[53] Second, the undisclosed element must be recognized by a person with ordinary skill in the art.[54]

---

45. *See id.* at 1267.

46. *See id.*

47. *See id.* at 1268.

48. *Id.*

49. *See id.* at 1269.

50. *See* Carlson, *supra* note 9, at 300; Miller, *supra* note 10, at 446–47.

51. *See Cont'l Can*, 948 F.2d at 1268; Carlson, *supra* note 9, at 300.

52. *See, e.g.*, Carlson, *supra* note 9, at 300 ("[I]t is inadequate to show that the prior art process would probably, or possibly, produce the undisclosed element."); Miller, *supra* note 10, at 446 ("[T]he missing descriptive matter must be 'necessarily present', i.e. invariability . . . .").

53. Carlson, *supra* note 9, at 300.

54. *See Cont'l Can*, 948 F.2d at 1268; Miller, *supra* note 10, at 446–47 ("[The missing descriptive matter] would be so recognized by persons of ordinary skill in the art, i.e. recognition."). "A widely held interpretation of *Continental Can* is that the inherent feature must be proved by evidence within the prior art time frame . . . . [T]his means that for anticipation by inherency, knowledge or appreci-

Continental Can was cited for this two-part test in *In re Robertson* in 1999.[55] In *Robertson*, a case involving fastening and disposal systems for diapers, the Federal Circuit overturned a finding of inherent anticipation by the Board of Patent Appeals and Interferences ("Board").[56] The Federal Circuit noted that the Board failed to "show that the fastening mechanisms of [the prior art] that were used to attach the diaper to the wearer . . . 'necessarily' disclosed the third separate fastening mechanism of [the later invention] used to close the diaper for disposal, or that an artisan of ordinary skill would so recognize."[57] Under the *Continental Can* test, both prongs need to be satisfied; in *Robertson* neither was, so the court found that the earlier art did not anticipate the later invention.

B. Scientific Understanding was One Limitation on Continental Can

At first glance, the court in *Atlas Powder Co. v. IRECO Inc.* appeared to take a different approach on the issue of recognition.[58] This case involved the Clay patent, which claimed "composite explosives made from the combination of an [ammonium nitrate and fuel oil] composition and an unsensitized water-in-oil emulsion."[59]

---

ation of the inherent feature must be found in the prior art." Michael K. O'Neill & George K. Ng, *Doctrine of Inherent Anticipation is Clarified*, NAT'L L.J., Dec. 8, 2003, at S6, S7.

55. 169 F.3d 743, 745 (Fed. Cir. 1999); *see* Miller, *supra* note 10, at 447.

56. *Robertson*, 169 F.3d at 745. The relevant claim recites:

> [A] mechanical fastening system for forming side closures . . . comprising a closure member . . . comprising a first mechanical fastening means for forming a closure, said first mechanical fastening means comprising a first fastening element; a landing member . . . comprising a second mechanical fastening means for forming a closure with said first mechanical fastening means, said second mechanical fastening means comprising a second fastening element mechanically engageable with said first element; and disposal means for allowing the absorbent article to be secured in a disposal configuration after use, said disposal means comprising a third mechanical fastening means for securing the absorbent article in the disposal configuration, said third mechanical fastening means comprising a third fastening element mechanically engageable with said first fastening element . . . .

Id. at 744. The prior art did not explicitly include a separate fastening means to secure the diaper for disposal. *See id.* at 745.

57. *Id.* at 745.

58. 190 F.3d 1342 (Fed. Cir. 1999).

59. *Id.* at 1344. The claim recites:

> A blasting composition consisting essentially of 10 to 40% by weight of a greasy water-in-oil emulsion and 60 to 90% of a substantially undissolved particulate solid oxidizer salt constituent, wherein the emulsion comprises about 3 to 15% by weight of water, about 2 to 15% of oil, 70 to 90% of powerful oxidizer salt comprising ammonium nitrate which may include other powerful

The only element in the Clay patent not explicitly disclosed in prior art was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree."[60] The trial court determined that this sufficient aeration was an inherent element in prior art composite explosives.[61]

On appeal, the Federal Circuit affirmed the finding of anticipation, holding:

> Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably [sic] new to the discoverer.[62]

The court concluded that sufficient aeration was inherent in the prior art, noting once more that "[i]nsufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation."[63]

In *MEHL/Biophile International Corp. v. Milgraum*, decided shortly after *Atlas Powder*, the Federal Circuit once again found inherent anticipation without recognition by those skilled in the art.[64] This case involved a patent for a method of hair depilation, claiming a method for removing hair using a laser, thereby destroying the papilla and preventing hair re-growth.[65] The defendant in this infringement action relied on a prior art article on the effects of

---

oxidizer salts, wherein the solid constituent comprises ammonium nitrate and *in which sufficient aeration is entrapped to enhance sensitivity to a substantial degree*, and wherein the emulsion component is emulsified by inclusion of 0.1 to 5% by weight, based on the total composition, of an [oil-in-water] water-in-oil emulsifier to hold the aqueous content in the disperse or internal phase.

Id. (alteration in original).

60. *Id.* at 1345 (internal quotations omitted).

61. *Id.*

62. *Id.* at 1347 (citations omitted).

63. *Id.* at 1349.

64. MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999); *see* Miller, *supra* note 10, at 448.

65. *MEHL/Biophile*, 192 F.3d at 1364. The claim recites:

> A method of hair depilation, comprising the steps of:
> a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla;
> b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its

lasers on guinea pig skin to show invalidity of the MEHL/Biolphile patent for anticipation.[66] Although MEHL/Biophile argued that the prior art did not mention hair depilation, the Federal Circuit nevertheless found the patent invalid as anticipated.[67] The court held that "[w]here . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."[68]

One might be tempted to read the *Atlas Powder* and *MEHL/Biophile* holdings broadly, eliminating the recognition prong of *Continental Can*. However, it is possible to reconcile these cases with *Continental Can* based on the nature of the inherent element.[69] Lawrence B. Ebert wrote in November 1999 that *Atlas Powder* stands for the proposition that "[o]ne can't patent 'scientific understanding' of that which was already being done."[70] It is possible to read these cases narrowly, merely limiting the *Continental Can* test when the inherent element is solely the understanding of the process which is already occurring in the prior art.

The correctness of this narrow reading of these cases was affirmed in 2001 in *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, a case involving metal fuses for semiconductor chips.[71] Manufacturers disconnect dysfunctional portions of chips by melting the fuses with lasers.[72] Once the industry switched from polysilicon fuses to metal fuses, there arose a problem whereby the high-energy lasers needed to melt the metallic fuses caused damage to the underlying structure of the chips.[73] EMI owned patents relating to a metallic fuse structure that melts under a low energy laser, thereby obviating the need to use high-energy lasers in the disconnecting process.[74] Cypress used a similar structure and EMI sued

papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.

Id.

66. *Id.* ("Milgraum . . . relied on the Polla article entitled 'Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin.'").

67. *See id.* at 1366–67.

68. *Id.* at 1366.

69. *See, e.g.*, Lawrence B. Ebert, *Inherent Difficulties*, INTELL. PROP. TODAY, Nov. 1999, at 28; *see also* Feit & Warrick, *supra* note 10, at 19 (noting that Ebert "thought the two lines of cases could be reconciled based on the nature of the claimed element that was missing from the prior art.").

70. Ebert, *supra* note 69, at 28.

71. 268 F.3d 1342 (Fed. Cir. 2001); *see also* Feit & Warrick, *supra* note 10, at 21 (concluding that the "EMI decision appears to agree with Ebert.").

72. *See EMI*, 268 F.3d at 1344.

73. *See id.*

74. *See id.* A sample independent claim of these patents recites:

Cypress for infringement of the patents. At trial, Cypress argued that EMI's claims were invalid because they were anticipated by the prior art, which differed only in that EMI claimed a vapor-induced explosion mechanism for melting the fuses, a property of the mechanism of the prior art which existed but had not been recognized.[75] After a jury verdict for Cypress, the district court granted in part EMI's motion for judgment as a matter of law based on its determination that the claims were not inherently anticipated, because one of ordinary skill in the art would not recognize that the explosion mechanism was necessarily present in the prior art.[76]

On appeal, the Federal Circuit reversed the district court's finding of no inherent anticipation. Relying on *Atlas Powder* and *MEHL/Biophile*, the court held:

> Theoretical mechanisms or rules of natural law that are recited in a claim, that themselves are not patentable . . . do not need to be recognized by one of ordinary skill in the art for a finding of inherency. A person of ordinary skill does not need to recognize that a method or structure behaves according to a law of nature in order to fully and effectively practice the method or structure.[77]

The court, however, distinguished other types of inherent anticipation, noting that "this requirement, that a person of ordinary skill in the art must recognize that the missing descriptive matter is necessarily present in the reference, may be sensible for claims that

---

A method of fabricating on a substrate surface a fuse forming an integral part of a metallic interconnect line joining elements in an integrated circuit, the method comprising:

forming a metal interconnect layer above the substrate surface;

forming a layer of an optically absorptive refractory transition metal above said metal interconnect layer, said refractory metal having a higher boiling point than said metal interconnect layer;

defining said metal interconnect layer and said optically absorptive layer into a patterned metallic interconnect for the integrated circuit including a fuse portion therein, *said refractory metal forming a cap to prevent evaporation of said fuse portion when said fuse portion is exposed to a directed energy source to increase the vapor pressure under the cap to produce an explosive removal of said fuse portion*; and removing said fuse portion from said interconnect line by exposing said optically absorptive refractory metal to directed energy source that explosively removes said fuse portion without damaging the substrate.

Id. at 1345–46.

75. *See id*. at 1346–47.

76. *See id*. at 1350.

77. *Id*. at 1351.

recite limitations of structure, compositions of matter, and method steps which could be inherently found in the prior art."[78]

Finding that the claimed vapor-induced explosion mechanism was simply a scientific explanation or rule of nature that explained the way in which the fuses in the prior art ruptured under a laser, the court found EMI's invention inherently anticipated.[79] The court concluded its opinion by stating that its holding did "not foreclose an inventor from claiming an invention in terms of a structure that achieves a specific claimed result. In this case, however, the claim merely explains the operation of the claimed structure, [and] . . . in explaining the operation, the claim merely recited a purported law of nature."[80]

Clearly this case did not overrule the second prong of the *Continental Can* test; rather, the court merely clarified the limitation which cases such as *Atlas Powder* and *MEHL/Biophile* had added to the test. "In cases where the allegedly inherent element is simply a rule of natural law or a theoretical mechanism of operation, there is no requirement that the element be recognized by persons of skill in the art."[81] The opinion plainly acknowledged that the recognition requirement is sensible for some claims but not for this other type of inherent element.[82] Thus, EMI affirmed Ebert's notion that the *Atlas Powder* holding should be read narrowly.[83] "Accordingly, the *Continental Can* rule still exists [after *Atlas Powder*, *MEHL/Biophile*, and *EMI Group*]."[84]

C. Inherent Characteristics was a Second Limitation on Continental Can

A second limitation on the *Continental Can* recognition prong relates to inherent characteristics or properties of the prior art. "A common notion of inherency is that prior art references have certain inherent . . . properties that are a part of the anticipatory scope

78. *Id.* at 1350.

79. *See id.* at 1351.

80. *Id.*

81. *Casenotes and Recent Developments*, 11 FED. CIR. B.J. 789, 828 (2002); *see EMI*, 268 F.3d at 1351.

82. *See EMI*, 268 F.3d at 1350–51.

83. *See* Feit & Warrick, *supra* note 10, at 21 ("[T]he 'theoretical mechanisms or rules of natural law' of the EMI decision can be considered equivalent to the 'scientific understanding' of the Ebert article.").

84. *Id.* at 21 (further noting that "[t]he cases appear to be consistent with the proposition that the ultimate standard for determining whether a claimed element is inherent in the prior art is the objective understanding of a person having ordinary skill").

of the references, even if these properties are not expressly disclosed."[85] This principle predates *Continental Can* but still holds true after it, as evidenced by cases such as *In re Cruciferous Sprouts Litigation*.[86] In *In re Donohue*, the Federal Circuit held that solubility and melting point characteristics are inherent properties of chemical compounds that do not need to be explicitly disclosed by the prior art.[87] Similarly, in *Hazani v. United States International Trade Commission*, the Federal Circuit "ruled that more complex physical properties, such as the overall capacitance of semiconductor circuitry, are also inherent characteristics that need not be expressly disclosed."[88] Likewise, in *Titanium Metals Corp. of America v. Banner*, the court held that the property of "good corrosion resistance" was inherent in the prior art, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties."[89]

In 2002, the Federal Circuit in *In re Cruciferous Sprout Litigation*, clarified that these types of inherent characteristics do not need to be recognized by persons of ordinary skill in the art even after *Continental Can*.[90] *In re Cruciferous Sprout Litigation* involved patents related to growing and eating sprouts to reduce the risk of developing cancer.[91] Foods rich in glucosinolates have high potential for inducing Phase 2 enzymes, which detoxify potential carcinogens.[92] The inventors recognized that certain sprouts such as broccoli and cauliflower contain higher enzyme-inducing potential, and that it is desirable to select the seeds of those sprouts containing the highest levels.[93] Brassica Protection Products LLC, which held the exclu-

85. Carlson, *supra* note 9, at 307.

86. 301 F.3d 1343, 1349 (Fed. Cir. 2002).

87. 766 F.2d 531, 534 (Fed. Cir. 1985); *see* Carlson, *supra* note 9, at 307.

88. Carlson, *supra* note 9, at 307–08 (citing 126 F.3d 1473, 1477 (Fed. Cir. 1997)).

89. 778 F.2d 775, 782 (Fed. Cir. 1985).

90. *See In re Cruciferous Sprout Litig.*, 301 F.3d at 1350.

91. *See id.* at 1345. The patents claim:

> A method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts . . . . [A] method of preparing a human food product from sprouts . . . . [A] method of increasing the chemoprotective amount of Phase 2 enzymes in a mammal, as well as a method of reducing the level of carcinogens in a mammal, by creating a food product from sprouts and then administering said food product to a mammal.

Id. (internal quotations omitted).

92. *See id.*

93. *See id.*

sive license for the patents, sued a number of defendants for infringement.[94] The defendants countered by filing a summary judgment motion for invalidity, arguing that the prior art, which disclosed growing and eating sprouts, anticipated the patents.[95] Brassica contended that "the prior art merely discusse[d] growing and eating sprouts without mention of any glucosinolates or Phase 2 enzyme-inducing potential."[96] The district court sided with the defendants, stating that "a plant (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[.]"[97] The Federal Circuit affirmed, noting that "Brassica has done nothing more than recognize properties inherent in certain prior art sprouts, just like the corrosion resistance properties inherent to the prior art alloy in *Titanium Metals*. While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."[98] Noting that the *Continental Can* recognition prong does not apply to inherent characteristics, the court explained that "[i]t matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics of the sprouts."[99]

IV.
THE *SCHERING* COURT DEVIATED FROM PRECEDENT AND APPLIED INHERENT ANTICIPATION TO STOP EXTENSION OF PATENT MONOPOLIES THROUGH THE USE OF METABOLITE PATENTS

A. Schering Tried to Extend its Monopoly with a Metabolite Patent

Schering Corp. v. Geneva Pharmaceuticals involved an infringement suit against pharmaceutical companies attempting to manufacture a generic version of the drug loratadine.[100] In 1981, Schering was issued the patent U.S. 4,282,233 (the '233 patent), which covered loratadine, an antihistamine that does not cause

94. *See id.* at 1345–46.

95. *See id.* at 1346.

96. *Id.* at 1349.

97. In re Cruciferous Sprout Patent Litig., 168 F. Supp. 2d 534, 537 (D. Md. 2001), *aff'd*, 301 F.3d 1343.

98. *In re Cruciferous Sprout Litig.*, 301 F.3d at 1350–51.

99. *Id.* at 1350.

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

drowsiness.[101] The '233 patent disclosed administration of loratadine to mammals to treat allergic reactions.[102] Schering sells this drug under the brand name Claritin.[103]

The defendants, including Geneva Pharmaceuticals, sought to manufacture generic versions of this popular drug when the '233 patent expired at the end of 2002.[104] However, the defendants were alerted to a second patent owned by Schering, U.S. 4,659,716 (the '716 patent).[105] The '716 patent was issued in 1987 and covered descarboethoxyloratadine ("DCL"), a metabolite of loratadine.[106] A metabolite is a compound that is formed in a patient's body after a chemical conversion that takes place during the digestion process.[107] DCL differs structurally from loratadine in that it has a carboethoxy group on a ring of nitrogen instead of a hydrogen atom.[108] In other words, it is a compound with a slightly different chemical structure than that covered by the '233 patent. The '716 patent claims the metabolite's chemical structure, its fluorine analog, and their salts.[109] This patent was not scheduled to expire until February 2004.[110]

The defendants filed an Abbreviated New Drug Application ("ANDA") with the FDA to produce a generic version of Claritin, certifying that the '716 patent was invalid and therefore did not prevent the production of the generic drug.[111] Schering responded by filing a suit for patent infringement.[112] The parties

101. *See* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1375 (Fed. Cir. 2003) ("Unlike conventional antihistamines . . . loratadine does not cause drowsiness . . . .").

102. *See Schering*, 275 F. Supp. 2d at 535.

103. *See id.* at 536.

104. *See id.* at 535–36.

105. *See id.* at 537.

106. *See Schering*, 339 F.3d at 1375.

107. *See id.*

108. *See id.*

109. *See id.*

110. *See id.*

111. *See id.* at 1376. When filing an ANDA with the FDA, the applicant must certify that "to the best of his knowledge, with respect to each patent which claims the . . . drug . . . for which the applicant is seeking approval . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). This is known as a Paragraph IV certification.

112. *See Schering*, 339 F.3d at 1376. Although the defendants had not yet actually made the generic drug, Schering was able to file for infringement because the patent code states that "[i]t shall be an act of infringement to submit an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . ." 35 U.S.C. § 271(e)(2)(A) (2000).

then filed cross-motions for summary judgment on the sole issue of the validity of the '716 patent.[113]

The defendants argued that the '716 patent was invalid because it was anticipated by the '233 patent.[114] The '233 patent was issued more than one year prior to the filing of the '716 patent application, and therefore, the '233 patent constituted prior art to the '716 patent under § 102(b).[115] The defendants relied on evidence showing that DCL was formed in detectable amounts in the bodies of humans upon ingestion of loratadine to argue that the '233 patent inherently anticipated DCL.[116] However, the '233 patent neither expressly disclosed DCL nor referred to metabolites of loratadine at all.[117] Furthermore, it was undisputed that when the '716 patent application was filed, one of ordinary skill in the art would not have recognized that administration of loratadine to humans results in the production of DCL[118] so it could not be said that this knowledge was in the public domain.

B. The Court Found Schering's Metabolite Patent Inherently Anticipated

The district court sided with the defendants, finding that the '233 patent inherently anticipated the '716 patent.[119] The court relied on the fact that ingestion of loratadine, as disclosed in the '233 patent, inevitably results in the production of DCL in the human body.[120] It interpreted the prior Federal Circuit cases on inherent anticipation as signifying that knowledge or appreciation of the inherent anticipation does not need to be contemporaneous with the application for or issuance of the patent.[121] In other words, the district court did not believe that inherent anticipation included a requirement of recognition by one of ordinary skill in the art. The court stated that:

---

113. *See Schering*, 339 F.3d at 1376.

114. *See* Schering Corp. v. Geneva Pharm., Inc., 275 F. Supp. 2d 534, 535 (D.N.J. 2002), *aff'd*, 339 F.3d 1373 (Fed. Cir. 2003).

115. *See id.* at 536. 35 U.S.C. § 102(b) (2000) states that "[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 . . . more than one year prior to the date of the application for patent in the United States . . . ."

116. *See Schering*, 339 F.3d at 1379 ("DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratadine.").

117. *See id.* at 1376.

118. *See Schering*, 275 F. Supp. 2d at 537.

119. *See id.* at 542.

120. *See id.* at 541.

121. *See id.*

> [T]he 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 . . . . Therefore, that patent inherently anticipates . . . the '716 patent, rendering [it] invalid.[122]

On appeal, the Federal Circuit affirmed the judgment of the district court, finding that DCL was inherently anticipated by the '233 patent on loratadine.[123] The court began its opinion by "reject[ing] the contention that inherent anticipation requires recognition in the prior art."[124] It stated that the "precedent does not require a skilled artisan to recognize the inherent characteristics in the prior art that anticipates the claimed invention."[125]

The court also explained that the doctrine of inherency could be used to demonstrate anticipation of the totality of a claim.[126] The fact that the '233 patent did not even mention metabolites of loratadine was inconsequential in the court's decision. The court found "no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter . . . . [I]nherency operates to anticipate entire inventions as well as single limitations within an invention."[127]

Having found no bar to inherent anticipation based on either recognition or the fact that there was no mention of metabolites in the '233 patent, the court went on to analyze the '233 patent in terms of enabling the production of DCL. It explained that "anticipation requires only an enabling disclosure" so the relevant ques-

---

122. *Id.* at 542.

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

124. *Id.* at 1377.

125. *Id.* at 1378.

126. *See id.* at 1379 ("[I]nherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter."); Robert M. Schulman, *A Review of Significant 2003 Federal Circuit Decisions Affecting Chemical, Pharmaceutical, and Biotech Inventions*, INTELL. PROP. & TECH. L.J., Mar. 2004, at 1, 1 ("[T]he court clarified that it is proper to rely on the doctrine of inherency to demonstrate anticipation of the totality of a claim, not just one or two elements of the claim.").

127. *Schering*, 339 F.3d at 1379–80. *Schering* has been widely cited for this proposition in recent cases. *See, e.g.*, Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., No. Civ. 02-332-SLR, 2004 WL 1739720, at *24 (D. Del. Aug. 3, 2004); Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V., 315 F. Supp. 2d 589, 603 (D. Del. 2004); Arthrocare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 661 (D. Del. 2004).

tion was whether the '233 patent enabled DCL.[128] The court answered this question affirmatively, relying on the fact that the '233 patent disclosed administering the drug to patients.[129] It concluded that because "[t]he inherent result of administering loratadine to a patient is the formation of DCL[,] [t]he '233 patent . . . provides an enabling disclosure for making DCL."[130]

Thus, the court ruled that the '233 prior art inherently anticipated the claims of the '716 patent because DCL is necessarily present as a "'natural result flowing from' the explicit disclosure of the prior art."[131] "[E]ven though (1) there was no recognition of the metabolite and (2) inherency was relied upon for the entirety of the claimed subject matter, Schering's DCL metabolite was found to be inherently anticipated by its original loratadine patent."[132]

C. Subsequent Dissents Disagreed with the Finding of Inherent Anticipation

On October 28, 2003, the Federal Circuit denied Schering's petition for rehearing en banc.[133] Judges Newman and Lourie each separately dissented from that decision. Judge Newman strongly felt that "[n]o precedent supports the position that a product whose existence was not previously known and is not in the prior art is always unpatentable on the ground that it existed undiscovered."[134] The judge objected to the court's ruling that inherent anticipation does not require recognition by one of ordinary skill in the art, as well as to its ruling that an invention can be anticipated entirely through inherent anticipation, where no express disclosure of the later invention exists in the prior art.[135] Judge Newman completed her dissent with an expression of doubt as to "[w]hether it is desirable new policy to bar the patentability of products that have not yet been discovered . . . ."[136]

Judge Lourie questioned the court's finding of enablement in the '233 patent for the production of DCL. The judge acknowledged that were loratadine "*in actual public use* prior to the filing of

128. *Schering*, 339 F.3d at 1380.
129. *See id.* at 1380–81.
130. *Id.* at 1381.
131. *Id.* at 1379.
132. Schulman, *supra* note 126, at 5–6.
133. Schering Corp. v. Geneva Pharm., Inc., 348 F.3d 992, 993 (Fed. Cir. 2003).
134. *Id.* at 993 (Newman, J., dissenting).
135. *See id.* at 993–96.
136. *Id.* at 995.

a patent application on its metabolite, the metabolite will also have been in public use and hence will be unpatentable."[137] However, Judge Lourie believed that the fact that the "patent simply included a minimal, boilerplate statement of how to use" loratadine, i.e. administering the drug to humans, was "hardly an enabling disclosure of how to make any metabolites, whatever they might turn out to be, sufficient to anticipate them by inherency."[138]

D. A Benefit of and Potential Driving Force in the Schering *Decision was the Prevention of Inequitable Extensions of Pharmaceutical Patents*

With such strong dissenting opinions from two of the judges on the Federal Circuit deciding whether to rehear this case en banc, it seems prudent to undertake a scrutiny of the court's decision in *Schering*. The court invalidated Schering's patent on DCL; this decision prevents pharmaceutical companies from unfairly extending the length of their patent monopolies on profitable drugs through the patenting of their underlying metabolites. Assuming this was the true impetus for the decision,[139] the court's desire to curb this admittedly inequitable practice of monopoly extension was so great that it was willing to expand the entire doctrine of inherent anticipation in order to do so.[140]

The expiration of the loratadine patent cleared the way for many cheaper, generic versions of the drug able to capture a large share of Schering's market.[141] Claritin accounted for $2.1 billion in sales in 1998, 34% of Schering's profits,[142] and in 2000 and 2001 sales exceeded $3 billion.[143] Patented drugs such as Claritin ac-

137. *Id.* at 996 (Lourie, J., dissenting). See *infra* note 183 (detailing the public use doctrine).

138. *Id.*

139. This, of course, would not be the first time a court has been swayed by ulterior motives. "[Critics] contend[ ] that 'the life of the law' is based not on logic, but rather that 'the felt necessities of the time,' avowed and unconscious intuitions of public policy, and even judicial prejudices have more to do with legal decisions than the formal axioms of logical inference." Dan Simon, *A Third View of the Black Box: Cognitive Coherence in Legal Decision Making*, 71 U. CHI. L. REV. 511, 512 (2004). "[T]he Critics question the legitimacy of legal decision making, viewing it as propelled by ulterior motives, or driven by hidden biases or other fundamentally flawed forms of inference." *Id.* at 514.

140. *See* discussion *infra* Part IV.E (detailing the court's extension of inherent anticipation beyond the dictates of the precedent).

141. *See* Amy Barrett, *New Teeth for Old Patents*, BUS. WK., Nov. 30, 1998, at 92.

142. *Id.*

143. Krishan Maggon, *The Ten Billion Dollar Molecule*, PHARMACEUTICAL EXECUTIVE, Nov. 2003, at 60, 64.

count for a considerable portion of a high revenue industry, and the exclusive monopolies granted by the patent system are obviously financially significant to Schering and other drug manufacturers.[144] More than three dozen of the patents on the most profitable pharmaceuticals in the United States were set to expire by the end of 2002.[145] "If the makers of those branded drugs [could] delay generic entry by only a few months, they [would] stand to gain millions."[146]

Congress grants an exclusive monopoly to inventors in exchange for the knowledge they add to the public domain.[147] This monopoly allows patent-holding drug companies to charge a much higher price for their drugs than they would be able to if they had to compete with companies producing generic drugs; therefore, it is very much in the interest of these drug companies, and not in the interest of consumers looking for cheaper alternatives, for the drug companies to try to extend their monopolies for as long as possible. Patenting metabolites is one method drug companies can use to extend their monopolies beyond the time allotted in the quid pro quo patent system. For example, in the United Kingdom, the patent holder of the antihistamine terfenadine obtained a further patent on the active metabolite and attempted to block competition after the original patent had expired.[148]

Schering, with its DCL patent, was attempting to block generic drugs from taking over part of its Claritin market share even though its deal with the government had expired. As seen in its case against Geneva, Schering was using its DCL patent to argue

144. For example, Schering's sales of Claritin decreased by over 40% because the patent expired. *See id.*

145. Barrett, *supra* note 141, at 92.

146. *Id.*

147. *See, e.g.*, 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01 (2005) ("The requirement of adequate disclosure assures that the public receives 'quid pro quo' for the limited monopoly granted to the inventor."); Duane M. Linstrom, *Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as it Applies to Genetic Patents*, 40 SAN DIEGO L. REV. 947, 948 (2003) ("The United States patent system functions on the rationale of quid pro quo, by which the law grants a temporary monopoly on the production and use of an invention in exchange for the knowledge of the invention's being made public."); Peter D. Sabido, Group One, Ltd. v. Hallmark Cards, Inc.*: The § 102(B) On Sale Bar Bright-Line Test of* Pfaff v. Wells Electronics, Inc. *Just Got Brighter*, 6 J. SMALL & EMERGING BUS. L. 583, 586 (2002) ("The national patent system is a quid pro quo that gives inventors a limited monopoly in exchange for disclosing their inventions.").

148. Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 32 (2001). "This was deemed to be an unacceptable attempt to extend patent protection." *Id.*

that "any competing drug that produces the same metabolite in the body infringes on this patent, which [would not] expire until 2004."[149] If Schering won its infringement action based on its metabolite patent, competitors such as Geneva would have only two options: they could abandon the Claritin market completely until 2004, or they could attempt to develop "a generic compound that is metabolized in a completely different way [than loratadine]—an extremely difficult task."[150] If the '716 patent on DCL were allowed to block generic versions of Claritin, Schering would effectively be able to extend the monopoly granted by the '233 patent on loratadine until the later expiration of the '716 patent, a result which seems highly unfair given that the monopoly the government granted to Schering in exchange for its disclosure of loratadine to the public had already run its course.[151]

The public should be protected against pharmaceutical companies using metabolite patents to inequitably extend their monopolies on profitable drugs. However, the means by which the court chose to accomplish this objective presents reason for concern. Declaring a metabolite patent inherently anticipated by the prior art patent on the drug itself unwisely extends the doctrine of inherent anticipation beyond the dictates of the precedent.[152]

E. The Schering *Result was not Dictated by the Precedent*

In *Schering*, the court expanded the doctrine of anticipation beyond the scope of the precedent in two ways, by completely eliminating the recognition requirement and by allowing inherent anticipation for the totality of a claim. This stark result means that the Federal Circuit can now invalidate patents on inventions of which the public had absolutely no knowledge of prior to the inventor's discovery, an unusual and dangerous result in light of the incentives which the patent system is designed to provide for: the discovery of new information and the disclosure of it to the public.

149. Barrett, *supra* note 141, at 92.

150. *Id.* at 92–93.

151. "[T]here is a natural temptation for inventors to try to extend patent protection as far as possible—sometimes beyond the statutory period." MILLER & DAVIS, *supra* note 23, at 97. "Extensions that thwart competition by generics only work to extend price gouging and do not promote any social good. Patents have limits for a reason . . . ." Abraham N. Saiger, Note, *In Search of a Government that Will Govern: Senate Bill 812 and "Reimporting" Prescription Medication from Canada*, 12 ELDER L. J. 177, 194 (2004).

152. *See* discussion *infra* Parts IV.E & V.C.

The Federal Circuit in its *Schering* opinion rejected the recognition prong of the doctrine of inherent anticipation for all types of inventions.[153] It cast the *Continental Can* ruling in a new light by stating that "*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."[154] Instead, the court expressed that:

> *Continental Can* stands for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art. A court may resolve factual questions about the subject matter in the prior art by examining the reference through the eyes of a person of ordinary skill in the art, among other sources of evidence about the meaning of the prior art. Thus, in *Continental Can*, this court did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference.[155]

This explanation of the meaning of *Continental Can* is absolutely not in line with the precedent as detailed above. It is clear that *Continental Can* held that recognition was a requirement of inherent anticipation.[156] As discussed, there existed two clear exceptions to this recognition requirement prior to the court's decision in *Schering*. The first exception involved situations in which the inherent element is merely a scientific understanding of the underlying expressly disclosed processes or structures.[157] The second exception related to inherent characteristics.[158] Schering had patented neither a scientific understanding nor an inherent property; instead, it had discovered and patented a chemical structure. Therefore, the DCL patent falls under neither of the two excep-

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

154. *Id.*

155. *Id.* at 1377–78.

156. *See supra* note 48 and accompanying text (stating the two prong test from *Continental Can*, including the second prong requirement of recognition by persons of ordinary skill); *see also* Miller, *supra* note 10, at 445–46 ("Putting aside Schering for a moment . . . it is clear that other cases, including Continental Can Co. USA, Inc. v. Monsanto Co. and the relatively recent In re Robertson, have held that recognition was required.").

157. *See supra* Part III.B.

158. *See supra* Part III.C.

tions to the rule of *Continental Can* and thus recognition should have been required under the precedent.[159] However, rather than even attempting to rely on one of these two exceptions, the court chose to abandon the recognition prong of the test altogether. By altering the overall interpretation of *Continental Can* instead of attempting to fit metabolites within the prior scope of the doctrine, the court changed the scope of inherent anticipation for all inventions, not just for metabolite patents.

Under the court's explanation of *Continental Can* in *Schering*, all that is meant by the recognition requirement, the second prong of the test, is that persons of ordinary skill in the art must recognize that the characteristic is inherent in the prior art at the time of trial.[160] Under this interpretation, however, the second prong is rendered redundant; it is no different than the first prong, that the inherent element be necessarily present in the prior art. The purpose of requiring recognition is that before people of skill in the art recognize the presence of an element in prior art, incentives for innovation are still necessary to add knowledge of that element to the public domain.[161] The court cast this reasoning aside and interpreted *Continental Can* as a one step "necessarily present" test with recourse to the opinions of those with skill in the art at the time of trial.[162] *Continental Can*'s recognition requirement must at a minimum be interpreted as recognition before the critical date[163] of the later invention if it is to have any real meaning separate from the first prong of the test.

159. *See infra* text accompanying notes 187–89 (further detailing the application of the two exceptions of the *Continental Can* test to a metabolite patent).

160. This explanation of the recognition requirement is antithetical to the widely held interpretation of *Continental Can*. *Compare supra* note 155 and accompanying text, *with supra* note 54.

161. The recognition requirement of inherent anticipation serves the same fundamental purpose as the doctrine of accidental anticipation, which allows for the "granting of a patent to an applicant who subsequently appreciates [an] accidental prior process . . . because the public gains knowledge of the process in return for temporally-limited exclusive rights." Paul G. Alloway, Note, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 SUFFOLK U. L. REV. 73, 78 (2004). "Courts have developed the Doctrine of Accidental Anticipation . . . because an unintended and unappreciated prior product or process does not provide knowledge to the public." *Id.* at 77. Likewise, an unrecognized element in prior art has not increased the public store of knowledge.

162. "In expressly rejecting the recognition element and inferentially rejecting the importance of intention, the Federal Circuit has seemingly undermined the Doctrine of Accidental Anticipation, and focused solely on the necessity requirement of inherent anticipation." *Id.* at 92.

163. The critical date is one year prior to filing, a date used for anticipation analyses.

The Federal Circuit thus expanded the doctrine of inherent anticipation beyond the dictates of the precedent by allowing inherent anticipation to encompass situations in which the presence of the element was not recognized as present in the prior art. *Schering* has been cited in subsequent cases dealing with inventions apart from metabolites for the proposition that recognition is no longer the law in inherent anticipation.[164] "Notwithstanding prior precedent, the current state of the law, at least according to *Schering*, is that recognition is not required."[165] The court has plainly changed the law on the recognition requirement, misconstruing the meaning of *Continental Can* in an attempt to square its recent holding with the precedent.

The court thus expanded a doctrine which affects all types of inventions rather than focusing on the real problem at hand. The net result was not just the elimination of metabolite patents, but rather the elimination of the recognition requirement of inherent anticipation for all patents.[166] Some pharmaceutical companies attempt to extend their monopolies by using metabolite patents to prevent the public from practicing the teachings of their expired drug patents.[167] However, rather than candidly discussing an underlying objection to this inequitable patent extension, the court chose to alter the precedent, all the while feigning that it had not changed a thing. The court made a modification to inherent anticipation which affects all different categories of inventions seemingly without fully considering the policy implications of what it was doing.[168]

164. *See, e.g.*, Toro Co. v. Deere & Co., 355 F.3d 1313, 1321 ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention." (citing Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377–78 (Fed. Cir. 2003))).

165. Miller, *supra* note 10, at 451; *see also* Mark Goodman, *Survey of Intellectual Property Case Law, Patent*, Schering Corp. v. Geneva Pharmaceuticals, Inc., INTELL. PROP. L. BULL., Winter 2003, at 38, 39 ("Recognition is no longer relevant to the question of inherent anticipation.").

166. Nowhere in its opinion does the court limit its new slant on the recognition requirement to patents on metabolites. *See* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373 (Fed. Cir. 2003).

167. See *supra* text accompanying notes 148–49.

168. Deviation from precedent is not necessarily problematic on its own; there are clearly situations in which it is proper to depart from prior judicial decisions. *See, e.g.*, Brown v. Bd. of Educ. of Topeka, 347 U.S. 483 (1954) (overruling the separate but equal doctrine established in Plessy v. Ferguson, 163 U.S. 537 (1896)). However, the concern here is that the court altered precedent without acknowledging that it had done so, thereby allowing it to expand the doctrine of

Schering further expanded inherent anticipation beyond the scope of the precedent by allowing a completely inherent disclosure to anticipate without any express disclosure. Ordinarily, inherent anticipation has been applied to invalidate patents in instances where the prior art reference "contains an incomplete description of the [later] invention and the missing features are proved to be necessarily present in the [express] disclosure of the reference."[169] In other words, inherent disclosure is used to fill in the gaps in an otherwise express disclosure of the claimed invention. In *Schering*, however, the prior art '233 patent made no explicit mention of either DCL or metabolites of loratadine.[170] The court faced a situation completely different from the one dealt with in the precedent.

The Federal Circuit made note of this, stating that *Schering* "may be a case of first impression, because the prior art supplies no express description of any part of the claimed subject matter."[171] It contrasted this with the court's prior inherency cases, where "a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects[,]" and "[i]nherency supplied the missing aspect of the description."[172] Nevertheless, the court ruled that the "extent of the inherent disclosure does not limit its anticipatory effect . . . . [I]nherency operates to anticipate entire inventions as well as single limitations within an invention."[173]

Thus, for the first time ever, the court held that an entire structure was inherently anticipated.[174] The doctrine of inherency was expanded to demonstrate anticipation of the totality of a claim, not just individual limitations of otherwise expressly disclosed subject matter.[175] "With its decision in *Schering*, the Federal Circuit

inherent anticipation without fully considering the effect such a decision might have on future patents. The trouble with this course of action is that when the courts made the original decisions setting the limits on inherent anticipation, careful thought was given to the policy implications and the effect on patent law; by altering the precedent without acknowledgement, the law proceeds in a new direction without revisiting the prudence of the policy. *See infra* Part V.C. for a discussion of these policy implications which the Federal Circuit failed to properly consider.

169. Goodman, *supra* note 165, at 39.

170. *See Schering*, 339 F.3d at 1376.

171. *Id.* at 1378.

172. *Id.* at 1378–79.

173. *Id.* at 1379–80.

174. *See Cases and Recent Developments*, 13 FED. CIR. B.J. 295, 358 (2003); Paul Devinsky & Mark G. Davis, *2003 Patent Law Decisions of the Federal Circuit*, 53 AM. U. L.R. 773, 794 (2004).

175. *See* Schulman, *supra* note 126, at 1.

broaden[ed] the scope of the anticipation by inherency doctrine to cover not only features of an invention but the entire invention."[176] Again, this case of first impression was seemingly decided without any consideration of the effect it would have on inventions apart from the metabolite patents the court was trying to invalidate. Rather, the court acted as though anticipation through total inherency, a situation admittedly not addressed in the precedent, followed logically from the court's prior applications of the doctrine of inherent anticipation, without stopping to consider the stark difference between an invention the public had no prior awareness of and a mere gap in the disclosures of the prior art.

When these two deviations from the dictates of the precedent are combined, it is clear the court drastically expanded inherent anticipation.[177] In one fell swoop, inherent anticipation was transformed from a doctrine encompassing only inventions which were recognized as present in the prior art reference and truly belonged to the public but for a gap in the reference's express disclosure, to inventions which were neither recognized as present nor even mentioned at all in prior art. Suddenly, a product which had never been disclosed, and but for the newly claimed invention the public would have no idea even existed, is considered inherently anticipated so long as it is eventually found to be present in the prior art.

176. *Cases and Recent Developments*, *supra* note 174, at 359.

177. This is not the first time the Federal Circuit has drastically expanded the patent law by deviating from precedent. In *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, the Federal Circuit found that a computer algorithm was patentable so long as it produced a concrete result, a marked deviation from a prior decision by the U.S. Supreme Court. *Compare* State St. Bank & Trust v. Signature Fin. Group, Inc., 149 F.3d 1368, 1374 (Fed. Cir. 1998) ("[T]he mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, of course, its operation does not produce a 'useful, concrete and tangible result.'"), *with* Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972) (holding that a "mathematical formula [with] no substantial practical application except in connection with a digital computer" was non-patentable subject matter). The *State Street* court also eliminated the business method exception to patentability. *See State St.*, 149 F.3d at 1375. "The business method exception was a judicially-created standard for patentability which prevented methods of doing business from gaining patent protection." David S. Evans & Anne Layne-Farrar, *Software Patents and Open Source: The Battle Over Intellectual Property Rights*, 9 VA. J.L. & TECH. 1, 6 n.24 (2004) (citation omitted). Elimination of this exception, along with the allowance of patents on computer algorithms, greatly expanded patentable subject matter; "there have been a host of problems associated with this decision, from a patent flood, to increased patent litigation, to increased costs of doing business." Douglas L Price, *Assessing the Patentability of Financial Services and Products*, 3 J. HIGH TECH. L. 141, 159–60 (2004).

It is clear that the policy implications in such an expansion of the doctrine of inherent anticipation relate to all types of inventions, but the court never articulated its argument for this alteration. Instead, the court matter-of-factly claimed that its finding of inherent anticipation of Schering's metabolite patent fit squarely within the dictates of the prior case law; as this Note has demonstrated, it did not.

V.
THE DOCTRINE OF INHERENT ANTICIPATION SHOULD NOT BE EXPANDED

A. There are Alternative Ways to Stop Metabolite Patents

Expanding inherent anticipation is not the only possible means to hinder attempts by pharmaceutical companies to extend their drug monopolies through the use of metabolite patents.[178] One idea that has been suggested is to alter the patent laws "so as to allow claims on only specific manufacturing processes and specific uses of chemical structures, but never on the chemical structures

178. The alternatives discussed in this section demonstrate that broadening the doctrine of inherent anticipation is not the only means to curb the extension of drug monopolies through metabolite patents. Generally "[w]hen faced with a choice between deciding a case on narrow factual grounds or by creating a new broad rule, the Court often sensibly chooses the narrower route. The benefits of such an approach are many, not least that it prevents the Court from blundering into a rule that carries many unintended consequences." *The Supreme Court, 2000 Term—Leading Cases*, 115 HARV. L. REV. 306, 497 (2001) (footnote omitted). Justice Ginsberg noted that "[m]easured motions seem to me right, in the main, for constitutional as well as common law adjudication. Doctrinal limbs too swiftly shaped, experience teaches, may prove unstable." Ruth Bader Ginsburg, *Speaking in a Judicial Voice*, 67 N.Y.U. L. REV. 1185, 1198 (1992). An example of a broad ruling in patent law leading to unintended consequences is seen in the expansion of patentable subject matter to include computer programs and business methods. *See supra* note 177. "Business method inventions are likely to cluster around the time that a new market opens. The cluster of inventions gives rise to a flood of patents. Patent floods create social costs that exceed the simple aggregate of the social costs associated with each patent in the flood." Michael J. Meurer, Business Method Patents and Patent Floods, 8 WASH. U. J.L. & POL'Y 309, 338 (2002). Additionally, many commentators argue that patents are unnecessary to incentivize the development of business methods. *See, e.g.*, Jay Dratler, Jr., *Does Lord Darcy Yet Live? The Case Against Software and Business Method Patents*, 43 SANTA CLARA L. REV. 823, 874 (2003) ("Is there any technological risk in implementing such a business method . . . ? Hardly . . . . If there were any risk at all, it would be a . . . market risk that every business has taken in market competition since time immemorial."). As with the expansion of inherent anticipation, the Federal Circuit in eliminating the business method exception adopted a broad ruling without fully considering the alternatives, the policy implications and the possible future consequences.

themselves."[179] Under this system, patents on metabolites would not be allowed unless the inventor could demonstrate novelty beyond the utility of the drug it was derived from.[180] While this system would seem to eliminate the current "practice of pursuing . . . meaningless variant structures for the sake of market positions against competitors," it is unlikely that such a change would be made in the patent system after allowing for the patenting of chemical structures for so long.[181] Furthermore, this would need to be a legislative solution.[182]

A second possibility to impede the extension of the monopolies on drugs through the use of metabolites would be to apply the public use bar.[183] Under this bar, metabolites could not be patented after they have been in public use. Judge Lourie referred to this alternative in his *Schering* dissent, explaining that "when a pharmaceutical product has been *in actual public use* prior to the filing of a patent application on its metabolite, the metabolite will also have been in public use and hence will be unpatentable."[184] In *Schering*, this would not have served as a bar to the patent on DCL because loratadine was not actually administered to the public one year prior to the filing of the '716 application, but rather it was tested in secret.[185] However, in many instances this bar could be expected to

179. Shayana Kadidal, *Digestion as Infringement: The Problem of Pro-Drugs*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 241, 270 (1996) (citations omitted). While the United States has historically allowed patents covering chemical structures, "it is worth noting that not all industrialized countries have always had chemical structure patent protection; several traditionally had denied chemical compound patents, while accepting process patents." *Id.* at 271.

180. *See id.* at 270.

181. *Id.* at 271, 274.

182. Section 101 of the Act states that "[w]hoever 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." 35 U.S.C. § 101 (2000). "[C]hemical compounds are viewed as 'compositions of matter' . . . ." DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 92 (3d ed. 2004). In fact, legislative history shows that Congress intended the broad language of § 101 to "include anything under the sun that is made by man." S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

183. The public use bar and the public sale bar are codified at 35 U.S.C. § 102(b) (2000), which states that "[a] person shall be entitled to a patent unless . . . the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ."

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

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

prevent pharmaceutical patent extension through the use of metabolites. At a minimum, this serves to limit the length of the extension, because the secondary patent on the metabolite could not be filed more than one year after the sale of the earlier patented drug. However, for those who see any extension of the monopoly grant on drug patents as unfair to both generic manufacturers and consumers seeking cheaper alternatives to name brand drugs, this limit may not do enough to curb the inequity.[186]

Another option at the court's disposal was to try to fit metabolite patents within the exceptions to the *Continental Can* rule, namely scientific explanations and inherent properties. Although in a sense metabolites do help explain the scientific process behind drugs such as loratadine, it would be difficult to fit metabolite patents within the scientific understanding exception to the rule of *Continental Can* because metabolite patents cover new chemical structures, not rules of natural law. Unlike in *Atlas Powder* where the newly claimed invention merely added a scientific explanation for the explosion process already occurring in the prior art, inventors of metabolites have discovered and isolated an actual compound, and the patent covers its structure, not its use as an explanation for the way the formerly invented drug works.[187] Likewise, it would be difficult to fit metabolite patents within the second exception to *Continental Can*, inherent properties. Unlike properties such as corrosion-resistance[188] and enzyme-inducing potential,[189] a metabolite patent does not merely define an inherent characteristic of the prior drug invention, but rather details a new chemical compound. While inherent characteristics merely further describe already disclosed products, metabolite patents stand alone as unique (albeit only slightly modified) structures. However, while metabolite patents do not appear to neatly fit within the narrow exceptions of the precedent, had the court at least attempted to make this argument rather than expanding inherent anticipation it could have curtailed the use of metabolite patents without creating such drastic effects for other types of patents. Instead, rather than even mentioning the exceptions to *Continental Can*, the court sim-

186. *See* Saiger, *supra* note 151.

187. *Compare* Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1345 (finding scientific understanding of the aeration involved in the explosion process contained in prior art), *with* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373 (finding a metabolite patent inherently anticipated).

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

189. *See* In re Cruciferous Sprout Litig., 301 F.3d 1343 (Fed. Cir. 2002).

ply redefined inherent anticipation so as to not require recognition in any situation and to always encompass totally inherent disclosures, thereby affecting a range of patents much larger than just metabolites.

In her *Schering* dissent, Judge Newman briefly suggested another alternative for the court. The defendants accused of infringing were merely "doing what was claimed in the expired loratadine patent."[190] Rather than "strain[ing] to hold that this newly discovered, previously unknown product cannot be validly patented," the court could have "simply rul[ed] that Schering cannot prevent the practice of [an] expired patent in accordance with its teachings."[191] As previously mentioned, the United States patent system is designed such that an inventor receives a limited monopoly as a quid pro quo exchange for adding knowledge to the public domain.[192] Once that monopoly has run its course, the knowledge is available for the public to freely use.[193] The court could have therefore bypassed the issue of novelty and anticipation completely, avoided broadening the doctrine of inherent anticipation and still ruled that the defendants did not infringe because the public has the right to practice inventions after limited monopolies have expired. In other words, the court could have upheld the validity of the metabolite patent but held that it could not be used to block the use of loratadine or its generics because loratadine belonged to the public by virtue of the expired patent. Such a ruling would put an end to the undesirable extensions of pharmaceutical monopolies through the use of secondary metabolite patents without altering the doctrine of inherent anticipation.

A final alternative to expanding inherent anticipation would be to create a special exception for metabolites, finding that they are never novel or non-obvious over the drugs which they are derived from. This result could be reached either judicially or legislatively. It may seem unfair to pharmaceutical companies to carve out an exception limited to drug metabolites, but if the inequities of using metabolites to extend patent monopolies was what was truly driving the court, at least this alternative would reach the over-

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

191. *Id.* (Newman, J., dissenting).

192. *See supra* notes 24, 147 and accompanying text.

193. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152 (1989) ("We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law.").

all outcome the court wished to attain without sacrificing the incentives behind all other types of inventions. By being forthright in what it was trying to accomplish, the court could have avoided the mistake of making a far-reaching alteration in a doctrine which applies to all kinds of inventions; instead, it pretended that the expansion of inherent anticipation is right for all of patent law without considering the policy implications of its actions.

B. Drug Companies Should Not Be Permitted to Extend Their Monopolies, But Expansion of Inherent Anticipation was Unnecessary

Protecting the public by preventing the unfair use of metabolite patents to extend drug patents is admirable. Schering had made a deal with the government by applying for a patent. The terms of this deal were simple: in exchange for sharing its discovery of loratadine with the public, Schering was granted a limited monopoly with which to profit from its invention as it saw fit. Claritin was immensely popular and Schering made large amounts of money from this monopoly, but in 2002 the terms of the deal came to an end and the public had a right to practice what it had learned from Schering. If drug companies were allowed to extend the monopolies granting them the right to exclusively produce and sell drugs, the public would be inequitably injured, paying higher prices beyond the length of time the government has found necessary to incentivize the discovery of new inventions.[194] After the patent on an invention has expired, the information disclosed in it belongs to the public and should not be taken out of their control simply because big pharmaceutical companies have found ways to cheat the system by extending their monopolies through patents on metabolites.

However, the court did not need to expand the doctrine of inherent anticipation in order to curb this unjust practice of monopoly extension. As discussed earlier, the court could have carved out a special exception for metabolites, thereby curing the inequities of metabolite use to extend patent monopolies without affecting the entire doctrine of inherent anticipation. Alternatively, the court could have taken this as an opportunity to reinforce the quid pro quo patent system by ruling that one cannot stop the public from practicing an expired patent.[195] Schering's '233 patent was for administration of loratadine; in exchange for a limited monop-

194. *See* Saiger, *supra* note 151.

195. *See supra* notes 191–93 and accompanying text.

oly, Schering had disclosed to the public the chemical structure of this drug and the knowledge that it could be used to treat allergies. After the patent expired in 2002, this information belonged to the public and could be practiced and sold by anyone. The generic companies such as Geneva were merely practicing what was taught in the '233 patent, knowledge which belonged to the public and which they were free to use. The court could have ruled that the discovery of the metabolite DCL was novel and thus the '716 patent was valid, but that this patent could not be used to block the use of information belonging to the public. In other words, Schering could own the exclusive rights to DCL, but this grant could not stop anyone from using loratadine to treat allergies because that invention now belonged to the public, regardless of the fact that the use of loratadine entails the creation of DCL. Such a ruling would emphasize the incentive structure of the patent system, ultimately benefiting the public. This would stop inequitable monopoly extensions without altering the doctrine of inherency and twisting the meaning of anticipation and novelty.

Were metabolite patents found valid but unable to block expired patents, the patenting of metabolites such as DCL could be used to exclude any drug which broke down in the body to the patented metabolite other than previously disclosed drugs such as loratadine.[196] However, for most metabolite patents, the effect of allowing them as valid patents but preventing them from stopping the production of generics of the drug they are derived from, as opposed to just invalidating the metabolite patents completely, may in fact be a distinction without a difference. The metabolite may serve no other purpose but as a product of the drug from which it is derived, and if the metabolite patent is not able to prevent generic drug-producers from entering the market, the incentives to discover and disclose it to the public may be eliminated either way. In this sense, the alternative of allowing the patent but not allowing it to block the use of inventions which were the subject of previously expired patents may be in substance no different for metabolites than just carving out an exception and invaliding metabolite patents completely. However, the important difference between either of these approaches and the approach the court took in *Schering* is that the latter method expands inherent anticipation for all pat-

196. *See, e.g.*, Hoechst-Roussel Pharm., Inc. v. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997) ("[T]he right to exclude may arise from the fact that when administered, tacrine hydrochloride metabolizes into another product, 1-hydroxytacrine, which Hoechst has claimed." (citing Zenith Labs. v. Bristol-Myers Squibb, 19 F.3d 1418, 1422 (Fed. Cir. 1994))).

ents, not just metabolites. This wide-sweeping approach of expanding the entire doctrine is unnecessary in light of the possible alternatives that have been described in this Note. The inequitable problem of metabolite patents being used to injure the public could be cured without the drastic measure of affecting the incentives for discovery and disclosure of other types of inventions. As will be argued below, the expansion of inherent anticipation is an unwise policy choice in light of the purposes of the overall patent system.

C. Expanding Inherency is Not the Right Way to Curb Unfair Monopoly Extension

Rather than choosing one of the aforementioned alternatives, the court opted to modify the novelty requirement. Bearing in mind that this does not limit the effect to metabolite patents but rather can inhibit all types of inventions, the proper inquiries are whether this decision is consistent with the statutory definition of novelty and whether the extension of inherent anticipation is wise or unwise policy.

A finding of anticipation under 35 U.S.C. § 102(a) means that the newly claimed invention is not, in fact, new; it signifies that this subject matter has been invented or in the public grasp at an earlier time. As Judge Newman points out in her *Schering* dissent, "[t]he term 'invention' means invention or discovery."[197] This means that an invention can encompass something which previously existed but was undiscovered before the inventor found it. For example, DNA sequences for formation of proteins such as Erythropoietin ("EPO"), a protein which stimulates the production of red blood cells, are patentable once they are isolated in a laboratory and their structures are determined, even though the sequences exist in nature.[198] In *Schering*, the chemical DCL existed as a metabolite of loratadine produced in the bodies of those patients Schering administered the drug to in its testing; however, no one knew it was there. No one was aware of its chemical structure, and therefore it

197. Schering Corp. v. Geneva Pharm., Inc., 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting); *see also* 35 U.S.C. § 100(a) (2000).

198. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991). "Courts . . . consider a chemical to be patentable when researchers have isolated the chemical from its natural state and determined its chemical structure. Courts have determined that DNA is a type of 'chemical compound, albeit a complex one,' and so satisfies the test for patentable subject matter." Mary Breen Smith, Comment, *An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines*, 73 U. COLO. L. REV. 747, 760 (2002).

was undiscovered. Like the DNA sequence for EPO formation, when Schering first isolated this chemical in a laboratory and discovered it structure, it was then and only then "invented." Prior to this discovery, no one had any knowledge of the structure of DCL. To hold that this was anything but a novel discovery merely because it existed unrecognized and completely undisclosed in prior art defies common sense and statutory meaning.

The expansion of inherent anticipation does not fit with the statutory definition of novelty nor the precedent interpreting it; therefore, the next relevant inquiry must focus on the policy reasons behind such an expansion to determine if it can be justified. The court discussed the policy behind this expansion in *Schering*, explaining that "[b]ecause 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."[199] Under this logic, the expansion of inherency to encompass situations where there is no express disclosure is justified because it prevents the removal of inventions from the public domain. The court is trying to prevent monopolies from being granted on inventions to which the public previously had free access. If the public already had access to an invention before the inventor discovered it, granting a monopoly is harmful rather than beneficial to the public. Innovation is unnecessary when the invention is already in the public domain, so the incentives of the patent system are merely detrimental in this situation. However, the expansion of inherency by removing the recognition requirement cannot be justified by claiming that the public has prior knowledge of the invention; the court moves beyond the use of inherent anticipation to accommodate common knowledge that judges might not know but that would be known to those with skill in the art.[200] The argument for this extension of the doctrine of inherent anticipation rests on the theory that even without recognition by those of ordinary skill in the art, and even without a trace of express disclosure, the claimed invention still exists in the public domain and thus should not be removed.[201] This is a highly protective stance, more

199. Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003).

200. *See supra* note 33 and accompanying text.

201. *See, e.g.*, Matthews & Troilo, *supra* note 11, at 785 ("To provide complete protection of public knowledge, the law of inherency protects the naturally flowing consequences of practicing subject matter already in the public domain even if those consequences are unknown."); Miller, *supra* note 10, at 452 ("[I]f a com-

concerned with the possibility of taking an invention away from the public than with furthering complete understanding.

This theory, however, is flawed. Without recognition or any express disclosure, such knowledge can hardly be considered "in the public domain." Just as with the DNA sequence for EPO, or any invention which was undiscovered before the inventor found it or isolated it, if the public does not have knowledge of an invention it does them no good; people cannot use or sell a product that has not been found, and other inventors cannot build off of it to form new and improved inventions. Therefore, to hold such an invention invalid for anticipation is contrary to the policy of encouraging people to discover previously unknown inventions.[202] Congress has determined the proper balance to best serve the public interest and the aims of the patent system; it has found that the proper tradeoff to encourage innovation and disclosure is a specified period of exclusivity in exchange for adding to the public's store of information.[203] Without recognition of the new invention in the prior art, and without any express disclosure, the public is no better off with regard to that invention than it would be without the prior art; therefore, innovation and disclosure are still as necessary as ever. The extension of inherent anticipation robs inventors of the valuable incentives of the patent system, thereby making it less likely that knowledge of the product will ever truly reach the public domain in a manner in which the public can understand it and utilize it. This is antithetical to the predetermined balance struck by Congress; Congress found that granting the patent monopoly was a price worth paying for the transfer of knowledge, but when the court expands inherent anticipation to remove these incentives it disregards the importance of true discovery and understanding. Precisely because the effects of labeling an invention "not novel" are so striking, the court should be very wary about extending the scope of inherent anticipation. In a situation where the court has other options

pound is invariably produced by the prior art, the compound, whether recognized or not, has already entered the public domain, and should therefore not be taken away.").

202. *See, e.g.*, Miller, *supra* note 10, at 451–52 ("[F]ailure to require recognition is arguably contradictory to the public policy goal of encouraging inventors to 'discover' compounds that were not previously recognized.").

203. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989); Miller, *supra* note 10, at 438 ("The patent system . . . encourages inventors to add to the already available body of knowledge by conferring upon the patentee a right to temporarily exclude others from that which he contributed."); *see also supra* note 2 and accompanying text (discussing the overall purpose of the patent system as expressed in the U.S. Constitution).

available, in particular either reinforcing the patent system by ruling that even a patent on a metabolite cannot prevent the public from practicing the teachings of an expired patent or carving out a specific exception for metabolite patents, it is unwise policy to expand inherent anticipation to a scope that no longer protects the public domain but rather prevents it from growing.

Furthermore, one must bear in mind the enablement requirement of anticipation. The purpose of this requirement is to ensure that the public had true control over the invention and was able to practice it before it can be said that an invention is not novel. As Judge Lourie pointed out, it is unconvincing to say that DCL was "enabled" by the prior art merely because the loratadine patent disclosed administering the drug to a patient and, although it had not actually been administered to the public before the critical date of the '716 patent, loratadine necessarily metabolizes into DCL in the human body.[204] The public did not know DCL existed, nor was it aware of its structure; it just so happened that the drug it was given knowledge of would transform into this chemical inside the human body. This further stresses the point that it is illogical and damaging to say that such an invention is not novel. Especially when enablement is weak and there is no express mention of any of the elements of the claimed invention, the court should avoid tossing aside the recognition requirement and finding an entire invention invalid for inherent anticipation.

Judge Newman worried that the court's new, broad doctrine of inherent anticipation could mean that "no newly discovered product found in an organism [could] be patented[.]"[205] As discussed, this broad doctrine is contrary to the statutes, the precedent and the enablement requirement. Moreover, this is unwise policy, as these undiscovered products could represent great advances in medicine as well as other applications. Without discovery, the public will never fully understand nor be able to use these potentially valuable products. This highlights the trouble with the expansion of inherent anticipation to solve the inequities of monopoly extension. By altering the patent system for all inventions instead of narrowly dealing with the real problem of metabolite patents, the incentives for all types of inventions are affected in a manner which Congress did not intend when it created the balance of the current system. The patent system was designed to supply inventors with the proper incentives to add to the public knowledge, and this is

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

205. *Id.* at 994 (Newman, J., dissenting).

what it should be used to do. A narrower doctrine of inherency better serves the ultimate purpose of the patent system: to encourage discovery of heretofore unknown products.

VI.
CONCLUSION

A broad doctrine of inherent anticipation is a dangerous weapon against innovation. Preventing drug companies from extending their patents beyond the limited monopoly granted by Congress is admirable, but there exist alternative means to accomplish this goal. In particular, the court could rule that metabolite patents are valid but a drug company cannot prevent generics from practicing the teachings of an expired patent because that information is freely available in the public domain, or it could carve out an exception for metabolite patents and find them invalid whenever the drugs from which they are derived have been previously patented. When alternatives exist, the court should be wary about using the doctrine of inherent anticipation to invalidate a patent for a product that existed unrecognized and completely undisclosed in the prior art. Finding such an invention anticipated removes the incentives necessary to encourage discovery of unknown products; this unwise solution affects a wide range of possible inventions in order to cure the problems associated with only one small subset of inventions. As long as products exist unrecognized and undisclosed, they serve no public benefit. The patent system should encourage activity that truly adds this knowledge to the public domain.