

NOTES

Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions

*“Chaos is inherent in all compounded things. Strive on with diligence.”*¹
*Inherency is chaotic in all compounded things. Strive on with diligence.*²

I. INTRODUCTION

Congress, through the actions of the United States Patent and Trademark Office (USPTO), issues patents to “promote the Progress of Science and useful Arts.”³ In exchange for contributing an invention to the public, the USPTO grants to the contributing inventor a temporally-limited exclusive right to that invention.⁴ Accordingly, for the USPTO to grant a patent to an invention, it must satisfy a number of statutory requirements, including that it be novel, nonobvious, and directed to patentable subject matter.⁵

One of the requirements that a patentable invention must satisfy is that it is novel or new.⁶ Section 102 of title 35 of the United States Code, which contains multiple subsections, lists certain conditions that an invention must meet to be novel.⁷ For example, section 102(a) states that one shall be entitled

1. Buddha, <http://www.brainyquote.com/quotes/quotes/b/buddha142582.html> (last visited Aug. 29, 2004).

2. In the context of inherency in biotechnology patent law, an apt modification of the afore-mentioned quotation attributed to Buddha.

3. U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress’ power to issue patents). Article I, § 8 states that “[t]he Congress shall have 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.” *Id.*; 35 U.S.C. § 2 (2004) (delineating powers and duties of United States Patent and Trademark Office).

4. U.S. CONST. art. I, § 8, cl. 8 (highlighting limited, exclusive right to invention); 35 U.S.C. § 271 (listing rights of patent owner subject to infringement).

5. 35 U.S.C. § 101 (describing statutory requirements for patentable subject matter); *id.* § 102 (listing statutory requirements for novelty); *id.* § 103 (providing statutory requirements for nonobvious subject matter); *id.* § 112 para. 1 (describing statutory requirements for written description, enablement, best mode, and claim definiteness).

6. *Id.* § 102 (describing conditions resulting in loss of right to patent for lack of novelty).

7. *Id.* (listing requisite conditions, such as lack of particular prior art, no abandonment, and inventive contribution). Specifically, section 102 contains three categories of prior art resulting in loss of patentability of an invention. Lisa A. Dolak & Michael L. Goldman, *Responding to Prior Art Rejections—An Analytical Framework*, 83 J. PAT. & TRADEMARK OFF. SOC’Y 5, 5 n.4 (2001). The first category, namely sections 102(a),

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”⁸ Under section 102, an invention is anticipated, and therefore unpatentable, if a single “prior art” reference teaches each and every limitation of the claimed invention.⁹ An anticipatory reference, however, does not need to utilize identical word-for-word language to anticipate a claimed invention.¹⁰ It is a question of fact as to whether a particular prior art reference anticipates a patent claim.¹¹

Courts have interpreted section 102 to cover a prior art reference that teaches, either expressly or inherently, each and every limitation of a particular patent claim.¹² While the analysis of the express teachings of a particular reference is generally straightforward, the analysis of its inherent teachings is often difficult.¹³ As with anticipation generally, it is a question of fact whether a particular claim element is inherently present in a prior art reference.¹⁴ Under

102(b), 102(e), and 102(g), concerns prior art subject matter that precludes novelty of an invention. 35 U.S.C. § 102; Dolak & Goldman, *supra*, at 5 n.4. The second category, namely sections 102(c) and 102(d), concerns events by which an applicant loses the right to patent an invention, notwithstanding legal novelty of the invention. 35 U.S.C. § 102. The third category, specifies loss of the right to a patent if the applicant did not in fact “invent the subject matter sought to be patented.” *Id.* § 102(f).

8. 35 U.S.C. § 102(a) (addressing loss of patent right for known inventions and inventions described in printed publications). While section 102(a) addresses inventions that are previously known by individuals in the United States or described in a printed publication, section 102(b) addresses inventions that are patented or described in a printed publication, or in public use or on sale in the United States, more than one year before the filing date of the subject application. *Id.* §§ 102(a)-(b).

9. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (describing necessary requirements for prior art reference to anticipate); *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995) (stating requirements for anticipatory prior art reference).

10. *Ecolochem, Inc. v. S. Cal. Edison Co.*, No. 95-1320, 1996 U.S. App. LEXIS 13330, at *9 n.2 (Fed. Cir. June 5, 1996); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991) (stating identical language not required for anticipation). In *Ecolochem*, the court held that the patentee’s claims, which were directed to a deoxygenation process, were anticipated by a prior art reference. *Ecolochem*, 1996 U.S. App. LEXIS 13330, at *8-9. As stated by the court:

[t]he test for anticipation, however, is not a literal word for word comparison between the prior art and the commercial embodiment of the patentee’s invention; the test is whether ‘each and every element *as set forth in the claim* is found, either expressly or inherently described, in a single prior art reference.’

Id. at *9 n.2 (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1260, 1270 (Fed. Cir. 1988)).

11. *Finnegan Corp. v. U.S. Int’l Trade Comm’n*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) (highlighting factual nature of analysis to determine anticipation by prior art reference).

12. *Id.* at 1365 (describing and analyzing express and inherent teachings of prior art reference); *Verdegaal Bros. v. Union Oil of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (noting express and inherent teachings of reference can anticipate claim).

13. Irving N. Feit & Christina L. Warrick, *Inherency in Patent Law*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 5, 5 (2003) (summarizing relative ease in analyzing express teachings of claim elements). Unlike the procedure for determining whether a prior art reference expressly anticipates a particular patent claim, the procedure for establishing inherent anticipation is much more complex. *Id.* at 14. Established case law dictates that one must examine the prior art disclosure and determine whether the prior art disclosure necessarily or invariably results in the claimed invention. *Id.* at 15.

14. *Hazani v. U.S. Int’l Trade Comm’n*, 126 F.3d 1473, 1477 (Fed. Cir. 1997) (outlining factual analysis required to determine whether inherent disclosure of claim element exists).

the Doctrine of Inherent Anticipation, even where a prior art reference fails to explicitly disclose the entire subject matter of a patent claim, the reference can inherently anticipate the claim if it is the ‘natural result flowing from’ the explicit disclosure of the prior art reference.¹⁵ Under the judicially-created Doctrine of Accidental Anticipation, however, inherent anticipation does not apply if the prior art accidentally or unwittingly discloses the claimed subject matter.¹⁶

Inherency is particularly problematic for modern biotechnology inventions.¹⁷ One problem with biotechnology inventions is that they often relate to discoveries of already-existing natural biological compositions or mechanisms.¹⁸ From a patentability standpoint, the discovery of an already-existing natural biological composition or mechanism is not novel.¹⁹ Thus, in order to patent a biological composition that is already present in nature, such as a particular naturally-occurring nucleotide or amino acid sequence, it is necessary to distinguish the claimed composition from the previously-existing, naturally-occurring composition.²⁰ One can accomplish such a distinction by introducing a claim limitation that the composition is isolated, purified, or produced through recombinant DNA technology.²¹

15. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (quoting *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001)) (describing situation where inherency provides entire anticipatory subject matter). In *Schering*, the court held that a composition claim to the metabolite descarboethoxyloratadine (DCL), which is formed upon ingestion of loratadine (the active ingredient in the antihistamine drug Claritin[®]), was inherently anticipated by a prior art patent disclosing loratadine but not DCL, because DCL was necessarily and inevitably produced upon administration. *Id.*

16. John Kilyk, Jr., Note, *Accidental Prior Use*, 64 J. PAT. & TRADEMARK OFF. SOC’Y 392, 394 (1982) (describing applicability of Doctrine of Accidental Anticipation for accidental and unwitting uses). Kilyk notes that it is well settled that the Doctrine of Accidental Anticipation exists, however, the case law discussing and utilizing it do not present a clear rule for application of it. *Id.* at 392.

17. Jeffery M. Duncan, *The Court is Listening*, LEGAL TIMES, Nov. 4, 2002, at 26 (noting inherency problems related to biotechnology inventions).

18. *Id.* (highlighting inherency problem for naturally-occurring biotechnology inventions).

19. See 35 U.S.C. § 101 (2004) (describing statutory requirements for patentable subject matter). Section 101 states that “whoever invents or discovers any *new* and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” *Id.* (emphasis added).

20. 1-2 MARTIN J. ADELMAN, PATENT LAW PERSPECTIVES § 2.2[1] (2d ed. 2000) (describing meaning of “new” under section 101 and “novelty” under section 102). As Adelman notes, the general rule is that novelty does not exist for that which occurs in nature. *Id.* The rule of thumb that developed was that if one did enough work on a naturally-occurring composition, such that it was no longer naturally occurring, the modified composition would be novel under section 101. *Id.* In practice, the distinction between what is new, under section 101, and what is novel, under section 102, has become blurred. *Id.*

21. See *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (noting novelty of pure, naturally-occurring compounds). In *Bergstrom*, the court held that although prostaglandins PGE(2) and PGE(3) existed in nature, claims to pure forms of these compounds were novel and patentable. *Id.* As stated by the court, “by definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situation here, perforce the ‘pure’ materials are ‘new’ with respect to them.” *Id.* (footnote omitted); see also Bradford J. Duft & Eric P. Mirabel, *Principles of Inherency*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 539, 544 (1995) (highlighting novelty of purified forms of naturally-occurring compositions).

A second problem that biotechnology inventions often encounter is that particular observed biological results and underlying mechanisms of biological action are often not understood until well after publication of initial experimental findings.²² As a result, the early publication of an initial experimental finding can inherently anticipate, and thereby preclude, a patent applicant from acquiring a patent on an invention that is based on a later-achieved understanding of that earlier-published finding.²³ Although, notably, a patent applicant need not understand the mechanism underlying an invention in order to obtain a patent. Compounding these problems is the fact that scientific and technological limitations often limit understanding of a biotechnology invention at the time that a court is determining whether that invention is inherently anticipated.

This Note will first discuss the development of the Doctrine of Inherent Anticipation and the Doctrine of Accidental Anticipation.²⁴ Part III.A will address the distinction between inherent claimed compositions and inherent claimed methods.²⁵ Part III.B will analyze the major factor that courts emphasize in finding a claim inherently anticipated, namely that the anticipatory inherent feature or result must be necessary and inevitable, and not merely possible or probable.²⁶

In Parts III.C and III.D, this Note will describe recent Federal Circuit cases that have had an impact on the Doctrines of Inherent Anticipation and Accidental Anticipation.²⁷ Part III.C will discuss the recent decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,²⁸ which clarifies seemingly conflicting decisions by the Court of Appeals for the Federal Circuit, by holding that recognition of an inherent characteristic by a skilled artisan is not required to find inherent anticipation.²⁹ Part III.D will comment on the recent decision in *Elan Pharmaceuticals, Inc. v. Mayo Foundation For Medical Education Research*,³⁰ which considered, but did not decide, the issue of whether a prophetic disclosure is sufficient to inherently anticipate a patent claim.³¹ In view of these and other recent Federal Circuit cases, this Note will

22. Duncan, *supra* note 17, at 26 (describing inherency problem for biotechnology inventions not initially observed or understood).

23. Duncan, *supra* note 17, at 26 (suggesting earlier publication can inherently anticipate invention based on later-observed result).

24. See *infra* Part II (addressing counterbalancing equitable doctrines).

25. See *infra* Part III.A (comparing inherent anticipation analysis of compositions and methods).

26. See *infra* Part III.B (addressing essential inevitability factor for inherent anticipation); see, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) (describing requirement of inevitability for inherent property or result); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (same); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (same).

27. See *infra* Parts III.C, III.D (analyzing cases dealing with recognition factor and prophetic inherency).

28. 339 F.3d 1373 (Fed. Cir. 2003).

29. See *infra* Part III.C (noting impact of *Schering* decision).

30. 346 F.3d 1051 (Fed. Cir. 2003).

31. See *infra* Part III.D (addressing issue of prophetic inherency and requirement for enabling anticipatory

then examine the current status of the Doctrines of Inherent Anticipation and Accidental Anticipation.³² Finally, given the particular problems associated with biotechnology inventions, and other inventions for which technological understanding is limited, this Note will argue that courts should apply less stringent requirements for holding patent claims to such inventions inherently anticipated.³³

II. DEVELOPMENT OF THE DOCTRINES OF INHERENT ANTICIPATION AND ACCIDENTAL ANTICIPATION

The Doctrine of Inherency is a judicially-created doctrine that prevents the removal of features or properties that inherently exist, but are unknown and not taught in the prior art, from the public domain.³⁴ Thus, the discovery of a feature or characteristic that is inherent or otherwise implicit in a prior art reference, even if unrecognized and unappreciated, does not make it novel for purposes of patentability.³⁵ Importantly, such inherent features or characteristics must be necessary and inevitable, and not merely possible or probable.³⁶

Inherent anticipation, however, does not apply in the case of an accidental or unwitting anticipation.³⁷ Courts have developed the Doctrine of Accidental Anticipation, also known as the Doctrine of Accidental Prior Use,³⁸ because an unintended and unappreciated prior product or process does not provide knowledge to the public.³⁹ For example, in a seminal case, *Tilghman v. Proctor*,⁴⁰ the Supreme Court held that the previous unintended and unappreciated practice of a process for separating fats and oils was insufficient to anticipate, and thereby invalidate, a subsequent patent claim to that

prior art).

32. See *infra* Part III.E (highlighting difficulty in reconciling Doctrines of Inherent Anticipation and Accidental Anticipation).

33. See *infra* Part IV (arguing for increased leniency in inherency determinations for complex or poorly-understood biotechnological inventions).

34. HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE § 4.I.C, at 68-69 (4th ed. 2003) (outlining development of Doctrine of Inherency); Michael D. Nelson, *Doctrine of Inherency*, 55 J. PAT. OFF. SOC'Y 589, 589 (1973) (describing development of Doctrine of Inherency with respect to validity, patentability, and priority); Kilyk, *supra* note 16, at 414 (noting consistent, but unappreciated, prior use prevents patenting and removal from public domain).

35. See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.03, at 67 (2003) (describing inherent anticipation notwithstanding previous lack of recognition); Nicole Marie Fortune, *On-Sale Bar: Scaltech Inc. v. Retec/Tetra L.L.C. & Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 15 BERKELEY TECH. L.J. 185, 189-90 (2000) (same).

36. See *infra* Part III.B (stressing importance of inevitability of inherent feature or characteristic).

37. See 1 CHISUM, *supra* note 35, § 3.03, at 67 (addressing non-assurance of similar future result in accidental anticipation); Kilyk, *supra* note 16, at 392 (describing non-anticipatory accidental prior use).

38. Kilyk, *supra* note 16, at 392 (describing Doctrine of Accidental Prior Use).

39. Kilyk, *supra* note 16, at 414 (describing policy considerations supporting judicially-created Doctrine of Accidental Prior Use).

40. 102 U.S. 707 (1881).

process.⁴¹ Accordingly, if the unintended and unappreciated prior process is not necessary and inevitable—that is, not an inherent process⁴²—it will not anticipate a subsequent patent claim directed to the later-appreciated process.⁴³ The granting of a patent to an applicant who subsequently appreciates the accidental prior process is justified because the public gains knowledge of the process in return for temporally-limited exclusive rights.⁴⁴

Subsequent cases, such as *Eibel Process Co. v. Minnesota & Ontario Paper Co.*⁴⁵ and *In re Seaborg*,⁴⁶ extended the Doctrine of Accidental Anticipation to cover unintended and unappreciated products or compositions.⁴⁷ In the case of a prior art product, however, the subsequent discovery of a new property of that product is anticipated and unpatentable, because it is inseparable from the

41. *Id.* at 710-13 (holding prior accidental and unwitting practice of process insufficient to anticipate subsequent claim). Tilghman's patent claimed a process of separating fatty bodies into their component parts, namely fat acids and glycerine, by treating the fatty bodies with water at a high temperature and pressure. *Id.* at 709. The prior art processes consisted of the incidental and unappreciated formation of fat acids in: a steam cylinder from tallow introduced to lubricate the piston; a water barometer; and a process for purifying fats and oils in preparation for making soap. *Id.* at 711-12. In each of these prior cases, the production of fat acids was unintended and unappreciated, and therefore insufficient to anticipate Tilghman's claimed process. *Id.*

42. See *infra* Part III.B (describing inherent process).

43. 1 CHISUM, *supra* note 35, § 3.03, at 67 (explaining anticipation not avoided where prior result intended, notwithstanding lack of recognition); ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT § 3.2(b), at 95 (6th ed. 2003) (noting inherent anticipation requires necessary presence of missing descriptive matter in claimed invention). As Harmon notes, to find inherent anticipation, the extrinsic evidence must demonstrate that the descriptive matter lacking in the prior art is necessarily and inevitably present in the claimed composition or process. HARMON, *supra*.

44. Kilyk, *supra* note 16, at 414 (outlining policy consideration for granting of patent in case of accidental prior use). As Kilyk notes, where the prior use of a claimed product or process is not an inherent result of a prior intended use, that is, not necessary or inevitable, or where an involved product is unknown, such as in the case of unknown coproduction of a product, the granting of a patent to one who subsequently appreciates that accidental prior process or product is justified. *Id.* This is because the public does not already possess knowledge or the benefits of the subsequently claimed product or process. *Id.*

45. 261 U.S. 45 (1923) (holding unintended and unappreciated accidental results nonanticipatory). In *Eibel*, the claims at issue were directed to a paper making machine having a mesh wire material that formed a continuous treadmill around a set of rollers. *Id.* at 56-57. Eibel's novel discovery was that increasing the pitch of the mesh, by elevating one end of the paper making machine, dramatically improved the efficiency of the machine and quality of the resulting paper. *Id.* The defendant relied on prior paper making machines that had introduced pitch for a different purpose, namely to overcome dryness. *Id.* at 67. The Court held that the evidence was insufficient to establish that the pitch brought about Eibel's desired result, and that "if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation." *Id.* at 66 (citing *Tilghman*, 102 U.S. at 711).

46. 328 F.2d 996 (C.C.P.A. 1964) (holding production of minute quantity of claimed composition insufficient for anticipation). In *Seaborg*, the claims were drawn to americium, which is element 95. *Id.* The prior art Fermi patent disclosed a nuclear reactor that produced radioactive uranium but did not disclose the production of americium. *Id.* at 996-97. Apparently, in addition to producing radioactive uranium, the Fermi reactor also produced americium. *Id.* at 996. The Court of Customs and Patent Appeals noted, however, that "the [Fermi] reactor could have produced no more than one billionth of a gram of americium-241, . . . [which] would have been distributed throughout forty tons of intensively radioactive uranium reactor fuel." *Id.* at 997. The court held that the production of such a minute quantity of americium, which was not (and could not) be detected, was insufficient to anticipate the claim to the element. *Id.* at 999.

47. 1 CHISUM, *supra* note 35, § 3.03, at 67 (highlighting cases focusing on accidental and unintended anticipations).

product, and therefore necessary and inevitable.⁴⁸

III. DISCUSSION

A. Product Claims and Process Claims

Webster's Dictionary defines "inherent" as "existing in someone or something as a natural and inseparable quality, characteristic, or right; innate; basic; inborn."⁴⁹ From the perspective of patentability, inherent anticipation differs with respect to products and processes.⁵⁰ In the case of a composition—such as a product, compound, or device—the composition and its properties are inseparable; "they are one and the same thing."⁵¹ Therefore, if a prior art reference teaches the identical structural composition as that being subsequently claimed, the claimed composition is inherently anticipated.⁵² The discovery and claiming of an unknown and unappreciated function, property or characteristic of a known product is insufficient to distinguish it from the prior art and avoid anticipation.⁵³ Indeed, section 101 precludes the patenting of a known product based on the discovery of a new use of the product.⁵⁴ Even if

48. See *infra* Part III.A (comparing inherent anticipation analysis of products and processes).

49. WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY OF THE ENGLISH LANGUAGE UNABRIDGED 943 (2d ed. 1980).

50. Karen Canady, Anticipation by Inherency or Accident, CASRIP (Ctr. for Adv. Study and Research on Intellectual Prop., Seattle, Wash.) Spring/Summer 1998, at pts. III-IV, <http://www.law.washington.edu/casrip/newsletter/Vol5/news5i2canady.html> (last visited Nov. 22, 2004) (highlighting different inherency analysis required for products and processes).

51. *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (highlighting inseparable nature of composition and its properties); see also *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (stating identical products cannot have mutually exclusive properties); *In re Higgins*, 369 F.2d 414, 417 (C.C.P.A. 1966) (noting inseparability of compound and its properties in patent law).

52. *Spada*, 911 F.2d at 709 (holding claimed product inherently anticipated). In *Spada*, the patent applicant claimed "a pressure sensitive adhesive composition comprising a water-based latex containing a normally tacky copolymer." *Id.* at 706. A prior art reference taught the same composition, but described it as a hard, abrasion-resistant adhesive composition. *Id.* at 707. The court held that these apparently identical adhesive compositions, which were formed using the same or similar polymerization technique, must, by necessity, have the same properties. *Id.* at 708.

53. *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (noting discovery of inherent properties of claimed alloy immaterial on issue of anticipation). In *Titanium Metals*, the applicant claimed a titanium alloy consisting essentially of about 0.2-0.9% nickel (Ni), 0.2%-0.4% molybdenum (Mo), and up to 0.2% iron (Fe), wherein the alloy was characterized by good corrosion resistance in hot brine environments. *Id.* at 776. A prior art Russian reference disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni, but did not disclose the property of corrosion resistance. *Id.* at 776-77. The Court of Appeals for the Federal Circuit held that it was immaterial what properties the claimed alloy possessed, or who discovered such properties, because the claimed alloy was the same as that disclosed in the prior art reference; therefore the alloy must necessarily exhibit the same properties. *Id.* at 782.

54. See 35 U.S.C. § 101 (2004) (defining patentable subject matter); *Old Town Ribbon & Carbon Co. v. Colom. Ribbon & Carbon Mfg. Co.*, 159 F.2d 379, 382 (highlighting non-patentability of known product). In *Old Town Ribbon*, the court stated that:

unless a patent disclosed a 'new and useful art,' a new 'machine,' a new 'manufacture,' or a new 'composition of matter,' it has not been a valid patent. If it be merely for a new employment of

the prior art teaches the product but fails to disclose a utility for that product, it is still sufficient to anticipate a subsequent patent claim to that product.⁵⁵

In the case of a process or method, however, the subsequent appreciation of a previously unknown result arising from a known process or method provides the public with knowledge of the new process.⁵⁶ Therefore, one who discovers a new use for a known product may be able to obtain a patent to a method of using that known product, provided that the discovery meets other conditions of patentability.⁵⁷ Although the discovery of a new use for a known compound is patentable, the mere discovery of a new benefit or advantage of a known process is not patentable.⁵⁸ The discovery of a new result of a known process that is directed to *the same purpose* as the known process is also inherently anticipated and therefore unpatentable.⁵⁹ Moreover, the discovery of an

some 'machine, manufacture or composition of matter' already known, it makes not the slightest difference how beneficial to the public the new function may be, how long a search it may end, how many may have shared that search, or how high a reach of imaginative ingenuity the solution may have demanded. All the mental factors which determine invention may have been present to the highest degree, but it will not be patentable because it will not be within the terms of the statute.

Id. at 382 (footnote omitted).

55. *In re Schoenwald*, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (holding teaching of utility not prerequisite for availability of anticipatory prior art reference). In *Schoenwald*, the appellants argued that the cited prior art reference, which disclosed appellants' claimed compound, N-cyclohexyl-N-methyl-2-phenylethylamine, did not teach a utility for the compound. *Id.* at 1123. The appellants had discovered that the compound was a useful ophthalmic composition for treating dry eye syndrome. *Id.* at 1122. The court held that the lack of a prior art teaching of a specific utility for the compound did not prevent it from anticipating appellants' claims directed to the compound. *Id.* at 1124.

56. Canady, *supra* note 50, at pt. IV (describing public benefit of disclosure of new process).

57. See *In re Marshall*, 578 F.2d 301, 304 (C.C.P.A. 1978) (holding weight control process claims with known compound patentable). In *Marshall*, the applicant's claims were directed to a weight control process utilizing an anesthetic, such as oxethazaine, to inhibit the release of hormones and pancreatic enzymes involved in the digestion of food. *Id.* at 302-03. The cited prior art reference, the Physician's Desk Reference (PDR), disclosed drugs containing oxethazaine, which could be used to treat esophagitis, gastritis, peptic ulcer and irritable bowel syndrome. *Id.* at 303. The court held that the reference did not anticipate the method claims because the PDR did not disclose anything remotely close to suggesting taking oxethazaine to lose weight. *Id.* As stated by the court, "[i]f anyone ever lost weight by following the PDR teachings it was an unrecognized accident." *Id.*; *In re Hack*, 245 F.2d 246, 248 (C.C.P.A. 1957) (holding product claims anticipated but recognizing patentability of new process with known product). In *Hack*, the claims at issue were drawn to a brazing alloy composed of particular percentages of gold, copper and nickel. 245 F.2d at 246. The court held that such an alloy was taught in the prior art but recognized that the discoverer of a new use with a known product can patent his discovery using process or method claims, but not product claims. *Id.* at 248.

58. See *In re Woodruff*, 919 F.2d 1575, 1577-78 (Fed. Cir. 1990). In *Woodruff*, the applicant claimed a process of inhibiting the growth of fungi on fresh leafy and head vegetables in a refrigerated environment. *Id.* at 1575. The prior art reference disclosed the same steps of the process for preventing deterioration, such as deterioration caused by respiratory changes, bacterial changes, or other enzymatic changes, but did not specifically disclose fungal deterioration. *Id.* at 1576. The court stated that while the applicant may have been the first to recognize that the known method could be used to inhibit the growth of fungus, this specific benefit was encompassed by the teaching of the generic purpose of the method for preventing deterioration of fresh vegetables. *Id.* at 1577. Consequently, the court held that the newly discovered benefit was insufficient to render the process claim patentable. *Id.* at 1578.

59. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (holding newly discovered result of known process directed to same purpose inherently anticipated). In *Bristol-Myers*

unappreciated feature or characteristic of a prior art process that is merely the “inventive concept” by which the process operates is not patentable over the prior art process.⁶⁰ Finally, if a subsequently claimed process is the result of utilization of a known product or apparatus, which, when utilized in its normal and usual operation, *necessarily* performs the process being claimed, that claimed process is inherently anticipated.⁶¹

B. Necessity and Inevitability

The issue of inherent anticipation can arise in several contexts, such as during the prosecution of a patent application before the USPTO or during a patent infringement litigation proceeding.⁶² Whether before the USPTO or a court, a claim containing an alleged inherently-anticipated feature or result is

Squibb, the claims were drawn to a method treating a patient comprising administering the antitumor drug paclitaxel. *Id.* at 1371-72. The prior art reference taught the same method for the same purpose. *Id.* at 1376. As stated by the court, “Bristol has done no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients [T]he purpose—treating cancer—is no different from the purpose disclosed by [the prior art reference of] Kris.” *Id.* at 1377; *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1367 (Fed. Cir. 1999) (holding claimed method of hair depilation inherently anticipated). In *MEHL/Biophile*, the court held that the claimed method of removing hair using a laser was inherently anticipated by a prior art reference that taught use of the laser to induce tissue damage and pigmented cell injury. 192 F.3d at 1364, 1367. Although the prior art reference did not teach hair removal using the laser, it did recognize that the laser damaged and disrupted hair follicles. *Id.* at 1366-67.

60. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d at 633 (Fed. Cir. 1987) (noting recognition of inventive concept feature of prior art process unpatentable). In *Verdegaal Brothers*, the applicant’s claimed a process for making a concentrated liquid fertilizer by exothermically reacting sulfuric acid and urea in the presence of a “heel” (i.e., a previously-made batch of liquid fertilizer), which could absorb the heat given off in the exothermic reaction. *Id.* at 630. The prior art reference taught all of the steps of the applicant’s claimed process, but did not explicitly disclose that the heel was a heat sink. *Id.* at 632-33. The court held that, even assuming the functioning of the heel as a heat sink was unrecognized and that this property was the “inventive concept” underlying the process, it was an inherent property of the heel and therefore anticipated. *Id.* at 633.

61. *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (holding claimed process resulting from usual operation of device inherently anticipated). In *King*, appellants claimed “a method of *enhancing* colors [from ambient light] produced by interference effects from various films applied to the [transparent solid] panes.” *Id.* at 1324-25. The court noted that such claims were atypical in that they were neither method of manufacture claims nor method of use claims, but rather were simply descriptions of what occurs when the known coated transparent material is placed in ambient light. *Id.* at 1325. The court further held that where a previously known product, in its normal and usual operation, performs the subsequent function claimed by the applicant, it inherently anticipates the later claimed process. *Id.* at 1326; *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977) (holding claimed process inherently anticipated because of necessity of non-disclosed cooling limitation). In *Best*, the applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate (zeolite), which included a step of cooling the steamed zeolite at a sufficiently rapid rate, such that the cooled zeolite exhibited a particular X-ray diffraction pattern. 562 F.2d at 1253. The court held that the applicant’s claimed process was inherently anticipated because the process taught by the prior art reference would necessarily be cooled to facilitate subsequent handling, and there was no data comparing the X-ray diffraction patterns of the zeolites produced using the claimed and prior art processes. *Id.* at 432-33.

62. *Duft & Mirabel*, *supra* note 21, at 541 (recognizing inherent anticipation arguments proffered by both USPTO and litigants). As *Duft and Mirabel* note, while the USPTO issues inherent anticipation rejections during the prosecution of a patent application, litigants may also challenge the validity of an issued patent as inherently anticipated by a prior art reference. *Id.*

anticipated only if that feature or result is necessary and inevitable.⁶³ The fact that it is possible or even probable that a particular result or feature will occur or be present is insufficient to establish the inherency of that result or feature.⁶⁴ Indeed, the high degree of certainty that an allegedly inherent product or process is disclosed in the prior art is a hallmark of both inherency rejections issued by the USPTO during prosecution of an application and arguments proffered by litigants in patent infringement cases.⁶⁵ It should be noted, however, that while a litigant challenging the validity of an existing patent as inherently anticipated must demonstrate the presence of the inherent subject matter by clear and convincing evidence, the USPTO needs only a reasonable basis to support an inherency determination.⁶⁶

In accordance with the necessity requirement, inherent anticipation is not established simply because a prior art reference does not explicitly describe anything inconsistent with the claimed product or process at issue.⁶⁷ Thus, one

63. *Hansgig v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939) (noting requirement for inevitability). In *Hansgig*, the court stated:

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

Id. (citations omitted).

64. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (stating extrinsic evidence must clearly show necessary presence of missing descriptive matter). In *Robertson*, the applicant claimed a disposable diaper having three fastening elements, two for attaching the diaper to the wearer and a third for securing the diaper for disposal. *Id.* at 744. The Board of Patent Appeals and Interferences (Board) held the claims anticipated by a prior art patent teaching a disposable diaper having two fastening elements, with the possibility of additional fasteners to secure the diaper, but not teaching a separate fastener for use in disposing of the diaper. *Id.* at 744-45. According to the Board, the person of ordinary skill in the art would readily understand that the prior art diaper could be disposed of using the additional fastener not with its mate, but rather with one of the primary fasteners. *Id.* at 745. Thus, the Board held the claimed diaper inherently anticipated. *Id.* On appeal, the Court of Appeals of the Federal Circuit construed the claims to require the three fastening elements, and overturned the holding of the Board because it failed to show that the prior art diaper *necessarily* contained the third fastening element for disposing of the diaper. *Id.* at 745; *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (reversing Board holding because inherency not inevitable, but rather result of optimized conditions). In *Rijckaert*, the patent application at issue possessed claims that were directed to an apparatus for recording and reproducing an electric signal on a magnetic record carrier. *Id.* at 1532. The court held that the Board, in affirming the claim rejections, had assumed particular values for the variables giving rise to the claimed time expansion or time compression limitations, and that such optimization was not sufficient to make the claimed invention inherently anticipated. *Id.* at 1533-34; *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990) (stating examiner must provide factual basis for necessary presence of inherent characteristic).

65. *Duft & Mirabel*, *supra* note 21, at 543 (noting importance of certainty of inherent feature or result).

66. *Duft & Mirabel*, *supra* note 21, at 541 (noting different standards for inherency determinations by USPTO and patent litigants). In asserting an inherency rejection during the prosecution of an application, the USPTO can shift the burden of proof to the applicant. *Id.* at 541. It is then incumbent on the applicant to demonstrate that the allegedly inherent feature or result is not present in the prior art. *Id.* The court has affirmed that in situations in which the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily possess the features of the claimed product. *See Best*, 562 F.2d at 1255.

67. *Rowe v. Dror*, 112 F.3d 473, 480 (Fed. Cir. 1997) (holding prior patent not anticipatory). In *Rowe*,

does not require that a prior art reference teach away from the alleged inherent feature or result to counter an inherency determination.⁶⁸ While necessity of the inherent feature or result is required, the court has held that inherent anticipation is not precluded simply because a prior art reference would not produce the claimed product if special, “extraordinary” non-disclosed measures were undertaken.⁶⁹

C. Recognition of an Inherent Feature or Result and the Schering Decision

Prior to the recent decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, Federal Circuit cases that analyzed inherency fell into one of two seemingly conflicting categories regarding the elements of inherent anticipation.⁷⁰ The first line of cases suggested that a finding of inherency required recognition of the purported inherent feature or result by a person of ordinary skill in the art.⁷¹ A representative case from this first group is *Rosco*,

the court interpreted the claims at issue to be drawn to a “balloon angioplasty catheter capable of expanding radially and exerting pressure on the plaque-encrusted walls of a surrounding blood vessel.” *Id.* The prior art Lemelson patent described a general purpose balloon catheter but did not suggest any kind of structural suitability of the balloon for angioplasty procedures. *Id.* The court held that the Lemelson patent was insufficient to anticipate the claims and concluded that at most, the prior art Lemelson patent did not explicitly describe anything inconsistent with angioplasty procedures. *Id.* As stated by the court, “this negative pregnant is not enough to show anticipation.” *Id.*

68. *Id.* (emphasizing anticipatory reference must describe claimed invention sufficiently to place in public domain).

69. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1349-50 (Fed. Cir. 1999) (stating nondisclosed extraordinary measures insufficient to rebut inherency determination). In *Atlas*, the claims at issue were directed to an explosive composition containing a particular percentage range of ingredients (10-40% water-in-oil emulsion and 60-90% solid ammonium nitrate) and required that the composition have sufficient aeration to enhance sensitivity to a substantial degree. *Id.* at 1344. Two prior art patents disclosed explosive compositions having the same ingredients with overlapping ranges (20-67% and 33-80% water-in-oil emulsion; 30-50% and 50-70% solid ammonium nitrate) but did not explicitly teach the element of sufficient aeration to enhance sensitivity to a substantial degree. *Id.* at 1345. Notwithstanding the lack of disclosure of the “sufficient aeration” limitation by the prior art patents, the court held that the claimed explosive composition was anticipated. *Id.* at 1350. Specifically, the court concluded that at a ratio of 30% emulsion and 70% solid ammonium nitrate—as taught by the two prior art patents—there is inherently sufficient aeration to sustain a stable detonation, unless extraordinary measures, such as grinding and screening the ammonium nitrate—which the prior art patents did not teach—were undertaken. *Id.* at 1349-50.

70. Todd J. Tiberi, *Section 102(a) Anticipation by Inherency: Is it in There?*, 756 PLI/PAT 21, 25 (2002) (noting two lines of cases regarding requirement for recognition of inherent feature or result).

71. *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2003) (stating recognition of missing descriptive matter by skilled artisans required for inherent anticipation); *Crown Ops. Int'l Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (same); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 545 (Fed. Cir. 1998) (same); *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995) (same); *Electro Med. Systems S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1052 (Fed. Cir. 1994) (same); *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (same). In *Continental Can*, the court stated:

This modest flexibility in the rule that ‘anticipation’ requires that every element of the claim appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

948 F.2d at 1269; *see also* Tiberi, *supra* note 70, at 30-32 (listing cases requiring recognition for inherency).

Inc. v. Mirror Lite Co.,⁷² where the claims at issue were drawn to an oval cross-view mirror having a varying radius of curvature along the major axis of the convex ellipsoid mirror lens.⁷³ This cross-view mirror was well suited for mounting on the front fender of a school bus to provide the driver a view of the front and passenger sides of the bus.⁷⁴ The prior art design patent disclosed a highly convex, curved-surface, three-dimensional oval mirror with a black, flat metal backing, but did not explicitly disclose the varying radius of curvature along the major axis of the mirror.⁷⁵ In focusing on the lack of recognition, the court held that there was no inherent anticipation by the prior art design patent because there was no evidence that one skilled in the art would read that design patent as inherently disclosing a mirror with varying radius of curvature along the major axis.⁷⁶ Some patent practitioners have interpreted the line of cases represented by *Rosco* to require that the inherent property or result be proven by evidence within the prior art time frame.⁷⁷

In contrast, the second line of cases suggested that recognition of the purported inherent feature or result by a person of ordinary skill in the art is not required.⁷⁸ A representative case from this group is *In re Cruciferous Sprout Litigation*,⁷⁹ where the patented claims at issue were drawn to a method for the production and consumption of broccoli seed sprouts with previously unrecognized, but naturally-occurring, cancer-fighting substances.⁸⁰ The court

72. 304 F.3d 1373 (Fed. Cir. 2002) (requiring recognition for inherent anticipation).

73. *Id.* at 1376 (describing claimed subject matter).

74. *Id.* (describing applicability of convex mirror).

75. *Id.* at 1378 (highlighting design of prior art mirror).

76. *Rosco*, 304 F.3d at 1381 (holding claims not inherently anticipated). The court stated:

[T]he question is not whether the manufacture of the [prior art] mirror using this process inherently results in a varying radius of curvature along the major axis, but whether one skilled in the art would read the [prior art design patent] as inherently disclosing the invention of the [patent], that is, whether one skilled in the art would read the [prior art design patent] as showing a mirror or varying radius of curvature along the major axis.

Id.

77. Michael K. O'Neill & George K. Ng, *Doctrine of Inherent Anticipation is Clarified*, 26 NAT'L L.J. S6, S6 (2003) (describing wide-spread interpretation requiring proof of inherent feature by evidence within prior art time frame). Based on a line of Federal Circuit cases requiring recognition of the inherent feature or result, it has been argued that inherent anticipation requires knowledge or appreciation of the inherent feature or result in the prior art. *Id.*

78. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1345 (Fed. Cir. 2002) (stating recognition of inherent feature or functioning not required for inherent anticipation); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (same); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (same); *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436 (Fed. Cir. 1988) (noting awareness of prior art product's properties not required to prove inherency); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (noting immateriality of discovery of inherent properties on issue of novelty); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983) (stating appreciation of inherent process irrelevant for operation of machine in consistent reproducible manner); see also Tiberi, *supra* note 70, at 29-30 (listing cases not requiring recognition for inherency).

79. 301 F.3d 1343 (Fed. Cir. 2002).

80. *Id.* at 1345 (claiming methods for preparing food products). Specifically, the applicants claimed methods of preparing food products containing high levels of substances that induce Phase 2 enzymes. *Id.*

concluded that the cancer-fighting properties of the sprouts were inherent characteristics that had always existed in the sprouts.⁸¹ As stated by the court, “[the patentee] has done nothing more than recognize properties inherent in certain prior art sprouts While [the patentee] may have recognized something quite interesting about those sprouts, it simply has not invented anything new.”⁸² The fact that those of ordinary skill in the art did not recognize the inherent cancer-fighting properties of the sprouts was irrelevant for purposes of inherent anticipation.⁸³

Inconsistency in Federal Circuit case law, represented by *Rosco* and *Cruciferous Sprout Litigation*, was likely the cause of one Federal Circuit panel’s attempt to distinguish categories of claims requiring recognition to be inherent from categories of claims not requiring recognition to be inherent.⁸⁴ In *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*,⁸⁵ the claims at issue were drawn to metallic fuses that could be used as interconnects, which are devices that connect sections of semiconductor chips but allow for disconnecting of dysfunctional portions of such chips.⁸⁶ The claimed fuses possessed an upper layer of an optically absorptive material (e.g., tungsten, titanium) and a lower layer of metal (e.g., aluminum).⁸⁷ The claimed fuses also included a mechanistic limitation that, upon directing a laser beam onto the fuse, the lower metal layer would vaporize and induce an explosion that would melt the fuse, thereby disconnecting an element of an integrated circuit.⁸⁸ Three prior art patents disclosed fuses with the same structure but did not disclose the vapor-induced explosion mechanism.⁸⁹ Notwithstanding the lack of teaching of the vapor-induced explosion mechanism, the court held that the prior art inherently anticipated the claimed fuses because it taught the same fuse structure, and therefore inherently disclosed the law of nature responsible

Phase 2 enzymes are involved in the detoxification of potential carcinogens and provide chemoprotection against cancer. *Id.*

81. *Id.* at 1350-51 (recognizing existence of glucosinolate content and Phase 2 enzyme-inducing potential in sprouts).

82. *Id.* (noting lack of novelty for claimed invention). The court further identified several prior art references, including a 1973 cookbook, which contained a reference to the use of health-giving sprouts by the Emperor of China in 2939 B.C. *Id.* at 1350.

83. *Cruciferous Sprout*, 301 F.3d at 1350-51 (dismissing recognition element for inherent anticipation).

84. Tiberi, *supra* note 70, at 31-32 (speculating on Federal Circuit panel attempt to clarify recognition requirement for inherent anticipation).

85. 268 F.3d 1342 (Fed. Cir. 2001).

86. *Id.* at 1344 (describing claimed metallic fuses). In view of the complexity of semi-conductor chips, they are typically manufactured with redundant circuitry. *Id.* at 1344. This affords manufacturers the opportunity to test the chips to determine if they contains any dysfunctional portions. *Id.* If a chip does contain a dysfunctional portion, that portion can be disconnected, and its function performed by the redundant circuitry. *Id.* This serves to greatly increase the percentage of manufactured viable semi-conductor chips. *See id.*

87. *Id.* (describing structure of claimed fuses).

88. *Id.* at 1344-46 (highlighting limitations of claimed fuses).

89. *EMI Group*, 268 F.3d at 1350 (noting identical structure of prior art fuses).

for the rupture of the fuses under the heat of a laser.⁹⁰

With regard to the recognition element of inherent anticipation, the court stated that recognition of missing descriptive matter may be appropriate for claims reciting limitations of structure, compositions of matter, and method steps, but that claims reciting theoretical mechanisms or rules of nature, such as the vapor-induced fuse explosion mechanism, do not require previous recognition by a person of ordinary skill in the art to be inherently anticipated.⁹¹ Thus, *EMI Group* established that, for different types of patent claims, recognition of the missing inherent feature or result is not necessarily required.⁹²

This seemingly contradictory case law was recently clarified by the seminal Federal Circuit case, *Schering Corp. v. Geneva Pharmaceuticals, Inc.*⁹³ In *Schering*, Geneva Pharmaceuticals and other generic drug companies challenged the validity of Schering's patent that claimed descarboethoxyloratadine (DCL), a non-drowsy antihistamine compound.⁹⁴ Schering had previously obtained a patent that claimed loratadine, the active component of the best-selling non-drowsy antihistamine drug, CLARITIN[®].⁹⁵ In preclinical studies, Schering determined that DCL was an active metabolite of loratadine, which was formed naturally in the human body upon ingestion.⁹⁶ Notwithstanding the lack of any prior art teaching of DCL, or any other metabolite of loratadine, the Federal Circuit held that Schering's prior art patent claiming loratadine inherently anticipated its subsequent patent claims to DCL.⁹⁷

The court recognized that the *Schering* decision was a case of first

90. *Id.* at 1351 (asserting recognition of theoretical mechanism of claimed composition not required for inherent anticipation).

91. *Id.* at 1350-51 (delineating types of claims requiring and not requiring recognition to be inherently anticipated).

92. *Id.* (attempting to make sense of inconsistent Federal Circuit case law). The Court of Appeals of the Federal Circuit panel asserted that recognition of an alleged inherent feature may be appropriate for compositions and method claims that do not recite theoretical mechanisms or rules of natural law. *Id.* This is because such recognition may be important to determine that the inherent feature is necessarily present. *Id.* In the case of claims reciting theoretical mechanisms or natural rules of law, however, recognition or understanding of the claimed underlying mechanism or rule is not required. *Id.* This is because a person of ordinary skill in the art can practice a claimed invention without understanding its underlying theoretical mechanism or natural rule of law. *Id.*

93. See generally 339 F.3d 1373 (Fed. Cir. 2003).

94. *Id.* at 1376 (typifying recurring battle between pioneering and generic drug companies); see also note 15 (outlining inherent anticipation holding in *Schering*). DCL, like loratadine, is a non-drowsy antihistamine, which is marketed by Schering Corporation as CLARINEX[®]. U.S. Food and Drug Administration, Clarinex Consumer Information, <http://www.fda.gov/cder/consumerinfo/druginfo/clarinex.htm> (last visited Nov. 21, 2004).

95. *Schering*, 339 F.3d at 1376 (describing Schering's prior art patent).

96. *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 535 (D.N.J. 2002), *aff'd*, 339 F.3d 1373 (Fed. Cir. 2003). A metabolite is a compound that is formed in the body upon ingestion of a pharmaceutical agent. *Schering*, 339 F.3d at 1375.

97. *Schering*, 339 F.3d at 1378-79 (holding claims to DCL invalid as inherently anticipated).

impression because, unlike other inherency cases in which the prior art typically provided a partial description of the anticipatory subject matter, the prior art in this case provided no express description of any part of the claimed subject matter.⁹⁸ The court noted, however, that the record established that DCL *necessarily and inevitably* forms when loratadine is administered to a patient, and that recognition of this inherent result by a skilled artisan is not required for inherent anticipation.⁹⁹ The court emphatically dismissed the notion that inherent anticipation requires recognition of the inherent characteristic or result in the prior art.¹⁰⁰

From a practical standpoint, the elimination of the recognition element is logical because inherent properties or results, by their very nature, are typically non-disclosed or non-described.¹⁰¹ If such properties or results are recognized, they are usually expressly taught in the prior art, and the difficult analysis required for inherent anticipation is unnecessary.¹⁰² From a legal standpoint, however, the elimination of the recognition element is problematic because it seemingly undermines the Doctrine of Accidental Anticipation.¹⁰³

While the *Schering* panel decision clarified the Doctrine of Inherent Anticipation by rejecting the recognition element, the analysis provided in the subsequent denial of Schering's petition for rehearing and rehearing en banc

98. *Id.* at 1378-79 (noting inherency can provide entire anticipatory subject matter). As stated by the court:

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

Id. at 1379.

99. *Id.* at 1378 (emphasizing necessary formation of claimed metabolite). The court emphasized that in situations where the claimed metabolite necessarily and inevitably forms when it is ingested under normal conditions, that it is inherently anticipated. *Id.* at 1380. The court noted that utilizing proper claiming strategies, one could avoid inherent anticipation and acquire patent protection for metabolites of known drugs. *Id.* at 1381. The court further suggested three ways that this might be done: using claims drawn to a pure or isolated form of the metabolite; using claims drawn to a pharmaceutical composition comprising the metabolite; and using claims drawn to methods of administering the metabolite. *Id.* From a practical standpoint, however, such claims were of limited value to Schering Corporation, because Geneva Pharmaceuticals was making loratadine and not DCL. O'Neill & Ng, *supra* note 78, at S6. In fact, Schering did have claims drawn to pharmaceutical compositions and methods of use, however, these were clearly not infringed and not asserted in the litigation. *Id.* Although not specifically addressed in the case, the court likely believed that the claims to the metabolite unfairly extended Schering's patent term for loratadine. Mark J. Cohen, *A Change in Pharmaceutical Prosecution Practice*, INTELL. PROP. TODAY, Oct. 2003, at 30.

100. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 1377 (Fed. Cir. 2003) (rejecting contention that inherent anticipation requires recognition in prior art).

101. Nelson, *supra* note 34, at 598 (noting nondisclosure of inherent events).

102. Feit & Warrick, *supra* note 13, at 5 (noting general non-difficulty in analyzing express teaching of claim element).

103. See *infra* Part III.E (addressing difficulty in reconciling Doctrines of Inherent Anticipation and Accidental Anticipation).

revealed that Federal Circuit opinion is not unanimous on the subject.¹⁰⁴ Specifically, Judges Newman and Lourie provided strong dissenting opinions, stating that the *Schering* holding violated longstanding and established requirements for anticipation.¹⁰⁵ Both dissenting judges questioned whether Schering's loratadine patent, which made no mention of DCL or any other metabolite, anticipated their DCL patent.¹⁰⁶ Judge Newman's dissent stated that the decision to bar patentability of products that have not yet been discovered contradicted established precedent, and therefore is an important question that should be decided by the Federal Circuit en banc.¹⁰⁷ Judge Lourie, in emphasizing the lack of an enabling disclosure by Schering's loratadine patent, noted that the *Schering* decision effectively precludes virtually all patents on human metabolites of drugs.¹⁰⁸

Notwithstanding the dissenting opinions expressed by Judges Newman and Lourie, a recent decision by the Federal Circuit upheld the *Schering* decision rejecting the requirement for recognition of the inherent property or result.¹⁰⁹ As stated by the court in *Toro Co. v. Deere & Co.*,¹¹⁰ "the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."¹¹¹ Given the difference of opinion regarding the recognition element among at least some members of the Federal Circuit, it remains uncertain whether the *Schering* and

104. *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 993-996 (Fed. Cir. 2003) (Newman, J., and Lourie, J., dissenting), *denying reh'g* to 339 F.3d 1373 (Fed. Cir. 2003).

105. *Id.* at 993, 996.

106. *Id.* at 995, 996 (questioning court of appeals' panel holding of inherent anticipation).

107. *Id.* at 995 (Newman, J., dissenting). As Judge Newman stated, "[t]he panel now contradicts this body of precedent, stating that it 'rejects the contention that inherent anticipation requires recognition in the prior art.' A rejection of precedent requires en banc action, not panel disruption." *Id.*

108. *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 995 (Fed. Cir. 2003) (questioning whether prior art patent enabling anticipatory reference). It is well established that for a prior art reference to anticipate a claim, it must provide an enabling disclosure. *Id.* at 996. According to Judge Lourie, by holding that the mere recitation that one can administer a prior art compound to humans provides an enabling disclosure of how to make metabolites, the court precludes the patenting of virtually all human metabolites of drugs. *Id.* at 995-96; *accord In re Donahue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (stating anticipatory reference must enable ordinarily skilled artisan to make and use claimed invention).

109. *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320-21 (Fed. Cir. 2004) (reaffirming that recognition of inherent feature not required).

110. 355 F.3d 1313 (Fed. Cir. 2004).

111. *Id.* at 1321. In *Toro*, the claims at issue were directed to a method of encouraging turf growth using jets of pressurized liquid (e.g., water) to lift and fracture the soil. *Id.* at 1317. The prior art patent claimed and described a product and method for pulse injecting liquid fertilizer into the ground. *Id.* The district court had found no inherent anticipation, stating "to prove anticipation when the prior art reference is silent about the asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by one of ordinary skill in the art." *Id.* at 1320 (alteration in original) (quoting *Toro Co. v. Deere & Co.*, 143 F. Supp. 2d 1122, 1129-30 (2001)). The court, citing *Schering* and relying on its holding that recognition of the inherent characteristic is not required, remanded the case to the district court to construe the alleged inherent claim limitation, and then decide whether the prior art patent sufficiently described and enabled the claimed invention. *Id.* at 1320-21.

Toro holdings and analysis will prevail.¹¹²

While the *Schering* decision clarified the Doctrine of Inherent Anticipation by rejecting the recognition element, it also created additional challenges for patenting biotechnology inventions.¹¹³ In particular, the *Schering* decision means that one may be able to invalidate a patent claim to a previously unknown compound as inherently anticipated by subsequently demonstrating that the compound is a metabolite of a known prior art compound.¹¹⁴ In view of the extraordinary expense in discovering and bringing a pharmaceutical drug to market and the importance of patent protection for that discovery, this decision may have significant impact for pioneering and generic drug companies.¹¹⁵

D. Prophetic Inherency, Enablement and the *Elan* Decision

The issue of whether an inherent anticipatory reference must be enabled, which was raised in the dissenting opinions of Judges Newman and Lourie in the subsequent denial of Schering's petition for rehearing and rehearing en banc, appeared in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*.¹¹⁶ In *Elan I, II, and III*, the claims at issue were drawn to a transgenic rodent having a particular mutation.¹¹⁷ The district court

112. See John L. Rogitz, *CAFC Happenings*, INTELL. PROP. TODAY, Oct. 2003, at 28 (advocating caution regarding *Schering* holding). In particular, it will be curious to see how future Federal Circuit panels containing Judges Newman and Lourie address inherent anticipation and enablement.

113. O'Neill & Ng, *supra* note 77, at S6 (noting additional challenges *Schering* decision creates for biotechnology and chemical patents).

114. O'Neill & Ng, *supra* note 77, at S6 (raising possibility of invalidating patent claim to previously unknown compounds).

115. Duncan, *supra* note 17 at 26 (highlighting importance of patent estate and impact of Federal Circuit decisions). As Duncan notes, in terms of importance for the success of a biotechnology company, its patent portfolio is only exceeded by its potential to solve a concrete biological problem. *Id.* A recent study estimated the cost of getting a pharmaceutical drug approved by the Food and Drug Administration and marketed in the United States at \$1.7 billion. Peter Landers, *Cost of Developing a New Drug Increases to About \$1.7 Billion*, WALL ST. J., Dec. 8, 2003, at B4. Given this extraordinary cost, the possibility that a biotechnology company's composition claims could later be invalidated if it is discovered that the composition is an inevitably-produced metabolite of a known prior art compound, is cause for concern. *Id.*

116. 346 F.3d 1051, 1052 (Fed. Cir. 2003) (clarifying invalidity based on inherent anticipation requires enabling prior art disclosure). It is basic patent law that a prior art reference that expressly teaches a claimed invention can anticipate only if it enables one of ordinary skill in the art to make and use the claimed invention. *Id.* at 1229. If the prior art publication presents only a starting point for further experiments, which may or may not succeed, it has not enriched the store of public knowledge, and is not anticipatory. *Id.*; see also *supra* note 108 and accompanying text (addressing necessity for enabling disclosure). *Elan* addressed the issue of whether a prior art reference that inherently teaches a claimed invention must be enabled. *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. and Research*, 175 F. Supp. 2d 1209, 1215 (N.D. Cal. 2000) (*Elan I*), *rev'd*, 304 F.3d 1221 (Fed. Cir. 2002) (*Elan II*), *vacated by* 314 F.3d 1229 (Fed. Cir. 2002), *rev'd*, 346 F.3d 1051 (Fed. Cir. 2003) (en banc) (*Elan III*).

117. *Elan I*, 175 F. Supp. 2d at 1212 (describing claimed subject matter). The claims at issue were drawn to a transgenic rodent having a transgene encoding a mutant human APP protein (the Swedish mutation) that is processed to ATF-betaAPP in a sufficient amount to be detectable. *Id.* at 1211. Transgenic mice harboring the Swedish mutation produce the mutant APP protein, which is cleaved into two fragments: Abeta, which is

held that Elan's claims to a transgenic rodent having the Swedish mutation were anticipated by a prior art patent that disclosed transgenic mice carrying the same mutation, even though the transgenic mice were not actually made.¹¹⁸ On appeal, a Federal Circuit panel reversed the district court decision, with the majority holding that the general recitation of known, failure-prone procedures that were never actually performed, is insufficient to anticipate the claimed transgenic mouse.¹¹⁹ The Federal Circuit Court, sitting en banc, subsequently vacated and replaced the Federal Circuit panel decision.¹²⁰ The en banc court clarified that inherent anticipation requires that the proffered anticipating prior art disclosure be enabling, and it remanded the case for such a determination.¹²¹

In deciding that the facts of *Elan* warranted analysis under enablement, and not inherency, the court wisely avoided further complicating what is already a difficult analysis.¹²² Indeed, from a patentability perspective, the art of biology has long been an unpredictable art.¹²³ Therefore, for the most part, a biological invention, because of its unpredictable nature, is inherently anticipated only if

believed to cause the plaques associated with Alzheimer's disease, and ATF-betaAPP. *Elan II*, 304 F.3d at 1223-24. While detection of Abeta in the mouse brain is difficult because of its small size, one can easily detect the larger ATF-betaAPP fragment, which can serve as an indicator of production of the smaller clinically-relevant Abeta fragment. Robert Schulman & Samson Vermont, *Can Old Products Now Be Patented Based on Newly Discovered Properties?: Federal Circuit Says Yes, but En Banc Panel Set to Re-visit*, PAT. STRATEGY & MGMT. (NLP IP Co., Inc.), Feb. 2003, at 1.

118. *Elan I*, 175 F. Supp. 2d 1212 (holding claims inherently anticipated). The prior art Mullan patent described the source and nature of the Swedish mutation, its role in Alzheimer's disease, and transgenic animals carrying the Swedish mutation. *Elan III*, 346 F.3d at 1055-56. The district court held that, notwithstanding the absence of teaching of the formation of ATF-betaAPP—an element of Elan's claimed method—its formation was inherent in, and therefore anticipated by, the general teachings of the prior art Mullan patent reference. *Elan I*, 175 F. Supp. 2d at 1212.

119. *Elan II*, 304 F.3d at 1229 (majority holding precatory suggestion of general procedures to make novel product not anticipatory). In holding the claimed transgenic mouse not inherently anticipated, the majority highlighted the difficulty of gene transfer between humans and animals. *Id.* at 1228. The majority further noted that the prior art Mullan patent did not teach all of the elements of Elan's claimed transgenic mouse and merely provided an invitation to experiment with no assurance of success. *Id.* In dissent, Judge Dyk asserted that the claimed transgenic mice were inherently anticipated. *Id.* at 1235 (Dyk, J., dissenting). Judge Dyk noted that in accordance with *Cruciferous Sprout*, recognition of an inherent characteristic is not required. *Id.* at 1231. Accordingly, Judge Dyk concluded that the prior art teaching of mice carrying the Swedish mutation, which necessarily will produce the claimed ATF-betaAPP fragment, is inherently anticipatory. *Id.* at 1235.

120. *Elan III*, 346 F.3d at 1051 (granting rehearing en banc).

121. *Id.* at 1052 (holding prior art reference not anticipatory unless enabled). To serve as an anticipatory reference, the reference must enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation. *Id.* at 1054. The en banc Federal Circuit held that the factual nature of the arguments were better characterized as an enablement rejection, rather than an inherency argument. *Id.*; *supra* notes 108, 116 and accompanying text (addressing requirement for enabling disclosure).

122. See Schulman & Vermont, *supra* note 117, at 1 (suggesting Federal Circuit reconcile its conflicting analyses of inherent anticipation during en banc review). Prior to issuance of the en banc decision and opinion, Schulman and Vermont argued that the court should ideally hold that one could establish inherency using evidence other than the prior art, but that under the facts of this case, the doctrine of inherency was inapplicable because actual production of the transgenic mouse was not disclosed in the prior art. *Id.* at 3.

123. 3 CHISUM, *supra* note 35, § 7.03(4)(d)(i), at 64 (noting unpredictable nature of biological materials and reactions).

the invention is actually made in the prior art.¹²⁴

E. Reconciliation of the Doctrines of Inherent Anticipation and Accidental Anticipation

The Doctrines of Inherent Anticipation and Accidental Anticipation attempt to strike a balance between granting a patentee temporally exclusive rights for publicly disclosing an invention, and removing that which is already in the public domain.¹²⁵ The factual determination of whether a particular invention is inherent, however, is often a difficult one.¹²⁶ Moreover, inconsistent case law in the Federal Circuit and the court's use of varying tests and analytical frameworks makes it difficult to predict how courts will apply these doctrines to a particular set of facts.¹²⁷ In particular, the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals, have examined a number of factors to determine whether the Doctrine of Inherent Anticipation or Doctrine of Accidental Anticipation apply to a particular set of facts.¹²⁸ Such factors include, for example: whether the prior art intended the claimed composition or process; whether the prior art includes knowledge of the claimed composition or process; whether the prior art includes knowledge of the newly discovered result of the claimed process or knowledge of the newly discovered function of the claimed composition; whether the prior art includes knowledge of a claimed component in the claimed composition; whether the prior art includes knowledge of the function of a component in a prior art process or composition; whether the prior art performs the claimed process or makes or uses the claimed composition for a different purpose; whether the claimed composition is useful in the prior art; whether the claimed process is useful to achieve the claimed result in the prior art; and whether the claimed process performs occasionally or under unusual conditions in the prior art or the claimed composition is formed occasionally or under unusual conditions.¹²⁹ Determining which of these factors a court will examine is difficult.¹³⁰

As described above, the recent *Schering* decision affirmed that inherent anticipation does not require recognition of an inherent feature or

124. Schulman & Vermont, *supra* note 117, at 3 (typically requiring actual making of biotechnological invention in prior art for anticipation).

125. See *supra* Part III (discussing Doctrine of Inherent Anticipation and Doctrine of Accidental Anticipation).

126. *Supra* note 13 and accompanying text (highlighting difficulty in analyzing inherent teachings).

127. Anne Brown & Mark Polyakov, *The Accidental and Inherent Anticipation Doctrines: Where Do We Stand and Where Are We Going?* (Mar. 30, 2004) (presented at the Third Advanced Forum on Biotech Patents: The Tactical and Practical Guide to Today's Most Complex Issues, Boston, Mass.) (highlighting various tests utilized by courts); see *supra* Part III.C (addressing inconsistent case law regarding necessity of recognition).

128. Brown & Polyakov, *supra* note 127, at 17-18 (noting factors used by courts to determine inherent or accidental anticipation).

129. Brown & Polyakov, *supra* note 127, at 17-18.

130. Brown & Polyakov, *supra* note 127, at 1.

characteristic.¹³¹ In cases where courts have applied the Doctrine of Accidental Anticipation, however, lack of recognition and lack of intention seemingly have been key elements.¹³² In *Schering*, the court addressed accidental anticipation and attempted to distinguish the facts at issue from those of *Eibel Process Co. v. Minnesota & Ontario Paper Co.* and *Tilghman v. Proctor*.¹³³ The court asserted that, unlike the facts of *Schering Corp.*, the record in these prior cases did not definitively demonstrate that the prior art produced the claimed subject matter.¹³⁴ This assertion, however, is somewhat misleading as the necessity requirement was not presented as the dispositive issue in *Tilghman* and *Eibel Process*.¹³⁵ Instead, these early cases emphasized that even if the prior art process had occurred, it was unintended and unappreciated.¹³⁶

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.¹³⁷ In the absence of some type of

131. See *supra* notes 94-104 and accompanying text (summarizing rejection of recognition element).

132. See *Tilghman v. Proctor*, 102 U.S. 707, 711-12 (1881) (noting unappreciated accidental formation of fat acid in prior art processes). As stated by the court:

If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery.

Id.; see *In re Marshall*, 578 F.2d 301, 304 (C.C.P.A. 1978) (highlighting nonanticipatory nature of unrecognized accidental anticipation); see also *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 66 (1923) (noting unintended and unappreciated accidental result not anticipatory).

133. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003) (discussing accidental anticipation).

134. *Id.* (arguing no recognition element in accidental anticipation cases). The Court of Appeals for the Federal Circuit noted that in *Tilghman*, the Supreme Court hypothetically referred to a possible prior art teaching of the claimed method of forming free fatty acids. *Id.* Similarly, the court pointed out that in *Eibel Process*, the Supreme Court did not find a prior art teaching of the claimed paper making machine. *Id.*

135. *Brown & Polyakov*, *supra* note 127, at 30 (noting dispositive issue in early accidental anticipation cases).

136. *Brown & Polyakov*, *supra* note 127, at 30 (highlighting importance of recognition and intention); see also *supra* notes 39-47 and accompanying text (discussing Doctrine of Accidental Anticipation).

137. *Schering*, 339 F.3d at 1378 (emphasizing necessity requirement for inherent anticipation). Specifically, the court stated that "DCL is not formed *accidentally* or *under unusual conditions* when loratadine is ingested. . . . [but rather is] a necessary consequence of administration of loratadine to patients." *Id.* (emphasis added). The court's use of the terms "accidentally" and "under unusual conditions" is troubling, however, as it is unclear what these terms mean. For example, "under unusual conditions" could mean that only under a subset of atypical conditions would the prior art composition or process result in the claimed subject matter. Such a scenario is addressed in *Atlas Powder*, where the court noted that the claimed "sufficient aeration" limitation would inherently be met by the prior art explosive compositions, unless extraordinary measures, such as grinding and screening, were undertaken. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1349-50 (Fed. Cir. 1999); see *supra* note 69 and accompanying text. Alternatively, "under unusual conditions" could mean that the prior art composition or process necessary and inevitably occurs, thereby satisfying the necessity requirement, but that it occurs in a previously unrecognized and unforeseen context. Such a scenario arguably appears in cases such as *Tilghman*, *Eibel Process*, and *Marshall*. See *supra* notes 41, 45, 57 (describing accidental anticipation cases). The tenor of the *Schering* decision apparently favors the former interpretation.

recognition or intention component, however, accidental anticipation may become a doctrine with no bite.¹³⁸ It will be interesting to see if, and how, future courts address this doctrine.

IV. CONCLUSION

Proper application of the Doctrine of Inherent Anticipation or Doctrine of Accidental Anticipation to a particular set of facts is difficult. The difficulty of applying these doctrines is compounded in situations where understanding of the invention is limited because of scientific and technological limitations, as with biotechnology inventions. While the *Schering* decision helps clarify the Doctrine of Inherency by expressly rejecting the recognition element, it seemingly undermines the viability of the Doctrine of Accidental Anticipation. By limiting the analysis of inherent anticipation solely to a determination of whether the inherent characteristic or result is necessary and inevitable, the courts may have created a burden that litigants will be unable to overcome. Given the limited understanding of many biotechnology inventions, it may not be possible for the courts to accurately determine whether an inherent characteristic or result is necessary and inevitable at the time that such a determination must be made. Scientific understanding of the mechanisms of biological action underlying an invention, which may be required to determine the necessity and inevitability of the inherent characteristic or result, may only occur years later. As such, courts should be wary of deciding that a poorly-understood biotechnological invention is inherent. Without a complete understanding of an invention, a court holding an invention inherently anticipated could present estoppel issues if later understanding of the invention reveals their inherency determination to be incorrect.

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138. *But see* Brown & Polyakov, *supra* note 127 at 33 (proposing *Schering* does not obviate Doctrine of Accidental Anticipation). Brown and Polyakov argue that even with elimination of the recognition element, the Doctrine of Accidental Anticipation is still a viable doctrine. *Id.* at 34.