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INHERENCY†

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INTRODUCTION

Inherency is a puzzle that runs throughout patent law. Patents are based upon descriptions of technology. The description of the invention in a patent distinguishes it from previous technologies described in the prior art. The description of the claimed invention in a patent determines whether an accused device infringes the patent. The description of the invention in a patent application is used to determine whether the claimed invention is sufficiently novel, useful, and nonobvious to merit a patent at all. Indeed, the fundamental premise of patent law is that of a bargain between the inventor and the public: the public authorizes twenty years of exclusive rights in exchange for the publication of a detailed description of how to make and use the claimed invention.

Technologies may have qualities that are unappreciated or unidentified in a patent description, but which are nonetheless present. The law refers to these unknown attributes as "inherent" in the product or process. What should be done about such characteristics or qualities of a technology that exist but are *not* explicitly described, either through ignorance or inadvertence? This problem is explicitly presented in at least five different patent doctrines: anticipation,[1] the on-sale bar,[2] priority disputes,[3] double-patenting,[4] and enablement[5]; and it casts its shadow across the law governing subject matter, infringement, and obviousness. The Federal Circuit has decided dozens of cases involving inherency in the last twenty years. Depending on how it has been applied,[6] the inherency doctrine permits defendants to invalidate a patent by showing that even though the prior art did not expressly disclose what the patentee claims to have invented, all or part of the patentee's invention was inherent in a particular piece of prior art. It may also permit patent owners to satisfy their obligation to provide an

1. 35 U.S.C. § 102(a) (2000).

2. *Id.* § 102(b).

3. *Id.* § 102(g)(1).

4. *See, e.g.*, Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 940-42 (Fed. Cir. 1992).

5. 35 U.S.C. § 112 (2000).

6. The caveat is intentional. Even the basic description of the doctrine is controverted, supplying further evidence of just how confusing the doctrine has become.

enabling disclosure, and perhaps even to prove a date of invention, based on information that they do not disclose but that is inherent in their invention.

Inherency is also perhaps the most elusive doctrine in all of patent law. It has confused and annoyed generations of law students. However, the confusion hardly ends there. Commentators have struggled to explain the doctrine and have come up with formulations strongly reminiscent of epicycles that are at least as confusing as the case law.[7] The courts, too, are confused. The cases appear to flatly contradict each other, are often accompanied by dissents, and in the last three years alone have triggered one abortive en banc rehearing[8] and strong calls for a second.[9] In particular, the courts have split sharply over whether an element can be inherent in a prior art reference even if people of ordinary skill in the art do not appreciate the existence of that element.[10]

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7. For example, John Kilyk argues that the cases up through 1982 could be reconciled on the basis that both "[s]ingle, appreciated prior uses and ... consistent result[s] of that which was intended, regardless of appreciation so long as the involved product in issue is known" are inherently anticipated. John Kilyk, Jr., *Accidental Prior Use*, 64 J. PAT. OFF. SOC'Y 392, 413-14 (1982). This explanation is both unnecessarily convoluted and incomplete in describing more recent cases. *See also* Steven C. Carlson, *Inherent Anticipation*, 40 IDEA 297, 306-18 (2000) (proposing a focus on knowledge coupled with a three-part rule that treats physical properties, methods, and uses differently); Irving N. Feit & Christina L. Warrick, *Inherency in Patent Law*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 5, 21 (2003) (finding a conflict in inherency cases and proposing to resolve it by focusing on the "objective understanding" of the prior art based on the timing of disclosure by a person having ordinary skill in the art (PHOSITA)); Todd R. Miller, *Patented Compounds Inherently Coproduced as Trace Impurities: Issues of Inherent Anticipation and Literal Infringement*, 32 AIPLA Q.J. 425, 442 (2004) (identifying a nine-part test attributable to another author); *cf.* Paul G. Alloway, Note, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 SUFFOLK U. L. REV. 73, 73 (2004) ("Inherency is chaotic ....").

8. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 314 F.3d 1299, 1299 (Fed. Cir. 2002) (en banc) (vacating an earlier panel opinion and taking the case en banc). The en banc appeal was dismissed when the panel wrote a new opinion that did not rely on inherency. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1052 (Fed. Cir. 2003).

9. *See* Schering Corp. v. Geneva Pharms., Inc., 348 F.3d 992, 995-96 (Fed. Cir. 2003) (Lourie, J., dissenting from denial of rehearing en banc).

10. One court attempted to reconcile the apparently conflicting cases involving knowledge by distinguishing between limitations of structure, where knowledge of the characteristics of the prior art is required, and natural laws, for which it is not. EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350-51 (Fed. Cir. 2001). This formulation seems to suggest that if the element adds to patentability, knowledge is required. This approach is mistaken insofar as it requires knowledge of an element that is determined to be

In this Article, we argue that this confusion is largely unnecessary. Examining the facts of the cases offers a simple way to understand them. While many courts have recited as gospel the idea that inherency requires knowledge or appreciation of the inherent element, in no case does the application of the inherency doctrine actually turn on knowledge of the element. Indeed, on reflection, application of a knowledge standard in inherency cases makes little sense. Inherency by definition concerns things that people of ordinary skill in the art do *not* know; if the person having ordinary skill in the art (PHOSITA) would know of the presence of an element based on the prior art disclosure, there is a straightforward case of anticipation based on that disclosure and no need for the inherency doctrine.[11] Rather, the inherency cases are all ultimately about whether the public already gets the *benefit* of the claimed element or invention. If the public already benefits from the invention, even if they don't know why, the invention is inherent in the prior art. If the public doesn't benefit from the invention, there is no inherency.

In Part I, we examine the main thread of inherency cases, those arising out of the novelty and statutory bar provisions of the Patent Act. We explain how the courts got off track in their focus on knowledge and why a focus on benefit clearly and consistently explains the doctrine. In Part II, we consider inherency in a different context, one in which the inventor must show possession of the claimed invention, either to prevent a "new matter" rejection or to establish priority of invention. Finally, in Part III, we discuss the broader implications of this rule, including what the inherency doctrine may mean for patents on DNA sequences and patents on drugs derived from traditional knowledge. A proper understanding

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present in the prior art. As explained in Part I.C, the cases themselves do not impose any such requirement. The mistake was dictum, though; the court itself found inherency despite the lack of knowledge by the PHOSITA of the vapor explosion mechanism at issue in that case. *Id*. at 1351.

11. The § 102(b) cases involving "hidden public use" prevent patenting when the public knows either how to make or use the invention. *See infra* Part I.C.

There may be cases in which the PHOSITA would know something but the patentee did not, but those too present straightforward cases of anticipation without the need for the inherency doctrine, since the PHOSITA would understand a piece of prior art as teaching the invention.

of the inherency doctrine may offer a logical explanation for the "product of nature" cases, undermining the last significant exception to patentable subject matter.

I. ANTICIPATORY INHERENCY

Although the inherency problem manifests itself across a range of patent doctrines, it is perhaps best known, and most often seen, in the context of 35 U.S.C. § 102, the statutory section dealing with novelty and "loss of right," the statutory bar to patentability.[12] Section 102 defines the novelty requirement in terms of public knowledge or use, or description in print prior to the date of invention.[13] It defines the statutory bar in terms of description in print or public use or sale more than one year prior to the filing of a patent application.[14] These criteria have led to a long line of cases struggling to determine precisely what aspects of an invention need to be known or described, what needs to be used or sold prior to the critical date in order to defeat patentability, and, most especially, what the consequence might be if the invention is inherent in the prior art. The knowledge and written description bars don't generally raise inherency concerns; an invention is either known or described or not. But these questions proved much thornier in the case of unwitting or inadvertent sales or uses.

A. False Starts

The story of inherency begins with the 1880 Supreme Court case of *Tilghman v. Proctor*.[15] The inventor in that case claimed a process for breaking down animal fat into glycerine and free fatty acids, both of which could be used to make products ranging from candles to soap.[16] The process required mixing fat with water and subjecting the mixture to high temperature and pressure.[17] As it turns out, the same process of separating glycerine from fatty acids had undoubt-

12. 35 U.S.C. § 102 (2000).
13. *Id*. § 102(a).
14. *Id*. § 102(b).
15. 102 U.S. 707, 711-12 (1880).
16. *Id*. at 711.
17. *Id*. at 709.

edly occurred fortuitously when a prior art steam engine was lubricated with animal fat, since a steam engine has water, pressure, and high temperature.[18] The Court concluded that the accidental anticipation of the patented process should not bar Tilghman from getting a patent on the process.[19] The Court emphasized that the separation of the tallow in the operation of the prior art steam engine was neither recognized by those of skill in the art nor used for the purpose for which it was later patented.[20] Rather, it was considered an unintended waste product, not an intended result of the use of the prior art machine. The Court wrote that

> [t]hose engaged in the art of making candles, or in any other art in which fat acids are desirable, certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids .... 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.[21]

This language has become the standard formulation of the doctrine of inherency. In *Eibel Process Co. v. Minnesota & Ontario Paper Co.*,[22] for example, where the Court found that there was no inherent production of the invention at all, the Court also noted in the alternative that "accidental results, not intended and not appreciated, do not constitute anticipation."[23]

The results in *Tilghman* and *Eibel* were overdetermined.[24] In *Tilghman*, the invention was neither understood nor used in the prior art. Similarly, in *Eibel,* the Court was not persuaded that the

18. *Id*. at 711.
19. *Id*. at 712.
20. *Id*. at 711-12.
21. *Id*.
22. 261 U.S. 45 (1923).
23. *Id*. at 66 (citing *Tilghman*, 102 U.S. at 711).
24. *Tilghman* may be overdetermined for another reason—the Court expressed some doubt as to whether the by-product was the same as the patented invention at all. 102 U.S. at 711. However, simple organic chemistry argues that the by-products would be present. *Cf. infra* note 70.

invention was produced at all in the prior art, so it was free to state the test for inherency without having actually to apply that test to the case before it. As a result, in both cases the Court could be imprecise in its formulation of the inherency test. And it was. The Court in *Tilghman* offered two different reasons why the invention was not inherently anticipated: those of skill in the art did not understand that it was present in that art and the public was not using or benefiting from the prior use of the process.[25] Were both elements required for inherency to attach? Would either one suffice to prove inherency? Or was one of the factors dominant and the other simply playing a supporting role? Because neither element was present, the Court did not resolve these questions.

The result was a general statement of the inherency test that is unworkable in practice and which has been responsible for much of the doctrinal confusion that has resulted. The Federal Circuit has repeatedly cited *Tilghman* for the proposition that inherent anticipation requires the PHOSITA to recognize and understand the presence of the anticipation in the prior art. In *Continental Can Co. USA v. Monsanto Co.*, for example, the court recited the requirement that the missing element must be both necessarily present and "that it would be so recognized by persons of ordinary skill."[26] *Continental Can* is a standard citation on inherency, and a number of subsequent Federal Circuit opinions repeat this language.[27] The reference to recognition and understanding in these cases, however, was unnecessary to resolve them because, like *Tilghman*, they had neither use nor recognition. In *Continental Can*, for example, the factual debate was over whether ribs in a prior art bottle were in fact hollow or solid, not whether their hollowness was known to the PHOSITA.[28] In other cases that recite the knowledge

25. *Tilghman*, 102 U.S. at 711-12.

26. 948 F.2d 1264, 1268 (Fed. Cir. 1991).

27. *See, e.g.*, Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1328 (Fed. Cir. 2001); Hitzeman v. Rutter, 243 F.3d 1345, 1355 (Fed. Cir. 2001); *In re* Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999); ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed. Cir. 1998); Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995); Electro Med. Sys. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1052 (Fed. Cir. 1994). Similarly, most commentators take the recognition requirement as gospel, trying to reconcile the apparent inconsistencies that result by explaining away the many cases that do not in fact apply that requirement. *See, e.g.*, Carlson, *supra* note 7, at 310-14; Feit & Warrick, *supra* note 7, at 18-21.

28. *Cont'l Can,* 948 F.2d at 1267-68.

test, such as *Rosco, Inc. v. Mirror Lite Co.*, the inherency claim fails not because of lack of knowledge, but because no proof exists that the supposedly inherent characteristic would be necessarily produced by the prior art process.[29]

The one case in which the Federal Circuit relied on the knowledge component of inherency is the panel opinion in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*.[30] In that case, the prior art, a patent by Mullan, gave a general description of embedding a particular Alzheimer-sensitive human gene mutation in a mouse, but the prior inventor did not actually make the transgenic mouse.[31] Elan patented a transgenic mouse containing the Alzheimer-sensitive human gene, distinguishing the Mullan prior art by adding a limitation that the modified polypeptide expressed by the Alzheimer gene be present in a detectable amount.[32] The district court found the patent anticipated, reasoning that Elan's patent differed from Mullan's disclosure only because of the "detectable" amount of the expressed polypeptide and that this last element would be inherent in any implementation of the Mullan disclosure.[33] The panel opinion reversed.[34] The court said that inherency must be "known to be present in the subject matter of the reference," and since Mullan did not know of this inherent effect, the court found no anticipation.[35] Judge Dyk dissented, saying that knowledge was not a requirement for inherency.[36] The Federal Circuit took the case en banc,[37] but then dismissed the case. The panel issued a new opinion remanding for a determination of whether Mullan enabled one of ordinary skill in the art to make the Elan invention, with no discussion of the inherent element.[38] As a

29. 304 F.3d 1373, 1380-81 (Fed. Cir. 2002).

30. 304 F.3d 1221 (Fed. Cir. 2002), *vacated*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc).

31. *Id.* at 1229-30.

32. *Id.* at 1226-27.

33. *Id.* at 1227.

34. *Id.* at 1223.

35. *Id.* at 1228-29.

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

37. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 314 F.3d 1299, 1299 (Fed. Cir. 2002) (en banc).

38. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051 (Fed. Cir. 2003).

result, *Elan* no longer stands for the proposition that inherency requires the PHOSITA to have knowledge of the anticipation.[39]

B. Public Benefit

Knowledge, then, is often recited as an element in inherency cases, but it never actually appears to have determined the outcome of an appellate case.[40] To the contrary, if the PHOSITA knows about a prior use that includes all of the elements of the patent, there is a clear-cut case of anticipation and no need to apply inherency at all. The issue of inherency comes up precisely when the PHOSITA at the time is not aware of an anticipating use.

The cases follow this logic, at least implicitly. A large number of cases find inherent anticipation in the absence of knowledge.[41] If knowledge is not present, though, how then are we to test inherency? Some commentators have come to the conclusion that after *Schering*, the only factor required for inherency is proof that the thing was in fact present,[42] but that overstates the case. There are still a number of cases that deny inherent anticipation even when it is clear with hindsight that the invention was present in the prior art.

Understanding inherency doctrine requires a closer look at the cases that actually find inherent anticipation. In those cases, the determining factor appears to be that the public has already benefited from the presence of the claimed invention in the prior art, even though it may not have been aware of the invention itself. The Supreme Court stated the general principle in *General Electric Co. v. Jewel Incandescent Lamp Co.*:[43] "If A without mentioning the element of strength patented a bulb which was extra strong, B could

39. There are also cases concerning priority of invention that rely on knowledge. Those cases are discussed in Part II.B.

40. We have not reviewed every district court ruling on inherency, and so we cannot make the same assertion as to district courts.

41. As Tracey Davies puts it, "[d]espite this commonly-cited [recognition] standard, however, the courts frequently ignore—or outright contradict—this standard, appearing rather, at least superficially, to only arbitrarily embrace the requirement of recognition of the inherent element by a skilled artisan." Tracey B. Davies, Inherent Anticipation: Turning the Written Description Requirement on Its Head, Paper Presented at the Eighth Annual Advanced Patent Law Institute 4 (Oct. 29, 2003) (on file with authors).

42. *See, e.g.*, Miller, *supra* note 7, at 452-53; Alloway, *supra* note 7, at 86-87.

43. 326 U.S. 242 (1945).

not obtain a patent on the bulb because of its strength, though he was the first to recognize that feature of it."[44] The Court here clearly thinks of inherency as dependent on use of the characteristic, not knowledge of it.

This focus on public benefit even in the absence of knowledge is a consistent theme in the Federal Circuit cases that actually find inherent anticipation. In *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*,[45] for example, the patent claimed a particular formulation of a pharmaceutical compound called Form IV. During litigation, the defendant discovered that an Australian company had sold the pharmaceutical compound into the United States, and it turned out, unbeknownst to either the buyer or the seller, that some of the product that was sold was in fact Form IV.[46] The court found inherent anticipation under § 102(b), reasoning that if the product sold actually possessed the limitations of the claim, § 102(b) barred a patent whether or not the parties to the sale knew that the product included those limitations.[47] The court distinguished *Tilghman*, saying that knowledge of the product did not matter because the invention here, "having been sold, was decidedly useful."[48]

Other cases have followed *Abbott*'s rule in finding inherency where the evidence indicates that a claimed compound was in fact produced or sold in the prior art, even if those of skill in the art did not know about the production or sale at the time. Most notable is the decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*[49] Schering patented loratadine, branded as the allergy medicine Claritin, and later patented a metabolite of loratadine that is inherently produced in the human body when loratadine is ingested.[50] When Schering's patent on loratadine expired, Schering began suing generics who copied loratadine after the first patent expired for violating the newer metabolite patent.[51] The court held

44. *Id.* at 247.

45. 182 F.3d 1315 (Fed. Cir. 1999).

46. *Id.* at 1317.

47. *Id.* at 1318.

48. *Id.* at 1319.

49. 339 F.3d 1373 (Fed. Cir. 2003).

50. *Id.* at 1375. Because the patent on the metabolite was filed after disclosure of loratadine, loratadine itself was prior art to the metabolite patent. *Id.* at 1376.

51. *Id.* at 1376.

that the metabolite was inherently produced when loratadine entered the human body.[52] Indeed, Schering itself premised its infringement claim on that inherent production. The court specifically rejected the idea, as embodied in the *Elan* panel opinion,[53] that inherency requires appreciation of the characteristics of the prior art.[54] Rather, the court found the metabolite patent inherently anticipated because the public would necessarily obtain the benefit of the metabolite by ingesting and metabolizing loratadine.[55] While three judges dissented from the decision not to take the case en banc, their concern was the fact that loratadine itself had not actually been used in public before the critical date; Judge Lourie's dissent did not "question 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" regardless of whether it was known to those of skill in the art.[56]

Schering and the rejection of *Elan* seem to have set the Federal Circuit firmly on the right course, recognizing that knowledge is not required for inherency. The court's 2004 decision in *Toro Co. v. Deere & Co.*[57] confirms this trend. In *Toro*, the Federal Circuit expressly rejected previous cases that based inherency upon knowledge or recognition by those of skill.[58] Instead, the court emphasized that the necessary presence of a claimed feature in a prior art embodiment is the critical element of inherency: "[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

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52. *Id.* at 1378.

53. *See* Elan Pharms., Inc. v. Mayo Found. for Educ. & Med. Research, 304 F.3d 1221 (Fed. Cir. 2002); *supra* notes 34-36 and accompanying text.

54. *Schering*, 339 F.3d at 1377.

55. *Id.* at 1380. Schering also argued that inherency could not apply because, unlike prior inherency cases, the doctrine was being used here to show anticipation of the entire invention, not just to supply one element missing from a prior art disclosure. The court correctly concluded that inherency can apply to an entire invention, not just to supply a missing element. *Id.* at 1379.

56. Schering Corp. v. Geneva Pharms., Inc., 348 F.3d 992, 996 (Fed. Cir. 2003) (Lourie, J., dissenting). Other decisions recognizing that knowledge is not required include *MEHL/Biophile International Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999), and *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

57. 355 F.3d 1313 (Fed. Cir. 2004).

58. *Id.* at 1320-21.

the time of the prior invention."[59] Considering the inherent anticipation of a claim limitation in a previous patent, the court observed that, for inherency, "neither description nor contemporaneous recognition of these necessary features or results was required."[60]

The focus on public benefit is also bolstered by cases that reject anticipation claims based on inherency in circumstances where—as in *Tilghman*—the prior art did not in fact give the public the benefit of the invention. One early case is *Edison Electric Light Co. v. Novelty Incandescent Lamp Co.*[61] In that case, Edison patented an improved light bulb in which the placement of the wires was changed.[62] The evidence at trial showed that occasional manufacturing defects in prior art light bulbs accidentally anticipated Edison's new invention.[63] The manufacturer was aware of the defects, but rather than making use of them, threw the light bulbs out as defective.[64] The court found no inherency because the prior use "gave nothing to the world"; indeed, it was treated as a problem rather than a benefit and was never sold to the public.[65] While the court recited the standard "not understood or appreciated" language from *Tilghman*,[66] the facts of the case make it quite clear that it was public benefit rather than knowledge that drove the court to reject the inherency argument. In this case, the manufacturers *did* understand what had happened. There was no inherency, however, because they did not use it to the benefit of the world or communicate to the public how they could use the design.

A focus on benefit rather than recognition is also the most logical way to reconcile the classic opinion in *In re Seaborg*[67] with the rest of the inherency canon. In that case, Glenn Seaborg claimed "element 95," a transuranic chemical element and therefore one not present in nature.[68] The court's discussion of inherency focused on

59. *Id.* at 1321.
60. *Id.*
61. 167 F. 977 (3d Cir. 1909).
62. *Id.* at 980-81.
63. *Id.* at 980.
64. *Id.*
65. *Id.*
66. *Id.*
67. 328 F.2d 996 (C.C.P.A. 1964).
68. *Id.* at 996. Whether element 95 was an unpatentable "product of nature" occupied a significant part of the court's opinion. *Id.* at 979-99.

the fact that physicists knew from their calculations that element 95 was inherently produced in trace amounts by the operation of nuclear reactors.[69] The trace amounts of the element were inaccessible, however, because they were scattered amidst a comparatively vast amount of radioactive uranium.[70] Glenn Seaborg's contribution was to isolate element 95 and therefore make it accessible to physicists. The court held that Seaborg was entitled to patent "element 95" itself.[71] If recognition were the touchstone for inherency, *Seaborg* would have come out the other way because it is clear that physicists understood that element 95 was already produced in Fermi's nuclear reactor. Instead, the court's opinion is consistent with a focus on benefit. Seaborg's contribution was not knowledge that the PHOSITA lacked, but the isolation of the element itself, permitting it to be used—at least to the extent that particle physicists really "use" an unstable, short-lived element—in a way that the prior art did not.

To be sure, some might question the wisdom of this approach as a policy matter. Part of the benefit the public gets from patentability is knowledge of the patented invention, and in various contexts patent law is willing to give patents even to those who were not the first to invent because they were the first to disclose the invention to the public.[72] But in cases in which the public is already benefiting from the invention, the additional value of learning exactly how or why they benefit does not seem worth withdrawing from the public the use of an invention they already enjoy.[73] Courts could balance those costs and benefits in each individual case, but only at the cost of abandoning any intelligible rule for determining anticipation. They have instead made the categorical judgment that an invention

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69. *Id*. at 996. The court expressed some skepticism as to whether americium was in fact produced in the reactor, since if it was, it was in undetectable amounts. *Id*. at 999; Miller, *supra* note 7, at 443. But the physics of the nuclear reaction suggest that it would be.

70. The court noted that element 95 could not be "detected" in the reactor, but there was no dispute that physicists understood that it would be present. *In re Seaborg*, 328 F.2d at 999.

71. *Id*.

72. *See, e.g.*, 35 U.S.C. § 102(g) (2000) (denying patent to the first inventor if she abandoned, suppressed, or concealed it); *id*. § 102(b) (requiring public use to preclude another from patenting).

73. *Cf*. Graham v. John Deere Co., 383 U.S. 1, 6 (1966) (suggesting that withdrawing inventions from the public domain would be unconstitutional).

already being used by the public shouldn't be patentable because someone discovers information about how it works.

C. Knowledge and Use

By far the most common type of inherency case litigated in the Federal Circuit involves efforts to patent a property or characteristic of an existing product or process. Where the product or process exists in the prior art and it inherently has a subsequently claimed property or characteristic, the courts will find anticipation even though no one knew of the property in the prior art. For example, in *In re Cruciferous Sprout Litigation*,[74] the patent claimed the discovery of the cancer-fighting effects of eating broccoli and cauliflower sprouts.[75] The court held that the claim to a process of using cruciferous sprouts to treat cancer was anticipated since the public was already eating broccoli sprouts and therefore getting the cancer-fighting benefits, even though they were not aware of those benefits.[76] Similarly, in *Atlas Powder Co. v. Ireco Inc.*,[77] the patent claimed a range of known chemicals used as explosives and required as an element of the claim that the explosives have "sufficient aeration."[78] Because the chemicals were already used as explosives and they would work as explosives only if they had sufficient aeration, the prior art explosives inherently had such aeration.[79] Thus, the court held that adding "sufficient aeration" as a limitation did not avoid anticipation.[80] The court specifically rejected a

74. 301 F.3d 1343 (Fed. Cir. 2002).

75. *Id.* at 1345.

76. *Id.* at 1351. To similar effect is *In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990). Like *Cruciferous Sprout*, the court held that a newly disclosed benefit of inhibiting fungal growth on vegetables does not justify a patent on a process that was already known, even though the PHOSITA did not know that the process inhibited fungal growth. *Id.* at 1577. The court emphasized that the newly discovered benefit "is at least generically encompassed by the prior art purpose of preventing the deterioration of leafy and head vegetables." *Id.* at 1578. In other words, the public was using the process for purposes related to the property that the patentee discovered, and therefore was already getting the antifungal benefits of the disclosed property. *See also* Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001) (claiming a newly discovered tumor-inhibiting property of a known method for administering a drug did not render the known method patentable).

77. 190 F.3d 1342 (Fed. Cir. 1999).

78. *Id.* at 1346-48.

79. *Id.* at 1348.

80. *Id.* at 1348-49.

proposed requirement that inherent anticipation require appreciation: "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."[81] *Eli Lilly & Co. v. Barr Laboratories, Inc.*[82] held that Lilly's own prior patent on a method of treating anxiety with Prozac inherently anticipated its later patent on a method of blocking serotonin uptake, since Prozac operates by inhibiting serotonin uptake.[83] Another Federal Circuit case found inherent anticipation where the prior art showed a metal alloy in the patentee's claimed range of compositions, but not the claimed attribute of "being characterized by good corrosion resistance in hot brine environments."[84] The court found inherent anticipation because the properties of the metal were inherent in their structure.[85]

Such cases are frequently cited to illustrate the so-called "incomplete" or "truncated" standard for enablement of anticipatory references. Typically, enablement is thought of as set out in § 112: in order to qualify for a patent, the inventor must teach those of ordinary skill in the art how to *both* make *and* use the invention.[86] Enablement also comes up in anticipation. To preclude a patent under § 102, a reference must be enabling,[87] but the standard for enablement is somewhat different for prior art that might anticipate a patent than it is for patentees. A prior art reference that enables one of ordinary skill in the art *either* to make the invention *or* to use it anticipates that invention. Thus, under the standard articulated

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81. *Id*. at 1347; *accord* MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

82. 251 F.3d 955 (Fed. Cir. 2001).

83. *Id*. at 969-70. This holding was not heavily disputed, although the panel's conclusion that the first Lilly patent was prior art, even though it was filed after the second patent, was quite controversial. *See id*. at 975 (Newman, J., dissenting).

84. Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 776 (Fed. Cir. 1985) (quoting U.S. Patent Application No. 455,964 (filed July 25, 1975)).

85. *Id*. at 782; *see also* E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1436 (Fed. Cir. 1988) (indicating that for anticipation of a patent with a tear strength limitation, the defendant need only show that prior art had the requisite strength, not that people were aware of that strength); Verdegaal Bros. v. Union Oil Co., 814 F.2d 628 (Fed. Cir. 1987) (finding anticipation where the reference discloses all the limits of the claim, even though it does not disclose the desirable property discovered by the patentee, where the property is inherent in the structure).

86. 35 U.S.C. § 112 (2000).

87. *Id*. § 102.

in *In re Hafner*,[88] disclosure of how to make the claimed invention is enough for anticipation, even if there is no disclosure of how to *use* the invention.[89] Publication of a structure, such as the composition of a metal alloy, even without any disclosure of its superior corrosion-resistant properties, is enough for anticipation.[90] Subsequent discovery of a new use for the structure may occasion a separate method patent for the new use, but not a claim to the previously disclosed structure.

The inverse of these incomplete enablement cases is found in the cases involving "hidden" public uses claimed to anticipate an invention. Those cases consistently find anticipation where the public knows how to *use* an invention, even if the nature of the invention and how to make it remain secret. For example, in *Lockwood v. American Airlines, Inc.*, the Federal Circuit rejected a patent on an airline reservation system as anticipated by the prior art SABRE system that had been in use for decades.[91] The patent holder argued that although SABRE had been in prior use, travel agents and other users knew nothing of its inner workings, as the essential algorithms were not apparent and the prior use could not have enabled one of ordinary skill to build such a system. Consequently, Lockwood argued, it could not anticipate or bar patents to a later-developed system.[92] The Federal Circuit rejected this argument, however, holding that such enablement was not required. The qualities of the SABRE system were available to the public and the public knew how to use the prior art SABRE system, even if it did not know how to make it.[93]

A similar result is found under 35 U.S.C. § 102(g) in the case of *Dunlop Holdings Ltd. v. Ram Golf Corp.*,[94] where a patent on Surlyn-covered golf balls was held invalid due to the prior sale of similar golf balls. The formula for making the prior art golf balls had been kept secret and examination of the golf balls would not have revealed their formulation. Consequently, the patent holder

88. 410 F.2d 1403 (C.C.P.A. 1969).

89. *Id.* at 1405-06. The Federal Circuit reaffirmed *Hafner* in *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325-26 (Fed. Cir. 2005).

90. *Titanium Metals*, 778 F.2d at 782.

91. 107 F.3d 1565, 1570 (Fed. Cir. 1997).

92. *Id.*

93. *Id.*

94. 524 F.2d 33 (7th Cir. 1975).

argued, the prior art invention had been abandoned, suppressed, or concealed, and so it was not valid prior art under § 102(g).[95] But the court held that the golf balls were in public use: Even though their nature might be veiled, the public received the benefit of their characteristics, making them valid prior art.[96]

Although these cases do not explicitly use the language of inherency, the issue is clearly the same: Devices that are available to the public, such as a computer reservation system or a golf ball, possess valuable unseen or concealed qualities.[97] These cases are sometimes designated "hidden public use" cases: the item is in public use, but its workings or qualities are not revealed by public inspection.[98] Such prior uses prevent a later patent because the public gets the benefit of the invention by actually using the product—or at least by being taught how to use it—even though its workings or qualities are naturally hidden.[99]

These results are consistent with inherency cases involving process claims—inventions where a use itself rather than a structure is the invention. In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, the Federal Circuit made it clear that a process claim is anticipated if it reads on the consistent, reproducible, commercial operation of a machine, even if the user did not appreciate that the machine performed the process.[100] Other opinions have taken the same approach, finding inherency "if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim,"[101] with no discussion of any requirement that the PHOSITA be aware of this function.[102]

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95. *Id.* at 35.

96. *Id.* at 36-37.

97. The only difference appears to be that in these cases, unlike the true inherency cases, the manufacturer knows what they are making, but that distinction should be of little consequence.

98. *See* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY 463 (3d ed. 2002).

99. *Id.*

100. 721 F.2d 1540, 1548-49 (Fed. Cir. 1983).

101. *In re* King, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

102. *Accord* Scaltech, Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1384 (Fed. Cir. 1999) (finding inherency "whether or not the seller recognized that his process possessed the claimed characteristics" if the "natural result flowing from the operation of the process ... would necessarily result in achievement of each of the claim limitations"). *Scaltech* might seem an inequitable case because the court held that an offer to use a process to produce a product was an "offer for sale" of the process because the process would inherently have been

The *Gore* court clearly favored use over knowledge in its inherency analysis, though it is worth noting that the case limits itself to consistent, reproducible, commercial uses.[103] The point of these limitations seems to be evidentiary—the court is trying to be sure in retrospect that an unrecognized process or product was in fact inherent in the prior art.[104] At the same time, knowledge of a given use does not necessarily confer upon the public the benefit of other uses for the same structure. In *Rapoport v. Dement*,[105] the court rejected an argument that the claimed use of buspirone to treat sleep apnea was inherently anticipated by its use for a

performed had the offer been accepted, even though no one appreciated it at the time. The inequity of raising a § 102(b) bar on an invention the patentee did not appreciate, and never in fact actually sold, is a function of the rule that even unconsummated offers can bar a patent.

103. *Gore*, 721 F.2d at 1548-49.

104. *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999), says an invention is not inherently present unless it is always produced by the prior art process. *See also* Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002); Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002); Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1377 (Fed. Cir. 2002); Mentor H/S, Inc. v. Med. Device Alliance, Inc., 244 F.3d 1365, 1376 (Fed. Cir. 2001) (stating that inherency "may not be established by probabilities or possibilities"). This requirement has been referred to as "inevitability." *See* Davies, *supra* note 41, at 3-4. That seems to overstate the rule. The right question is whether we are confident that the patented invention was present in the prior art, even if it was not always present. *See* Cynthia Chen, Schering Corp. v. Geneva Pharmaceuticals, Inc.*: Clarification of the Inherent Anticipation Doctrine and Its Implications*, 20 BERKELEY TECH. L.J. 95, 96 (2005) (speaking of "absolute certainty"). In *Abbott,* for instance, the court found inherency even though only some of the compound sold into the United States was the anticipating Form IV. Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315, 1317 (1999). The better understanding of the inevitability cases is that if the evidence does not *prove* that the invention was present at all in the prior art, there can be no inherency. *Mentor*, 244 F.3d at 1376 (rejecting inherency based on "probabilities or possibilities"); *Scaltech*, 178 F.3d at 1384 (same). An evidentiary certainty, even if partial, should suffice.

Occasionally, courts err by finding inherency even where it is not certain that the invention was present in the prior art. *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997), is such a case. There, the majority held that a conical oil dispenser inherently anticipated a claim to a conical popcorn dispenser, reasoning that the prior art could be resized to serve as a popcorn dispenser. *Id.* at 1476-77. Judge Newman dissented, correctly observing that an inherent disclosure "is necessarily contained in the prior art" and that in this case, the oil can was not of the right size to dispense popcorn and was not in fact serving that purpose. *Id.* at 1481 (Newman, J., dissenting). If the oil can was not in fact being used as a popcorn dispenser, Judge Newman is correct—*Schreiber* is really a case about obviousness rather than inherency. *Id.*

105. 254 F.3d 1053 (Fed. Cir. 2001).

different purpose, to treat anxiety.[106] The prior art did not teach or suggest the use of the drug on apnea patients, and unlike the inherent benefit arising from the product in *Cruciferous Sprout*, apnea patients were not benefiting from the drug without being aware of it.[107] Thus, in the use cases as well as the structure cases, the presence or absence of public benefit determines whether the inherency doctrine will apply.

The jurisprudence regarding structure and use does suggest that the court in *Seaborg* may not have reached the right result given the language of Seaborg's claim. The courts have made it clear in other cases that if a compound is present in nature, one who first discovers a use for the compound may not patent the compound itself.[108] On this view, Seaborg should have been entitled at most to a patent on isolated or purified element 95, because he did not invent the element itself.[109] Properly speaking, however, this is not an inherency issue at all, but a pure question of anticipation. The fact that the prior art taught the making of a product, even if it did not enable the use, is generally enough to preclude patenting of the product itself,[110] relegating those who give the public the benefit of its use a patent on the isolated or purified, and thus useful, form of the product.

II. POSSESSORY INHERENCY

While the overwhelming majority of inherency cases come up as questions of anticipation or public use bars under § 102, the inherency doctrine appears in other contexts as well. Section 112 of the Patent Act requires the inventor to provide a written description of the invention sufficient to enable those of ordinary skill to make and use the invention;[111] conveying such information to the public is the price for receiving exclusive rights in the invention. Requiring the description also ensures that the inventor had "possession" of

106. *Id*. at 1063.

107. *Id*. at 1060-63.

108. *See, e.g.*, *In re* Schoenwald, 964 F.2d 1122, 1124 (Fed. Cir. 1992).

109. *Cf.* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911), *aff'd in part*, *rev'd in part*, 196 F. 496 (2d Cir. 1912) (permitting the patenting of a natural chemical in its isolated and purified form, where the purification gave it a new commercial use).

110. *See* Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 781-82 (Fed. Cir. 1985).

111. 35 U.S.C. § 112 para. 1 (2000).

the invention and deters the introduction of "new matter" into the application. In a sense, the description requirement is intended to keep the inventor honest, preventing her from changing her story as to the nature of the invention later in the course of prosecuting the patent application.

The written description requirement is also closely linked with the conception standard for establishing invention. The written description may be used to show the date by which the inventor had fully conceived of the invention, by demonstrating possession of the invention as of a certain date. Because the United States grants patents to the first inventor, the description in the patent application may be important to establishing an inventor's priority date if others claim to have invented first. Other evidence showing conception prior to the filing of a patent application will need to show the same degree of detail, as the Federal Circuit has reasoned that "one cannot describe what one has not conceived."[112] Thus, both disclosure and conception may raise issues of inherency, although inherency may play out differently in each of these contexts for policy reasons.

A. Disclosure Cases

Disclosure cases that raise inherency questions tend to arise when the patentee files a continuation application during prosecution, adding new claims that were not present in the original application, and later seeks to claim priority to the original application. The Federal Circuit has held that where the new claims are drawn to a characteristic that was in fact present in the originally disclosed product or process, those new claims are enabled, even absent knowledge of the characteristic at the time of the original application. For example, in *Kennecott Corp. v. Kyocera International, Inc.*,[113] the patent application showed a sintered ceramic body. The patentee filed a continuation-in-part (CIP) application that disclosed and claimed an "equiaxed microstructure" that was a necessary property of this ceramic.[114] The court found

112. Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).
113. 835 F.2d 1419 (Fed. Cir. 1987).
114. *Id.* at 1420.

priority to the original application because the original disclosure inherently conveyed that the inventor possessed an invention with the characteristic of equiaxed microstructure, even though the property was not known when the first application was filed.[115] Similarly, in *Therma-Tru Corp. v. Peachtree Doors Inc.*,[116] the Federal Circuit held that a CIP was entitled to the priority date of the original application because a new limitation, added at the examiner's insistence, that a door be "essentially devoid of glass fibers for a predetermined depth of at least 0.005 inch" was inherent in the previously disclosed characteristics of the patentee's door.[117] Once again, the court focused on whether the fibers were in fact absent in the door, not whether the patentee or the PHOSITA would recognize their absence.[118]

The application of inherency principles to disclosure under § 112 seems at first blush to make sense, given that enablement by the patentee is in some sense the flip side of enablement by the prior art in the anticipation cases. It is not clear, however, that the two should in fact be treated as entirely parallel. Section 112 requires that the patentee teach the PHOSITA how to *both* make *and* use the patented invention.[119] For product patents, this means detailed disclosure of the structure of the invention and at least one substantial use. A disclosure of this type, as we have seen, enables and dominates future new uses of the claimed structure, even though newly discovered uses may be entitled to their own subservient patents. By contrast, as we have also seen, a prior art reference that teaches *either* the making *or* the use of the invention will preclude patentability. *Kennecott* and *Therma-Tru* do not present

115. *Id.* at 1423.

116. 44 F.3d 988 (Fed. Cir. 1995).

117. *Id.* at 991-93.

118. *Id.* at 992-93. By contrast, where courts find no inherent enablement, it is generally because the product characteristic was not in fact inevitable. *See* Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1576 (Fed. Cir. 1996) (Archer, C.J., concurring) (reasoning that a CIP was not entitled to claim priority to an original application where the CIP added claims referring to substrate crystals "with substantially no crystallographic slip," and it was not clear from trial testimony whether the priority application products had crystallographic slippage). Judge Archer was the only member of the majority to reach the inherency issue; Judge Newman dissented. As a result, the opinion is of doubtful precedential significance, but it is consistent with results in the other enablement cases.

119. 35 U.S.C. § 112 para. 1 (2000).

this difference because the manufacturing process taught in both cases actually did show the PHOSITA how to make and use the inherent feature, even if its nature was not fully understood. But the difference becomes important in the cases we discuss in the next section.

B. Priority Cases

Inherency is also sometimes raised as an issue when two putative inventors each claim to have been the first to reduce their invention to practice. Unlike the anticipation and enablement cases, the priority cases require knowledge to establish reduction to practice —specifically, an understanding and appreciation of the benefits of the invention. Both conception and reduction to practice require this appreciation.

For example, the court in *Hitzeman v. Rutter*[120] rejected a claim to have conceived an invention where the patent applicant was not in fact aware of the properties of the invention at the time, but later discovered that they were inherent in his work.[121] Inherent properties, the court observed, can only exist in the context of priority if they are "redundant" or "add[] nothing to the count," which is to say, if they were not claimed elements of the invention.[122] In *Mycogen Plant Science, Inc. v. Monsanto Co.*, the court said that

> [t]he precise language of the reduction to practice test states "[i]t is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention represented by the counts."[123]

120. 243 F.3d 1345 (Fed. Cir. 2001).

121. *Id.* at 1354-55.

122. *Id.* at 1355.

123. 243 F.3d 1316, 1335 (Fed. Cir. 2001) (quoting Breen v. Henshaw, 472 F.2d 1398, 1401 (C.C.P.A. 1973)) (second alteration in original); *see also* Manning v. Paradis, 296 F.3d 1098 (Fed. Cir. 2002); Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 593 (Fed. Cir. 1997) (summarizing past cases by stating that "[t]hese cases trumpet, therefore, the principle that a reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose").

The basis for this requirement actually has nothing to do with the inherency doctrine. Indeed, it does not make sense to talk of priority cases as inherency cases at all. Rather, courts require proof of recognition and appreciation in order for the patent applicant to prove possession of the invention as of a certain date.[124] Proof of possession is a characteristic of the written description doctrine,[125] and is particularly important in priority cases because in those cases, by definition, two different people invented the same thing, and it must be decided who really possessed the invention first. If the claimed invention is unappreciated, then there can have been no conception, and hence no invention. The references to inherency in the priority cases may well be responsible for confusing the issue in other contexts, because the possession requirement of the written description doctrine has been intermingled with inherency.

Contrasting *Chen v. Bouchard* [126] with the *Kyocera* case may help to illustrate the asymmetry between the possession requirement in priority, the enablement requirement in disclosure, and the inherency rule in anticipation. *Chen* was a priority case in which one of the claimants attempted to rely on the inherent presence of the invention to prove conception.[127] Chen manufactured a solution containing two chemicals, but only properly characterized one of them; he mischaracterized the solution as containing a different set of substances than were actually present.[128] When he later correctly recognized the presence of the second, more valuable chemical in the solution, he tried to claim it, but Bouchard had claimed the latter chemical first.[129] The court rejected Chen's attempt to rely on his erroneous disclosure to prove that he had invented the second chemical when he unwittingly produced it along with the first.[130] The court held that invention requires possession—and therefore

124. *See, e.g.*, *Estee Lauder*, 129 F.3d at 593.

125. Compare *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998), where the court found no written description of a genus of multiple shapes for hip implants in a patent specification that disclosed only conical shapes. The court said that for the written description requirement to be satisfied, missing descriptive matter "must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure." *Id*. at 1159.

126. 347 F.3d 1299 (Fed. Cir. 2003).

127. *Id*. at 1305.

128. *Id*. at 1301.

129. *Id*. at 1301, 1304.

130. *Id*. at 1305-07.

written description—of the second chemical.[131] But unlike *Kyocera*, where the additional description of "equiaxed microstrucure" merely characterized an inherent property already present in the invention disclosed, Chen had in fact described the wrong chemical. He had also claimed the method of production that inherently led to creation of the unrecognized chemical, but claiming a process is not the same as claiming the product of that process.[132]

As a result, *Chen* can be read to stand for the proposition that inherent production cannot be used as a basis for proving invention because the patentee has not in fact described the thing that she claims to have invented. Suppose that Chen's product, incorporating both the first and second chemicals, although he did not know about the second, was in public use before Bouchard made his discovery. Under the cases discussed in Part II.A, the court would have no trouble concluding that Chen's public use of the chemical anticipated Bouchard's patent application. Bouchard could avoid anticipation under § 102 only if he could show that the public did not get the benefit of the second chemical from Chen's use. If the public was benefiting from the second chemical, the case is indistinguishable from *Schering*. The result is an asymmetry between anticipation and priority—an inherent but unappreciated prior use that benefits the public will not qualify for a patent, but it will prevent others from later patenting the invention being used.

This result, while seemingly odd in its asymmetry, makes sense as a policy matter. In order to get a patent, an inventor must describe the invention in order to show that she is in possession of it. If she hasn't actually recognized the claimed invention, she can't do that, even though she may enable people to make and use the invention unwittingly. By contrast, if society is already benefiting from the invention, we do not want to give anyone else a patent on it. If the public is not getting the benefit of it, there is no inherent disclosure and hence no anticipation. In each case, the public benefit is paramount, but in a different context. Denying a patent in the case of inherent anticipation allows the public to retain the nonexclusive use of an invention that they are already enjoying,

131. *Id.*

132. *Cf. In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995) (indicating that the patentability of a product is a separate issue from the patentability of the method by which it is made); *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993) (stating the same).

while denying a patent to an inventor who fails to recognize an inherently prior invention preserves the option of a reward to subsequent inventors who recognize the invention and deliver its benefits to the public more quickly.[133]

III. EXTENDING INHERENCY ANALYSIS

The cases we have reviewed here reveal a common doctrinal thread in the issue of inherency: prior public benefit from a product that is actually used is sufficient to prevent patentability, even if people do not know that they are using and benefiting from it. This inherency principle combines with more traditional forms of anticipation, in which there is public knowledge of how to make the product, or public knowledge of how to use the product. These issues arise from the intricate concatenation of "knowledge" and "use" terminology dispersed throughout §§ 102, 112, 119 and 120 of the patent statute. The elements of "knowledge" and "use" appear in other doctrinal roles, and sometimes in other guises, in other sections of the patent statute. In this final section, we consider how the inherency doctrine, and particularly our "public benefit" formulation of inherency, may affect the operation of these other statutory sections, especially the sections on infringement and subject matter requirements for patentability.

A. Inherent Obviousness

So far, we have considered inherency under the novelty and statutory bar provisions of the patent statute, as well as under those provisions requiring disclosure and those assigning priority. But these are not the only requirements for patentability. The invention must also be nonobvious as defined in § 103.[134] Section 102 novelty and statutory bar references are part of the prior art considered for obviousness analysis under § 103. This raises the possibility that

133. This seems in some tension with the rules in § 102(b) and § 102(g) that encourage disclosure by treating affirmative concealment as disqualifying something as prior art, even if the public is benefiting from its use. However, the tension seems less a problem with the inherency doctrine than illustrative of a larger doctrinal confusion in § 102 over whether the right standard is one of absolute novelty or of relative novelty.

134. 35 U.S.C. § 103(a) (2000).

prior art inherently containing part, but not all, of the claimed invention could be fair game for an assessment of obviousness, and so the inherency problem deserves some consideration in this context.

Unlike anticipation and statutory bars, we do not expect inherency to be a significant issue in obviousness. By its own terms, § 103 eliminates much of the problem of inherency. Under § 103, obviousness analysis is geared to the knowledge of the PHOSITA.[135] Equally important, such knowledge is measured at the time the invention was made.[136] Hindsight reconstruction of the invention, looking back at the prior art to second-guess the inventor once the invention is available, is anathema to an obviousness assessment.[137] But inherency is all about hindsight—a recognition today that an invention was present in the prior art, even though it was not understood to be there at the time.

Given the hindsight limitations on obviousness, we expect the role of inherency under § 103 to be extremely limited, if not altogether nonexistent. One very narrow role for inherency might arise out of another difference between § 103 obviousness analysis and § 102 novelty analysis: the permissibility of combining references under § 103. Whereas § 102 requires that every element of the claimed invention be present in a single reference in order for the invention to be anticipated, § 103 allows assessment of obviousness against multiple references, provided that at the time of invention the PHOSITA would be motivated to combine those references and would have had a reasonable expectation of obtaining the claimed invention by doing so.[138]

A surprising instance of inherency from combined § 103 references arises out of the doctrine developed by the Federal Circuit in *In re Dillon*, where the inventor claimed both the combination of tetra-orthoesters with hydrocarbon fuel and the use of tetra-orthoesters to reduce soot emissions from combustion of hydrocarbon fuels.[139] Both tetra-orthoesters and a closely related class

135. *Id.*

136. *Id.*

137. *See, e.g.*, Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1320 (Fed. Cir. 2004).

138. *Id.*

139. 919 F.2d 688 (Fed. Cir. 1990) (en banc).

of molecules, tri-orthoesters, were known in the prior art. Combinations of tri-orthoesters and tetra-orthoesters with hydraulic fluids for scavenging water in such fluids were known, as were combinations of tri-orthoesters and hydrocarbon fuels for the same purpose. The specific, claimed combination of tetra-orthoesters and hydrocarbon fuels was not known in the prior art, nor was the use of either tri-orthoesters or tetra-orthoesters for reducing soot emissions.[140]

The Patent Office rejected the compositions claims as obvious, reasoning that the combination of tetra-orthoesters and hydrocarbon fuel was suggested, albeit for a different purpose, by the known tri-orthoester fuel combinations and the structural similarity of the two types of orthoesters.[141] The Federal Circuit, en banc, affirmed the rejection, holding that the use of a structurally similar molecule in prior art compositions, even for a different purpose, rendered the composition claims prima facie obvious.[142] The court held that the inventor could rebut the prima facie case of obviousness by showing that the structurally similar prior art compositions did not have the same properties as the claimed compositions—in other words, that the properties of the new compositions were not inherently present in the similar prior art compositions.[143]

Dillon was unable to present such a rebuttal in the particular case, as her application showed that in fact the tri-orthoesters had the same soot-reducing property as the claimed tetra-orthoesters, even though people didn't know that either had that property at the time of her invention. The Federal Circuit's articulation of a rebuttal standard that we might term "reverse inherency" or "inherent absence" is striking. In *Dillon*, a motivation to combine the prior art references was present, although for a purpose different than that discovered by the inventor. As it happens, such a combination would result in a composition with properties unknown to, and unexpected by, the PHOSITA. Consequently, to show nonobviousness, the inventor would have had to show that the PHOSITA's reasonable expectation in combining the prior art references would fail from an objective standpoint because the novel

140. *Id*. at 692-94.
141. *Id*. at 691.
142. *Id*. at 692-94.
143. *Id*. at 694.

property was inherently absent—not simply unknown to the PHOSITA, but in fact not objectively present in the prior art compositions.

This outcome seems congruent with the anticipation cases considering "new uses" of known structures. As we have indicated above, unknown and inherent uses of known structures are eligible for an improvement patent, but they confer no rights to the prior art structure. We have also noted the inherency ramifications of the structural disclosure rule from *In re Hafner*. Some commentators have observed that disclosure of a structure without a use will anticipate only the particular structure under the *Hafner* rule, as the absence of a disclosed use implies a lack of motivation to create structurally similar products.[144] The *Dillon* corollary, though, is that when the prior art discloses a different use from that later developed by an inventor, the inventor of a structurally related chemical will either be limited to a process patent for the new use or be forced to prove inherent absence of the new property in the old chemical in order to obtain a product patent.

Similarly, Dillon's problem looks a bit like that in the *Cruciferous Sprout* case. Like the patentee there, Dillon identified a previously unknown but inherent property; the difference is that she claimed a new but structurally obvious chemical. Because people would have been motivated to make the new chemical for the same reason as they made the old one, the only way Dillon could show patentability would be to demonstrate a new property of the new chemical. Because it turned out that the old chemical inherently had the property she identified, her new chemical was held an obvious variant of the old.

An analysis of *Dillon* also suggests a limited role for direct inherency under § 103. A variation on the facts of *Chen v. Bouchard*, taken from Bouchard's point of view, provides a possible scenario for obviousness inherency. Consider the situation in which the prior art reveals substances *A* and *B*, and provides the motivation to combine these substances to produce substance *C*. Assuming that there would be a reasonable likelihood of success in obtaining *C*, this combination is obvious under § 103. Undisclosed in the prior art, however, is the fact that combining *A* and *B* will also produce

144. *See* MERGES & DUFFY, *supra* note 98, at 832.

another substance, *D*. The prior art provides the motivation to combine *A* and *B*, but not for the purpose of obtaining *D*. Can the first to discover *D* claim it, much as Bouchard claimed the unappreciated product of Chen's synthesis, when it was inherent in the obvious combination of § 103 prior art materials?

This scenario is very close to the situation in *Dillon*, in that a motivation to combine the prior art references exists, though here the PHOSITA cannot foresee the new *product* to be generated, rather than the new *use* of an expected product, as was the case in *Dillon*. As in *Dillon*, given that there is a motivation to combine the materials, the answer as to the obviousness of the inherent product depends first upon the nature of the claims. The combination of the known starting materials was obvious, but the inventor in this situation is not claiming the known process of combination—he is claiming the unexpected product.[145] As the law stands today, the process of making *D* seems obvious, since the PHOSITA was already motivated to combine *A* and *B*.[146] But the inventor may be entitled to a product patent on *D* itself, because the prior art did not suggest that combining *A* and *B* would produce *D*, and in fact the combination produces unexpected results.[147]

But resolution of the issue also depends upon consideration of the applicable standard for "reasonable likelihood of success" in combining the materials. If the likelihood of success is viewed as a subjective question—that is, would the PHOSITA have expected the outcome of the combination?—the answer must be that the PHOSITA would not: the motivation to combine was directed to production of a different compound. On the other hand, if the likelihood of success is purely objective—that is, would one who combined *A* and *B* in fact succeed in producing *D*?—one could construct a theory under which the production of *D* is obvious: the

145. *See In re* Ochiai, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (indicating that a product's obviousness is distinct from its production method's obviousness); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993) (allowing a composition patent regardless of the method).

146. *See In re* Pleuddemann, 910 F.2d 823 (Fed. Cir. 1990); *In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985). Biotechnological processes may be an exception, not because of any difference in the technology, but for the simple reason that Congress passed a statute defining such changes as necessarily nonobvious. 35 U.S.C. § 103(b) (2000).

147. *See In re Ochiai,* 71 F.3d at 1572. "Unexpected results" are a secondary consideration supporting a finding of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

PHOSITA is motivated to combine *A* and *B*, and the combination will successfully produce the new substance, although unexpectedly.

We think that, once again, the public benefit standard provides the correct guidance to this conundrum. The public is presumably receiving no benefit today from substance *D*, since it is not actually present in the prior art and no one has been motivated to produce it. It would be congruent with patent policy to reward an inventor who places knowledge of the inherent compound into the public's possession. For similar reasons, the jurisprudence under § 103 rejects a finding of obviousness where the combination is merely "obvious to try"—that is, where there exists motivation to try a combination, but there is no reasonable expectation as to the outcome. Here, the outcome is truly unknown and unappreciated, and unanticipated new benefits are the sine qua non of non-obviousness determinations. By contrast, the PHOSITA is already motivated to combine *A* and *B*, so it would seem unreasonable to grant a patent on the process of combining the two.

B. Inherent Infringement

An additional recognizable (but perhaps unappreciated) manifestation of inherency is found in the exclusive rights granted to the patent holder: the exclusive rights to make and use the claimed invention, as well as exclusive rights to the specific uses of selling, offering for sale, and importing the claimed invention.[148] It is a well-established maxim of patent law that anything that would anticipate a patent if it predated the invention will infringe if it is introduced later than the issuance of the patent.[149]

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148. 35 U.S.C. § 271(a) (2000). Under § 271(b), the patent owner may also obtain some limited ability under certain circumstances to control the description of the claimed invention in a printed publication. *See* Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986). This is not a general exclusive right of the patent holder, presumably in part because public disclosure of the invention is part of the quid pro quo for obtaining a patent. Such a prohibition might also raise certain First Amendment issues. *See* Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99 (2000). As a practical matter, the availability of an enabling disclosure in the published patent makes control over republication of the disclosure less important.

149. *See, e.g.*, Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001).

Even though the publication of the patent's enabling disclosure places the knowledge to make and use the claimed invention constructively in the hands of the public, information dissemination is not perfect, and defendants may still make or use the invention without knowing they are doing so. As in the case of anticipation, the presence of the claimed invention need not be known or even knowable for infringement to occur, as long as there is certainty that it is there. In effect, this makes infringement a strict liability offense;[150] the public's ignorance of the fact that it is making the invention covered by the patent no more excuses unauthorized making or using the invention than the inventor's ignorance that the public already had the benefit of the claimed invention would excuse the improper issue of a patent on that invention.

The symmetric nature of inherent anticipation and inherent infringement liability is apparent in the Federal Circuit's opinion in *SmithKline Beecham Corp. v. Apotex Corp.*,[151] in which the court held that inadvertent production of trace amounts of a pharmaceutical compound may constitute infringement of a claim unambiguously drawn to that compound. Indeed, an accused infringer's inability to detect such traces of the claimed compound is irrelevant to the infringement inquiry.[152] The opinion underscores the resonance with § 102 by extending this analysis to hold that, by the same token, the *inventor's* inability to detect such traces of a structurally claimed compound more than a year prior to the date of filing a patent is no bar to the application of the inherency doctrine.[153]

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150. Roger D. Blair & Thomas F. Cotter, *Strict Liability and Its Alternatives in Patent Law*, 17 BERKELEY TECH. L.J. 799 (2002). While Blair and Cotter claim that the notice and marking requirements take patent law out of the realm of strict liability, that is not true here. *Id.* at 800-04. Where the defendant is not even aware that he is producing the patented invention, giving him notice of the patent by marking patented products will not affect his behavior.

151. 365 F.3d 1306 (Fed. Cir. 2004), *vacated*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc), *reinstated in relevant part*, 403 F.3d 1331, 1345-46 (Fed. Cir. 2005).

152. *Id.* at 1315. Judge Richard A. Posner, sitting by designation as the district court judge, rejected the claim of infringement in this case because the defendant had not acted voluntarily in inadvertently producing the infringing product. *See* SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1043-45, 1052 (N.D. Ill. 2003), *vacated*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc). The Federal Circuit reversed on this ground, though it ultimately invalidated the patent for the same reason—the inherent production that infringed also anticipated the patent. *SmithKline*, 365 F.3d at 1316.

153. The original panel opinion on experimental use was vacated en banc. SmithKline

As in the case of anticipation, infringement is asymmetric to enablement; either the making or the use of the claimed invention is sufficient to trigger the statute. Such inadvertent infringement by making is well illustrated by the facts of *Monsanto v. Schmeiser*,[154] a Canadian infringement case decided under section 42 of the Canadian Patent Act, the parallel provision to 35 U.S.C. § 271. Mr. Schmeiser, a canola farmer, was found to have infringed a Monsanto patent covering genetically modified "Roundup Ready" canola plants by growing such plants without authorization on his farm. Mr. Schmeiser alleged that the presence of infringing plants on his land was unintentional and involuntary, and thus not an infringement. He argued that he did not "use" the claimed invention because the plants either sprouted from Monsanto seeds blown there by the wind or resulted from the cross-pollination of his own plants by Monsanto plants grown in his neighbor's fields. Even assuming that Mr. Schmeiser's explanation for the presence of the plants was correct, his intent and knowledge were held to be irrelevant to the question of infringing "use."[155] The same results would be expected under the U.S. provision; every element of the claimed invention is inherently present in the accused device, whether the alleged infringer was aware of its presence or not.

Once again, benefit would properly seem to prevail over knowledge. While Schmeiser arguably did not know that he was producing the patented plants, he was benefiting from those plants by selling the canola and replanting the seeds. A public use of that type would

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Beecham Corp. v. Apotex Corp., 403 F.3d 1328, 1330 (Fed. Cir. 2005) (en banc). On remand, the Federal Circuit rested its conclusion that the patent was invalid firmly on inherency. SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1345-46 (Fed. Cir. 2005). Judge Gajarsa, concurring, would have held that patents written in such a way as to cover inadvertent production through natural processes were not patentable subject matter. *Id.* at 1347, 1359-62 (Gajarsa, J., concurring).

154. Monsanto Can. Inc. v. Schmeiser, [2001] F.C. 256, *aff'd*, [2003] 2 F.C. 165, *aff'd in relevant part*, [2004] 1 S.C.R. 902; *see also* Drew Kershen, *Of Straying Crops and Patent Rights*, 43 WASHBURN L.J. 575, 581 n.27 (2004). Judge Gajarsa's concurrence in *SmithKline* suggests he disagrees that this can be patent infringement. 365 F.3d at 1328-31 (Gajarsa, J., concurring).

155. *Monsanto*, [2004] 1 S.C.R. 902; *cf.* Monsanto Co. v. McFarling, 363 F.3d 1336, 1342-43 (Fed. Cir. 2004) (holding that a farmer who saved and replanted seeds generated by natural growth from patented seeds that he purchased from Monsanto infringed Monsanto's patents by making the patented invention). For a discussion of these issues, see Kershen, *supra* note 154.

anticipate Monsanto's invention if it occurred prior to patenting, and it infringes if it occurs after.

C. Inherent Products of Nature

Perhaps the most striking ramification of the inherency doctrine is its implications for the subject matter doctrine in patent law. Section 101 of the Patent Act specifies that patents may issue for new and useful processes, machines, compositions of matter, and articles of manufacture.[156] Over the years, this list of categories has been perceived to exclude various types of subject matter from patentability. In truth, the list largely provoked lawyerly word games, as inventors and their representatives applied different labels to ostensibly unpatentable subject matter in order to fit it into one or more of the categories. The Patent Office accepted applications only so long as the proper subject matter incantation was recited.

Beginning with the Supreme Court's holding in *Diamond v. Chakrabarty*, however, courts have treated the subject matter recitations as illustrative, rather than exhaustive, and taken seriously the maxim that patentable subject matter extends to "anything under the sun that is made by man[kind]."[157] As a result, the subject matter barriers to patentability began to collapse. The courts rejected the idea that patents were limited to the technological arts,[158] opening the door to patenting the liberal arts and professions.[159] They have overruled the traditional exclusion for business method patents.[160] They have not expressly overruled the

156. 35 U.S.C. § 101 (2000).

157. 447 U.S. 303, 309 (1980); *cf.* Harvard Coll. v. Canada, [2002] 4 S.C.R. 45 (holding that the Canadian Patent Act, unlike the United States Patent Act, does not automatically cover new technologies and specifically does not encompass transgenic higher organisms).

158. *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970), drew this line, but the software cases have since eroded it. *See* Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 970 (1986) (describing *Musgrave* as the "high water mark of rationality" in software patenting).

159. *See In re* Alappat, 33 F.3d 1526, 1553-54 (Fed. Cir. 1994) (en banc) (Archer, C.J., dissenting in part) (noting that under the court's precedents, there was nothing to prevent the patenting of a new song); John R. Thomas, *The Patenting of the Liberal Professions,* 40 B.C. L. REV. 1139 (1999) (exploring the expansion of patentable subject matter).

160. State St. Bank & Trust Co. v. Signature Fin. Group Inc., 149 F.3d 1368, 1375 (Fed. Cir. 1998) ("As an alternative ground for invalidating the ... patent under § 101, the court

exemption for abstract ideas, but neither have they applied it in the last 150 years.[161] The inevitable endpoint of this process was reached in *State Street Bank & Trust Co. v. Signature Finance Group, Inc.*, where the Federal Circuit held that patentable subject matter extends to any product of human ingenuity that yields a "useful ... result."[162]

Since the *State Street* decision, almost the last bastion of subject matter exclusion[163] appears to be the "product of nature" doctrine and its close relative, the "laws of nature" doctrine—the categories of items under the sun ostensibly *not* made by mankind, but rather occurring naturally, without human intervention. Almost sixty years ago, in *Funk Bros. v. Kalo*, the Supreme Court relied upon this exception to invalidate a patent drawn to a mixture of bacteria beneficial to root nodules.[164] Although the bacteria in the mixture

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relied on the judicially-created, so-called 'business method' exception .... We take this opportunity to lay this ill-conceived conception to rest.").

161. Arguably, the court has been right to do so. An early case often associated with this proposition is *O'Reilly v. Morse*, in which Samuel Morse, having developed the telegraph, applied for a patent with broad claims to any form of communication via electromagnetism. 56 U.S. (15 How.) 62, 112-21 (1854). The opinion invalidating his claims has been read as holding that claims so broad as to encompass a law or phenomenon of nature—in Morse's case, claims that effectively read on electromagnetism—are impermissible. *See, e.g.*, *Chakrabarty*, 447 U.S. at 309 (citing *O'Reilly*). In fact, however, the decision in *O'Reilly* may more properly be read to hold that Morse failed to enable the PHOSITA to make and use his broadest claims.

This reading of *Morse* also suggests that the statement of the majority in *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1316 (Fed. Cir. 2004), that patentable subject matter and scope of claims are unrelated is, at a minimum, overstated—had Morse narrowed his claims to match his disclosure, they would not have read on an abstract idea. *Cf. id.* at 1321-23, 1329-33 (Gajarsa, J., concurring) (applying a § 101 analysis to preclude the patenting of a hemihydrate even though it was man made).

162. *State St.*, 149 F.3d at 1373.

163. One other patentable subject matter doctrine that has shown surprising persistence is the "printed matter" exception, which requires patents to cover physical items or processes, rather than innovations composed entirely of new text. *See, e.g.*, Hotel Sec. Checking Co. v. Lorraine Co., 160 F. 467, 469 (2d Cir. 1908) (denying patent protection to a method of hotel management); *Ex parte* Gwinn, 112 U.S.P.Q. (BNA) 439 (B.P.A.I. 1955) (denying protection to a new board game). It might reasonably have been expected that this doctrine was dead in the wake of *State Street*, since both computer programs and business ideas that were implemented in paper were patentable. 149 F.3d at 1371-75; *see also In re* Lowry, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (rejecting the claim that a data structure contained within a computer's memory was "printed matter"). The Federal Circuit revived the doctrine in 2004 in *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (rejecting a patent claim for adding instructions to an RNA amplification kit).

164. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

were specifically chosen for their properties of infecting various types of nodules without interfering with one another, the Court reasoned that the bacteria in the mixture acted in precisely the same way that they did in nature, precluding a patent claim on the basis of their natural characteristics.[165]

In recent jurisprudence, product of nature questions have surfaced most often in relation to the chemical or biological sciences. Patent claims to various biomolecules, such as adrenaline or DNA sequences, are routinely granted, though these compounds surely exist in "nature" as part of the biochemical complement of living organisms. The courts have resolved this problem by permitting the patenting of products of nature only when they have been either physically transformed into something new or been isolated or purified in a way that changes their economic significance. This rule was established in the famous Learned Hand opinion in *Parke-Davis v. Mulford*, which held that adrenaline salts were not products of nature, despite having been drawn from human adrenal tissue, because the claims were directed to a purified and isolated form of the substance that was not found in nature and had significant advantages over the naturally occurring product.[166]

Similarly, to be patentable, claims to DNA are generally drawn to molecules that have been isolated and purified from their natural state—a product of human intervention, a state of the substance not found in nature.[167] Those isolated and purified DNA sequences can be used for purposes that naturally occurring DNA cannot, such as the creation of chimeric bacteria that will express large quantities of a protein. On this view, the product of nature exception will not be a significant limit on patentable subject matter because the act of isolation or purification will be sufficient to make an existing product into a new thing.

Yet this doctrine continues to trouble many who perceive, with some justification, that these inventions are in some sense inherent

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165. *Id.*

166. 189 F. 95, 113, 114 (C.C.S.D.N.Y. 1911), *aff'd in part*, *rev'd in part*, 196 F. 496; *see also In re* Bergstrom, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (holding pure form of natural prostaglandins patentable).

167. *See, e.g.*, Alloway, *supra* note 7, at 75. Another distinguishing factor is that some claims are drawn to cDNA, which is a construct made through reverse transcription of RNA and not actually found in nature itself.

in the natural world and that a biomolecule or other substance ubiquitous in living organisms is already in the "possession" of the public.[168] In part, this points to the problem of characterizing this subject matter category in terms of human intervention. The bacterial mixture in *Funk Bros.* was surely the product of human intervention, but the Supreme Court found that its properties were not, and therefore it was a product of nature. By contrast, the chimeric bacterium in *Chakrabarty*, which was also the product of human intervention to harness in one bacterium the petroleum-degrading properties of several natural organisms, was treated as a new product. This leaves open the question as to how much "intervention" or alteration is necessary to produce a product "made by man[kind]" rather than a "natural" product. Stated differently, if the sole remaining test for patentable subject matter focuses on products of human ingenuity that, per the *State Street* formula, produce a "useful result," might not that useful result be inherent in the products of nature from which the invention was drawn?

Similar difficulties appear in a variation of the product of nature doctrine dealing with laws of nature. Under this related doctrine, natural laws and statements of mathematics are held to be unpatentable as "discoveries" rather than "inventions." The assumption latent in this doctrine is that formulations of natural law, as well as the language in which such formulations are made—mathematics—are somehow hard wired into the fabric of the universe and so not the product of human ingenuity. The Supreme Court has relied upon this to deny patent protection to mathematical formulae and to computer algorithms that seemed to read on mathematical formulae.[169]

But read too broadly, the product of nature/law of nature doctrine might well eviscerate all of patent law; after all, every human creation draws upon materials from the natural world, assembled according to the principles of natural laws.[170] Each invention is in

168. *See, e.g.*, John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 127 (2001); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707 (2004) (discussing the patentability of DNA); Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life,* 98 AM. J. INT'L L. 641 (2004) (discussing patenting of genetic material).

169. *See* Gottschalk v. Benson, 409 U.S. 63 (1972).

170. *See* Diamond v. Diehr, 450 U.S. 175, 189 n.12 (1981) ("To accept the analysis proffered

some sense a specific manifestation of natural materials and natural laws, assembled by humans who are part of nature themselves. Viewed this way, it is unclear exactly what this doctrine is supposed to mean, or exactly where the dividing line might lie between natural and unnatural.[171] The products of nature doctrine might cover everything, or it might cover nothing.

Properly understood, the inherency doctrine may do the work that the products of nature doctrine attempts to do in distinguishing natural products from transformed ones, and therefore bringing greater coherence to the distinction between natural and artificial constructs. Having been conspicuously cast in terms of what it means to be "made by man[kind]" and to "produce a useful result," patentable subject matter has effectively been cabined in terms of making and using, the twin criteria we have already discussed as giving rise to the question of inherency elsewhere in the patent statute. This suggests that the touchstone to the subject matter question is the one we have already identified: whether a substance inherent in nature is already benefiting the public, or whether the inventor has made useable an otherwise unused thing.

As a policy matter, this approach makes perfect sense. If people already benefit from a product of nature, the discovery of that benefit or its causes adds only a modest amount to our technological capabilities and does not justify withdrawing from the public the benefit they already receive. By contrast, if the public does not already receive the benefit of a natural substance and it would not be obvious to modify a natural product to produce such a benefit, a discovery or modification that gives the world a new benefit is precisely the sort of improvement that we want to encourage through patent protection. In this view, the *Parke-Davis* holding aligns with anticipation cases such as *Cruciferous Sprout*; an inventor may properly patent isolated or purified products that

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by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.")

171. This is a common difficulty in appeals to "nature" or the "natural." *See generally* THE MORAL AUTHORITY OF NATURE (Lorraine Daston & Fernando Vidal eds., 2004) (presenting a series of essays reflecting on the meaning and authority of nature in historical and contemporary contexts).

provide a new benefit, but not merely a new discovery of a substance or property already benefiting the public in its natural state.[172]

Inherency also seems well-suited to explaining the prohibition against patenting laws of nature. The objection to patenting natural law or mathematical algorithms seems to be that such principles are "inherent" in the universe, waiting to be discovered, and so not the product of human ingenuity. Yet this characterization flies in the face of the current understanding that scientific "laws" are human constructs, clearly the products of human ingenuity,[173] as is the language of mathematics in which such laws are expressed.[174] The distinction between "invention" and "discovery" cannot credibly account for declining to patent such human formulations. However, these principles may well be said to be in public use, benefiting the public, even if their formulation is unarticulated or unexpressed. And, as elsewhere in patent law where inherency appears, mere articulation or description of an already operative principle does not qualify for patent protection.

In short, inherency can do the work that the products of nature and laws of nature doctrines have found it hard to do by providing a rationale for identifying those modified products of nature that are worthy of patents. The products of nature doctrine may still retain some vitality as a limitation on patenting unchanged natural products, such as a plant newly discovered in a remote jungle.[175] But as a practical matter, such a narrowed doctrine would almost never be used, and the doctrinal difficulties it has created could be resolved through reliance on the inherency doctrine.

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172. It is harder to square this result with *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641, 644 (3d Cir. 1928), which held that a claim to "substantially pure tungsten" was unpatentable because the characteristics of tungsten were natural products. Assuming that the patentee had in fact given the public the benefit of purified tungsten for the first time, however, it is likely that *General Electric* would come out the other way today.

173. *See* HENRY H. BAUER, SCIENTIFIC LITERACY AND THE MYTH OF THE SCIENTIFIC METHOD (1992); JACOB BRONOWSKI, *The Creative Mind*, *in* SCIENCE AND HUMAN VALUES 1, 4, 5, 7, 12-15 (rev. ed. 1965); JACOB BRONOWSKI, *The Abacus and the Rose: A New Dialogue on Two World Systems*, *in* SCIENCE AND HUMAN VALUES, *supra*, at 76, 88-91.

174. *See* PHILLIP J. DAVIS & REUBEN HERSH, THE MATHEMATICAL EXPERIENCE 410 (1981).

175. It is not clear that even this narrowed doctrine makes sense. There are perfectly good policy arguments for allowing the patenting of new natural discoveries, if we are persuaded that they are truly new to humans. *See, e.g.*, ROBERT NOZICK, ANARCHY, STATE AND UTOPIA 180-82 (1974) (arguing that one who discovers a new plant has a moral entitlement to a patent over it).

D. Foreign Inherency

While the concept of inherency as public benefit makes sense, it works only for existing benefits within the United States under current law. Much of the prior art for biological materials that might anticipate under the inherency doctrine is statutorily excluded from consideration because it exists outside of the United States. Although patents or printed publications from anywhere in the world are relevant prior art under § 102, knowledge, use, or sale of an item—the prior art most often at issue in inherency—are considered prior art only if they occur within the United States.[176] A charitable view of these restrictions might regard them as quaint relics of the nineteenth century, when transnational communications were less reliable and when tangible evidence, such as a printed publication demonstrating that an invention was anticipated, was deemed more solid than the rumor of foreign knowledge or use. A less charitable view might regard them as mercantilist provisions calculated to benefit American inventors, even if they merely rediscovered what foreign scientists already knew.

In either view, recent commentators have suggested that the exclusions have outlived their dubious usefulness and that domestic and international prior art should be considered equally.[177] Legislation pending in Congress at this writing would accomplish just that.[178] Eliminating the geographic bias in the novelty and statutory bar provisions would allow consideration of foreign knowledge, use, and sales. This would likely have a profound impact on patents drawn to the development of biological substances from traditional medicines or other indigenous knowledge. In many cases of such traditional knowledge, the public—albeit not the American public—has been receiving the benefit of the underlying substance, often for thousands of years.[179] Allowing the inherency doctrine full

176. 35 U.S.C. § 102(a)-(b) (2000).

177. Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 683-84 (2003) (asserting that relevancy classifications based on geographical origin conflict with the United States Constitution).

178. H.R. 2795, 109th Cong. § 3(b) (2005).

179. In one recent example in Europe, the EPO revoked EPO Patent 436,257, covering the process of extracting a fungicide from the neem tree, on the basis of evidence from India that the process had long been part of traditional knowledge. *See* Vir Singh, *India Wins Seminal Case Against Patent Relating to Traditional Indian Knowledge,* 69 PAT., TRADEMARK &

effect on such prior art might weaken some incentives for producing straightforward versions of traditional remedies, but it would also answer the increasingly loud charges of "biopiracy" leveled against patenting of known treatments by firms in the developed nations.[180] Moreover, if the inherency doctrine is understood as it seems the court now does understand it, globalizing prior art will not interfere with true cases of drug development because work that involves modifications to a product of nature that bring a new benefit to the world will still be patentable.

Changing these rules would require congressional action, as the discrimination is enshrined in the statute. Likely that will happen eventually, as the domestic prior art restriction seems an artifact of an older world. In the meantime, however, the Federal Circuit has expanded the practical reach of foreign prior art in the *Elsner* case, holding that a foreign publication that was not itself enabling could anticipate a patent if it convincingly demonstrated that the invention was in use abroad.[181]

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180. For discussions of the claims of ownership to traditional knowledge, see INTELLECTUAL PROPERTY RIGHTS FOR INDIGENOUS PEOPLES, A SOURCEBOOK (Tom Greaves ed., 1994); Charles R. McManis, *Fitting Traditional Knowledge Protection and Biopiracy Claims into the Existing Intellectual Property and Unfair Competition Framework, in* INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 425 (Burton Ong ed., 2004). *See also* GRAHAM DUTFIELD, CAN THE TRIPS AGREEMENT PROTECT BIOLOGICAL AND CULTURAL DIVERSITY? 5-13 (1997); Anupam Chander & Madhavi Sunder, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331 (2004) (discussing the public domain movement that argues against the privatization of knowledge); Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, 7 J. INT'L ECON. L. 371 (2004) (exploring protection for traditional knowledge); Shubha Ghosh, *Traditional Knowledge, Patents, and the New Mercantilism*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 828 (2003) (reflecting on the debate over the ownership of traditional knowledge and focusing on patents such as basmati rice and turmeric).

181. *In re* Elsner, 381 F.3d 1125, 1128 (Fed. Cir. 2004); *see also In re* Klopfenstein, 380 F.3d 1345 (Fed. Cir. 2004); TypeRight Keyboard Corp. v. Microsoft Corp. 374 F.3d 1151, 1152-58 (Fed. Cir. 2004). These prior art cases are part of a growing trend in the courts towards expanding the extraterritorial reach of U.S. patent law. *See, e.g.*, AT&T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005); Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325, 1338-41 (Fed. Cir. 2005); NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

CONCLUSION

The inherency doctrine is central to patent law—a puzzle itself inherent in the artifice of granting exclusive rights to the originator of a given human innovation. The concept of innovation is at some level a human conceit; patent law rewards "anything under the sun made by man" if it is new as well as useful, but in a very real sense there is nothing new under the sun. Much of our perception of inventive novelty stems from sheer ignorance of our surroundings or of the combinations already put into service by other persons, in other places, at other times. When, on rare occasions, we are confronted with the evidence of previous, often unwitting uses of a supposedly new invention, the inherency doctrine serves to distinguish beneficial from gratuitous conceit, directing the choice of fiction that will benefit the public most.

Inherency will serve that role only if it is properly understood, and the key to understanding the doctrine is to focus on public benefit, not knowledge. The long-standing judicial formulation of the inherency test obscured that distinction, creating a doctrinal morass. Fortunately, the Federal Circuit has recently put the doctrine on a more reasonable footing, one that now offers coherence to the previously fragmented concepts of inherency running throughout the fundamental precepts of patent law.