

# SCHERING CORP. V. GENEVA PHARMACEUTICALS, INC.: CLARIFICATION OF THE INHERENT ANTICIPATION DOCTRINE AND ITS IMPLICATIONS

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An invention must be new at the time of discovery to be patentable.<sup>1</sup> A patent fails the § 102 novelty requirement<sup>2</sup> if the invention is anticipated by prior art.<sup>3</sup> To demonstrate invalidity by anticipation, a single prior art reference must disclose “each and every limitation of the claimed invention.”<sup>4</sup> Under the doctrine of inherency, a patent is invalid based on anticipation even if a prior art reference failed to expressly disclose a feature of the claimed invention, as long as the missing feature is a “deliberate or a necessary consequence of what was intended.”<sup>5</sup> On the other hand, inherent anticipation requires certainty—a prior accidental achievement of a product or process does not constitute inherent anticipation, since a true accident gives the public no assurance that others can achieve the same result at a later time.<sup>6</sup>

In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, the Federal Circuit resolved a long-standing debate in the doctrine of inherent anticipation—whether recognition of an inherent feature in the prior art is required.<sup>7</sup> The court invalidated an allergy medicine patent claim on the ground that a prior drug patent inherently anticipated all of that drug’s metabolites.<sup>8</sup> The court held that inherent anticipation does not require that the inherent feature be appreciated at the time of the earlier patent, as long as the disclosure is a “necessar[y] and inevitabl[e]” consequence of the earlier invention.<sup>9</sup>

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1. See 2 JOHN GLADSTONE MILLS III ET AL., PATENT LAW FUNDAMENTALS § 10.1 (2d ed., rev. 2004).

2. See 35 U.S.C. § 102 (2000).

3. See 2 MILLS ET AL., *supra* note 1, §§ 10.2, 10.6.

4. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

5. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.03 (2004); see also *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

6. See 1 CHISUM, *supra* note 5, § 3.03.

7. 339 F.3d at 1377.

8. *Id.* at 1380. A metabolite is the compound formed by the body upon ingestion of a drug. *Id.*

9. *Id.* at 1378-80.

The *Schering* decision represents an effort by the Federal Circuit to balance two conflicting goals of the patent system: to stimulate inventive efforts by giving inventors exclusive rights for a limited period and to allow the public at large to derive benefits from the advances in technology.<sup>10</sup> While the decision arguably might create some challenges in biotechnology and pharmaceutical patents, it articulates a bright-line rule for future inherency cases and ensures that an invention passes to the public domain upon the expiration of the patent term. To minimize any potential negative impact on pharmaceutical innovations, the court also provided guidance on future patent protection on metabolites of known drugs.<sup>11</sup>

Part I of this Note examines the historical development and evolution of the inherency doctrine, from the Supreme Court's earlier emphasis on rewarding inventive efforts, to the conflicting decisions by the Federal Circuit before *Schering*. Part II provides a summary of *Schering*. Part III.A analyzes the underlying policy considerations of the inherency doctrine; Part III.B discusses the fairness of the *Schering* outcome; Part III.C discusses the implications of *Schering* on pharmaceutical drug innovations and argues that the chilling effects of *Schering* on metabolite research will be minimal; and finally, Part III.D argues that the "necessary and inevitable" test promulgated by *Schering* should be strictly applied in inherency analysis, and that invalidity should only be found in cases where there is an absolute certainty of inherent features.

## I. BACKGROUND

The patent system represents a carefully crafted bargain that promotes both innovation and public disclosure of new and useful technologies, in return for a limited monopoly.<sup>12</sup> While one goal of patent law is to give a reasonable reward to inventors in order to stimulate innovative efforts, the main objective is "to promote the Progress of Science and useful Arts."<sup>13</sup> The Supreme Court ruled that this could be best achieved "by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having a due regard to the rights of the inventor."<sup>14</sup>

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10. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

11. *Schering*, 339 F.3d at 1381.

12. *See, e.g., Pfaff*, 525 U.S. at 63.

13. U.S. CONST. art. I, § 8, cl. 8; *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829).

14. *Pennock*, 27 U.S. (2 Pet.) at 19.

The novelty requirement lies at the heart of the patent system and assures that knowledge already in the public domain “remain[s] there for the free use of the public.”<sup>15</sup> Granting a monopoly in existing public information serves no socially useful purpose and in fact injures the public.<sup>16</sup> A patent fails to meet the novelty requirement if the same invention is anticipated by prior art, that is, if a single prior art reference discloses “each and every element of the claimed invention.”<sup>17</sup>

Inherent anticipation can be established if a prior art reference functions in accordance with all the limitations of a claimed invention.<sup>18</sup> Thus, a prior art reference can anticipate a later invention without expressly disclosing every limitation, as long as the missing descriptive matter is inevitably present.<sup>19</sup> However, inherent anticipation requires absolute certainty, and “may not be established by probabilities or possibilities.”<sup>20</sup> “The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”<sup>21</sup>

#### A. *Tilghman and Eible Process: Accidental, Unintended Results Do Not Anticipate*

The Supreme Court established in *Tilghman v. Proctor* that an accidental, unintended, and unappreciated production of a product or process does not constitute anticipation.<sup>22</sup> In *Tilghman*, the patentee claimed a process of treating fats and oils by separating them into fatty acids and glycerine through the action of water at a high temperature and pressure.<sup>23</sup> Two of the prior art references the accused infringer cited were (1) the use of animal fat in a steam engine to lubricate the piston,<sup>24</sup> and (2) the purification of fats and oils in preparation for soap-making.<sup>25</sup> Despite

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15. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Section 102(a) of the Patent Act precludes patenting an invention that is previously in use or described in a printed publication. *See* 35 U.S.C. § 102 (2000).

16. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989).

17. *See* 2 MILLS ET AL., *supra* note 1, § 10.6.

18. *See id.* § 10.5.

19. *Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

20. *Id.* at 1269 (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)).

21. *Id.*

22. 102 U.S. 707, 711-72 (1881).

23. *Id.* at 708-09.

24. *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 314-15 (1873). A scientific article published thirty years before *Tilghman*'s invention made the observation that Perkins used animal fat in a steam engine to lubricate the piston and diminish friction. *Id.* The *Tilghman v. Proctor* case involved the same patent as in the *Mitchell v. Tilghman* case, and in fact, overruled *Mitchell* as to the validity of the patent. *Tilghman*, 102 U.S. at 708.

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

the possible production of fatty acids in these processes, the Supreme Court held that Tilghman's invention was not anticipated.<sup>26</sup> The Court found that the cited prior users never fully understood the process by which fatty acids were generated, and therefore, the "accidental[] and unwitting[]" formation of fatty acid was of "no consequence."<sup>27</sup> The Court emphasized the importance of subjective appreciation in the anticipation analysis, stating that:

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.<sup>28</sup>

Similarly, in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, the Supreme Court held that "accidental results, not intended and not appreciated, do not constitute anticipation."<sup>29</sup> In this case, Eibel's patent claimed an improved paper-making machine, by elevating the pitch of the paper-making wire by several degrees.<sup>30</sup> The challenger relied on prior machines that introduced some pitch for drainage purposes.<sup>31</sup> The Court found that the existence of any high pitch in prior machines was "under unusual conditions" because the pitch needed for drainage was usually small.<sup>32</sup> Therefore, inherent anticipation could not be established.<sup>33</sup> Citing *Tilghman*, the Court held that to serve the purpose of the patent system, courts should first "look[] into the art to find what the real merit of the alleged discovery or invention is and whether it has advanced the art substantially," and if so, courts should construe the patent to "secure to the inventor the reward he deserves."<sup>34</sup>

The Supreme Court in *Tilghman* and *Eibel Process* apparently disregarded accidental achievements in anticipation analysis.<sup>35</sup> The holdings are consistent with one goal of patent law—to stimulate inventive

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26. *Id.* at 711-12.

27. *Id.* at 711, 731.

28. *Id.* at 711-712.

29. 261 U.S. 45, 66 (1923).

30. *Id.* at 52, 58.

31. *Id.* at 58.

32. *Id.*

33. *Id.* at 66.

34. *Id.* at 63.

35. See 1 CHISUM, *supra* note 5, § 3.03[2].

efforts and public disclosure by giving inventors reasonable rewards.<sup>36</sup> In cases where the existence of a product or a process is either accidental or unappreciated, the public gains no new or useful knowledge from the prior user, nor has the prior user truly engaged in any innovative activity. Therefore, the Court found it “absurd” that unappreciated, accidental results would prevent an inventor from claiming a conscious and deliberate discovery she had made.<sup>37</sup>

A number of lower court decisions soon followed *Tilghman* and *Eibel Process*. In *Pittsburgh Iron & Steel Foundries Co. v. Seaman-Sleeth Co.*, the Third Circuit held that the prior production of an alloy “was not known to those who produced it” and not “recognized as a new product,” therefore the alloy was “without value as an anticipation.”<sup>38</sup> In *Munising Paper Co. v. American Sulphite Pulp Co.*, the Sixth Circuit held that the “prior accidental production of the same thing, when the character and function were not recognized until the invention of the later patent, does not effect anticipation.”<sup>39</sup> Finally, in *Toch v. Zibell Damp Resisting Paint Co.*, the Second Circuit similarly stated that novelty was not defeated if the prior user had no knowledge of the results.<sup>40</sup> These decisions generally followed the Supreme Court’s rationale in *Tilghman* that exclusive rights to inventions are granted to reward genuine innovative efforts and, that in exchange for granting patent rights, the public benefits from the knowledge of how to make and use the invention.<sup>41</sup>

## **B. Recognition of the Inherent Feature in the Prior Art: Two Lines of Federal Circuit Cases**

While the *Tilghman* decision is generally interpreted as holding that accidents do not anticipate later inventions, the scope of *Tilghman* depends on how courts construe the meaning of “accident.”<sup>42</sup> An earlier accidental achievement of a product may have been either (1) sporadic or unusual or (2) a consistent and necessary consequence of what was

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36. See *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *Eibel Process*, 261 U.S. at 63.

37. See *Tilghman v. Proctor*, 102 U.S. 707, 712 (1881).

38. 248 F. 705, 709 (3d Cir. 1918).

39. 228 F. 700, 703 (6th Cir. 1915).

40. 233 F. 993, 995 (2d Cir. 1916) (stating that “novelty is not negated by a prior accidental production of the same thing when the operator does not recognize the means by which the accidental result is accomplished, and no knowledge of them, or of the method of their employment, is derived from the prior use by any one”).

41. See *Pfaff*, 525 U.S. at 63-64.

42. See 1 CHISUM, *supra* note 5, § 3.03[2].

intended but nevertheless unappreciated.<sup>43</sup> Until the *Schering* decision in 2003, the Federal Circuit had oscillated on the issue of whether a person of ordinary skill in the art must recognize the inherent feature of a prior art reference.<sup>44</sup> Some decisions required recognition of the inherent feature, while others held the opposite.<sup>45</sup>

1. *The Atlas Powder Line of Cases: Recognition in the Prior Art Is Not Required for Inherent Anticipation*

In *Atlas Powder Co. v. IRECO Inc.*, the Federal Circuit held that “[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art,” and that insufficient understanding “does not defeat a showing of inherency.”<sup>46</sup> In *Atlas Powder*, the patents claimed composite explosives made from a particular blasting composition.<sup>47</sup> The claimed explosives were identical to the blasting compositions of two prior art references.<sup>48</sup> However, the prior art references did not explicitly include a “sufficient aeration entrapped” limitation.<sup>49</sup> Nevertheless, a calculation of the percentage of the water-in-oil emulsion showed that air was inevitably trapped in the prior art explosives.<sup>50</sup> Based on this calculation, the court concluded that the patents were anticipated even though entrapped air was not recognized as an ingredient in the prior art.<sup>51</sup>

A similar holding can be found in *Titanium Metals Corp. v. Banner*, in which inherent anticipation was established even though a critical property of a claimed alloy was not disclosed in the prior reference.<sup>52</sup> The Federal Circuit found that although the alloy’s “good corrosion resistance in hot brine environments” was an unappreciated property, the newly discovered characteristic did not “render the old composition patentably new.”<sup>53</sup> Therefore, the *Atlas Powder* and *Titanium Metals* decisions took the position that even though the inherent structure, composition, or function was unknown or unappreciated in the prior art, insufficient understanding

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43. *See id.*

44. *See id.* § 3.03[2][c].

45. *See id.*

46. 190 F.3d 1342, 1347, 1349 (Fed. Cir. 1999).

47. *Id.* at 1343-46.

48. *Id.* at 1345.

49. *Id.*

50. *Id.* at 1348-49.

51. *Id.* at 1347-48.

52. 788 F.2d 775, 781 (Fed. Cir. 1985). The prior art reference disclosed the same alloy composition without discussing its “good corrosion resistanc[t]” property. *Id.*

53. *Id.* at 782; *see Atlas Powder*, 190 F.3d at 1347 (interpreting *Titanium Metals*).

of the inherent feature should not defeat a finding of anticipation.<sup>54</sup> The decisions reflect the policy consideration that the public should remain “free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.”<sup>55</sup>

Cases following the reasoning of *Titanium Metals* and *Atlas Powder* include *In re Cruciferous Sprout Litigation*<sup>56</sup> and *MEHL/Biophile International Corp. v. Milgraum*.<sup>57</sup> In *Cruciferous*, the inventors recognized that certain sprouts and food products were rich in glucosinolates, which could reduce the risk of cancer.<sup>58</sup> The prior art included the same sprouts but did not recognize the existence of glucosinolates.<sup>59</sup> In finding the patent invalid, the court emphasized that since the patent owner merely discovered some inherent, unappreciated properties of the sprout products, the novelty requirement was not met.<sup>60</sup> Similarly, in *MEHL/Biophile*, the court held that a method claim of “hair depilation” was anticipated by a prior article teaching the “alignment of the laser light over a hair follicle.”<sup>61</sup> The fact that the article’s authors did not appreciate the results (that is, hair removal) was “of no importance.”<sup>62</sup>

2. *The Continental Can Line of Cases: An Inherent Feature in the Prior Art Must Be Recognized by Persons of Ordinary Skill for Anticipation*

Another line of inherency cases followed *Continental Can Co. USA v. Monsanto Co.*,<sup>63</sup> which some courts had read to suggest that an inherent feature must be recognized by a person of ordinary skill in the art within the prior art time frame.<sup>64</sup> The patent at issue in *Continental Can* claimed a

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54. See *Altas Powers*, 190 F.3d at 1347.

55. *Id.* at 1348.

56. 301 F.3d 1343 (Fed. Cir. 2002), cert. denied sub nom., Brassica Prot. Prods. LLC v. Sunrise Farms, 538 U.S. 907 (2003).

57. 192 F.3d 1362 (Fed. Cir. 1999).

58. 301 F.3d at 1345-47.

59. *Id.* at 1346.

60. *Id.* at 1350-51.

61. 192 F.3d at 1364, 1366.

62. *Id.* at 1366.

63. 948 F.2d 1264, 1268 (Fed. Cir. 1991).

64. See, e.g., *Toro v. Deere & Co.*, 355 F.3d 1313, 1320-21 (Fed. Cir. 2004) (commenting on the confusion over the interpretation of *Continental Can*); *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221, 1228 (Fed. Cir. 2002), vacated en banc, 314 F.3d 1299 (Fed. Cir. 2002) (holding that to prove inherency “it must be shown that the undisclosed information was known to be present in the subject matter of the reference”).

plastic bottle with hollow support ribs.<sup>65</sup> The prior art reference disclosed a bottle with support ribs but did not state that the ribs were “hollow”; nevertheless, the competitor provided expert testimony suggesting that the manufacturing process inherently produced hollow ribs.<sup>66</sup> Holding that it was improper to find invalidity based on the inherency doctrine, the Federal Circuit established a two-prong test for inherent anticipation: first, “evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference,” and second, the undisclosed feature must be “recognized by persons of ordinary skill.”<sup>67</sup>

*Continental Can* was followed by *Crown Operations International, LTD v. Solutia Inc.*<sup>68</sup> and *Rosco, Inc. v. Mirror Lite Co.*<sup>69</sup> In *Crown*, the challenger argued that if a prior art reference disclosed the same structure as the patent, then the resulting property (in this case, “two percent solar control reflectance”) was inherent.<sup>70</sup> The court declined to adopt the challenger’s approach and held that inherency could not be established if the “two percent” limitation was unrecognized in the prior art.<sup>71</sup> Similarly, in *Rosco*, the panel held that the inherency question was not based on whether a prior art process inherently resulted in a claimed invention, but whether one of skilled in the art would read the prior art as inherently disclosing the invention.<sup>72</sup>

### 3. EMI Group and Distinguishing Atlas Powder and Continental Can: Law of Nature Versus Undisclosed Physical Structure

In *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*,<sup>73</sup> the Federal Circuit articulated a distinction between *Atlas Powder* and *Continental Can*.<sup>74</sup> The patent in dispute in *EMI Group* claimed a metallic fuse for semiconductor chips that could be blown in a vapor-induced

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65. 948 F.2d at 1266.

66. *Id.* at 1266-68.

67. *Id.* at 1268; see, e.g., *AstraZeneca AB v. Mut. Pharm. Co.*, 278 F. Supp. 2d 491, 514 (E.D. Pa. 2003), *aff’d-in-part, rev’d-in-part, and remanded*, 384 F.3d 1333 (Fed. Cir. 2004) (stating that “certain Federal Circuit cases have referred to inherency as a two-prong determination”); Steven C. Carlson, *Inherent Anticipation*, 40 IDEA 297, 300-01 (2000) (stating that *Continental Can* established a two-prong test to determine inherency).

68. 289 F.3d 1367 (Fed. Cir. 2002).

69. 304 F.3d 1373 (Fed. Cir. 2002).

70. 289 F.3d at 1377.

71. *Id.* at 1378.

72. 304 F.3d at 1381.

73. 268 F.3d 1342 (Fed. Cir. 2001).

74. *Id.* at 1350-51.

step.<sup>75</sup> The prior art fuses had the same structure but did not include “vapor-induced explosion” in the claims.<sup>76</sup> The court found that the “vapor-induced explosion” was a “scientific explanation” on how the prior art fuses had functioned, and such theoretical explanation was inherent.<sup>77</sup> To reconcile *Continental Can* and *Atlas Powder*, the court stated that the requirement that persons of ordinary skill recognize the missing descriptive matter “may be sensible for claims that recite limitations of structure, compositions of matter, and method steps” to ensure that the undisclosed feature necessarily existed in the prior art.<sup>78</sup> In contrast, “[t]heoretical mechanisms or rules of natural law that are recited in a claim” were not patentable themselves and did “not need to be recognized by one of ordinary skill in the art for a finding of inherency.”<sup>79</sup> The panel gave a hypothetical example to illustrate the point: people had been using fires for thousand of years without knowing that oxygen was necessary for fire, and the first person to discover the oxygen could not patent “a method of making fire with oxygen.”<sup>80</sup>

Although *EMI Group*, to some extent, harmonized the apparent conflicts between *Continental Can* and *Atlas Powder*, the panel did not explicitly endorse the view that recognition should be required where an inherent feature is a physical structure or a method step.<sup>81</sup> Instead, the panel merely stated that the recognition requirement “may be sensible” in *Continental Can* type of scenarios, while stopping short of ruling that future inherent anticipation cases should be decided on the physical structure versus law of nature dichotomy.<sup>82</sup> The tension between *Continental Can* and *Atlas Powder* was not fully resolved by *EMI Group* and caused significant confusion regarding what was the correct test for inherent anticipation analysis.<sup>83</sup>

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75. *Id.* at 1344-48.

76. *Id.* at 1350.

77. *Id.* at 1349-50.

78. *Id.* at 1350-51.

79. *Id.* at 1351.

80. *Id.* The apparent tension between *Atlas Powder* and *Continental Can* was also noted by Judge Pfaelzer in *ICN Pharmaceuticals, Inc. v. Geneva Pharmaceuticals Technology Corp.*, 272 F. Supp. 2d 1028 (C.D. Cal. 2003). Following *EMI Group*, Judge Pfaelzer held that the inherent feature in *ICN* appeared to be related to a law of nature, thereby distinguishable from *Continental Can*. *ICN Pharms.*, 272 F. Supp. 2d at 1051-52.

81. See *EMI Group*, 268 F.3d at 1350-51.

82. See *id.* (emphasis added).

83. See, e.g., *Toro v. Deere & Co.*, 355 F.3d 1313, 1320-21 (commenting on the confusion over the interpretation of *Continental Can*).

## II. CASE SUMMARY

The Federal Circuit resolved the conflicting interpretations of *Atlas Powder* and *Continental Can* in *Schering*, taking the position that one of ordinary skill in the art is not required to recognize an inherent feature in the prior art reference.<sup>84</sup> The court held that inherency does not depend on whether the subject matter was recognized in prior art, but on whether it was an “accidental” result “under unusual conditions,” or a “natural result flowing from the explicit disclosure of the prior art.”<sup>85</sup>

### A. Facts and Procedural History

Plaintiff Schering Corporation (“Schering”) is a pharmaceutical company and the owner of U.S. Patent Nos. 4,282,233 (“the ’233 patent”) and 4,659,716 (“the ’716 patent”), both covering antihistamine drugs.<sup>86</sup> Antihistamines inhibit the histamines that cause allergic symptoms.<sup>87</sup> The ’233 patent covers the antihistamine loratadine, the active component of Claritin®.<sup>88</sup> The ’716 patent, which is more recent, covers a natural metabolite of loratadine called descarboethoxyloratadine (DCL).<sup>89</sup> A metabolite is a compound formed in a person’s body upon ingestion of a pharmaceutical drug.<sup>90</sup> The parties did not dispute the fact that the ’233 patent expired in December 2002 and constituted “prior art” to the ’716 patent under 35 U.S.C. § 102(b).<sup>91</sup>

The defendants are pharmaceutical companies who sought to manufacture a generic version of Claritin as soon as the ’233 patent expired.<sup>92</sup> After reviewing the FDA-approved drugs and related patents, the defendants challenged the validity of the ’716 patent, and Schering filed suit for infringement.<sup>93</sup> Both parties brought summary judgment motions.<sup>94</sup>

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84. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378-79 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

85. *Id.* at 1378-79.

86. *Id.* at 1375; *see* U.S. Patent No. 4,659,716 (issued Apr. 21, 1987); U.S. Patent No. 4,282,233 (issued Aug. 4, 1981).

87. 339 F.3d at 1375.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 536 (D.N.J. 2002).

92. *Id.* at 536.

93. *Id.* at 536-37.

94. *Id.* at 535.

The parties agreed that both claims 1 and 3 of the '716 patent cover DCL regardless of its method of production, including metabolic conversion of loratadine into DCL in the human body.<sup>95</sup> It was also undisputed that as of February 15, 1984, the date on which Schering's '716 application was filed, one of ordinary skill in the art would not have recognized that administration of loratadine to humans necessarily resulted in the metabolic production of DCL.<sup>96</sup> Shortly thereafter, starting in 1985, research and clinical studies consistently characterized DCL as the "active circulating metabolite" or "primary metabolite" of loratadine in humans.<sup>97</sup>

The district court found claims 1 and 3 of the '716 patent invalid because the '233 patent inherently anticipated the claims.<sup>98</sup> The court found that there was no genuine issue of material fact that the consumption of loratadine by humans necessarily resulted in the natural production of DCL.<sup>99</sup> Although the natural and inevitable production of DCL upon human ingestion of loratadine was not fully appreciated by persons of ordinary skill in the field until after 1984, the process was nevertheless an "inherent characteristic or functioning" of the use of loratadine."<sup>100</sup> Schering appealed from the finding of invalidity.

## B. The Federal Circuit's Analysis

The Federal Circuit affirmed the district court's summary judgment of invalidity.<sup>101</sup> The court clarified the previous misinterpretation of *Continental Can* and held that inherency does not require recognition in prior art references.<sup>102</sup> In distinguishing *Schering* from *Tilghman* and *Eibel Process*, the court held that inherency is established as long as the claimed invention is a "natural result" flowing from the prior art disclosure.<sup>103</sup> In contrast, if the subject matter is an "accidental" result "under unusual circumstances," novelty is not defeated by the accidents.<sup>104</sup>

The Federal Circuit addressed four issues in *Schering*. First, the court unambiguously resolved the conflict between the two lines of Federal Circuit cases discussed in Part I, and rejected the notion that inherent

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95. *Id.* at 537.

96. *Id.* at 538.

97. *Id.* at 537-38.

98. *Id.* at 539.

99. *Id.* at 541.

100. *Id.* at 542.

101. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378-79 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

102. *Id.* at 1377-78.

103. *Id.* at 1378-79.

104. *Id.*

anticipation required recognition in the prior art.<sup>105</sup> The court noted that *Continental Can* had been misinterpreted—*Continental Can* only allows parties to resort to “the opinions of skilled artisans” to determine whether an inherent feature exists.<sup>106</sup> The court further stated that in *Continental Can*, the summary judgment on anticipation was vacated not because “past recognition of the inherent feature” was required, but because there were conflicting expert testimonies as to whether the feature was inherent.<sup>107</sup> In contrast, summary judgment on invalidity in *Schering* was proper because undisputed evidence supported the conclusion that DCL was formed “necessarily and inevitably” when loratadine was ingested.<sup>108</sup> In ruling so, the court also distinguished *Schering* from other “accidental anticipation” cases such as *Eibel Process* and *Tilghman*.<sup>109</sup> Unlike the DCL patent in *Schering*, the disputed inventions in *Eibel Process* and *Tilghman* were either unintended, accidental results or formed under unusual circumstances, and thus did not constitute anticipation.<sup>110</sup>

Second, the court acknowledged that *Schering* was a case of first impression because the prior art supplied no express description of “any part of the claimed subject matter,” whereas in previous cases, the prior art reference contained an incomplete description and inherency supplied the missing aspect.<sup>111</sup> However, the court saw no reason to limit the doctrine of inherency to gap-filling situations.<sup>112</sup> Because inherency places subject matter in the public domain, “the extent of the inherent disclosure does not limit its anticipatory effect.”<sup>113</sup> Therefore, inherency should operate to anticipate entire inventions as well as limitations within an invention.<sup>114</sup>

Third, the court held that an anticipatory reference need “only enable subject matter that falls within the scope of the claims at issue, nothing more.”<sup>115</sup> Since the '716 patent claims DCL in any form, to qualify as an enabling reference, the '233 patent need only describe how to make DCL

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105. *Id.* at 1377.

106. *Id.* at 1377-78.

107. *Id.*

108. *Id.*

109. *Id.* at 1378.

110. *Id.*

111. *Id.* at 1379.

112. *Id.*

113. *Id.*

114. *Id.* at 1380.

115. *Id.* at 1381.

in any form, including a natural metabolite in a patient's body.<sup>116</sup> Therefore, the '233 patent provides an enabling disclosure.<sup>117</sup>

Finally, the court provided guidance on patenting metabolites of known drugs in the future. The panel advised that "[w]ith proper claiming, patent protection is available for metabolites of known drugs."<sup>118</sup> Three examples of such claiming were given. First, a metabolite could be claimed in its pure and isolated form.<sup>119</sup> Second, the court suggested a claim to a metabolite in a pharmaceutical composition, such as a claim directed to a metabolite coupled to a pharmaceutical carrier.<sup>120</sup> Schering's patent included such claims, and the court noted that those claims were not anticipated.<sup>121</sup> Third, the court suggested including method claims directed to the utilization or administration of the metabolites or the corresponding pharmaceutical composition.<sup>122</sup> Again, Schering's '716 patent included claims like this and such claims were not anticipated by the '233 patent.<sup>123</sup>

### C. The Denial of *En Banc* Review

Dissenting opinions in the Federal Circuit's denial of *en banc* review raised issues as to whether *Schering* violates one of the established requirements for anticipation.<sup>124</sup> Judge Newman's dissent questioned whether the loratadine patent satisfied the enablement requirement for inherent anticipation of DCL.<sup>125</sup> Since the '233 patent did not mention DCL, Judge Newman found no precedent supporting the position that a product whose existence was previously unknown and was not in the prior art is unpatentable on the ground that it "existed undiscovered."<sup>126</sup> Judge Lourie's dissent pointed out that an enabling disclosure was clearly necessary for anticipation.<sup>127</sup> Judge Lourie argued that since the '233 patent did not identify or even mention any metabolite of loratadine, it was "hardly an enabling disclosure."<sup>128</sup> Judge Lourie found the *Schering*

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116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *See Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992 (Fed. Cir. 2003), denying *en banc* review to 339 F.3d 1373 (Fed. Cir. 2003).

125. *Id.* at 993-94 (Newman, J., dissenting).

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

127. *Id.* at 995-96 (Lourie, J., dissenting).

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

decision “extraordinary” because it “effectively preclud[ed] virtually all patents on human metabolites of drugs.”<sup>129</sup>

### III. DISCUSSION

Patents are awarded as incentives for innovations that “promote the Progress of Science and useful Arts.”<sup>130</sup> Without upfront investments, many inventions would not be developed.<sup>131</sup> Therefore, patent law gives inventors a limited period of exclusivity to recover their investments.<sup>132</sup> Upon the expiration of the patent term, the invention enters the public domain, and the public can freely make and use the invention.<sup>133</sup> Any attempt to extend the term of the monopoly after a patent expires runs counter to the policy and purpose of the patent laws.<sup>134</sup>

#### A. *Tilghman* Versus *Schering*: Incentives for Knowledge Accumulation or Protecting Public Domain Subject Matters?

The Supreme Court in *Tilghman* and *Eible Process* suggested that only deliberate, intended efforts constitute prior use.<sup>135</sup> The Court took a Lockean position that ownership is derived from labor: when a person mixes his labor with his creations, he enjoys the natural right of intellectual property.<sup>136</sup> The holdings are consistent with an important goal of the patent system—the accumulation of public knowledge.<sup>137</sup> In exchange for granting patent rights to the inventor who made the actual discovery of the inherent feature, the public gains new and useful knowledge.<sup>138</sup> The rationale of the “accidental anticipation” exception was summarized by the Third Circuit in *Edison Electric Light Co. v. Novelty Incandescent Lamp Co.*: an accidental achievement entitles “no

129. *Id.* at 995 (Lourie, J., dissenting).

130. See U.S. CONST. art. I, § 8, cl. 8; *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829).

131. See generally Katherine J. Strandburg, *What Does The Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 90-91.

132. See *id.*

133. See *Pennock*, 27 U.S. (2 Pet.) at 19.

134. *Brulotte v. Thys Co.*, 379 U.S. 29, 31 (1964).

135. See 1 CHISUM, *supra* note 5, § 3.03[2].

136. See ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 2-5* (3d ed. 2003). See generally Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 36-45 (1989) (discussing labor, natural intellectual property rights, and the Lockean provisos); Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 296-330 (1988) (discussing Locke’s property theory).

137. See *Pennock*, 27 U.S. (2 Pet.) at 19.

138. See *id.*

consideration” because it “[gives] *nothing to the world*, standing in the way of discovery, indeed, instead of promoting it.”<sup>139</sup> By granting patent rights to those who discovered the previously unrecognized information, the rule rewards deliberate inventive activities and provides incentives to study existing products or processes. On the other hand, an incentive-orientated rule might injure the rights of prior users. If the steam engine cited in *Tilghman* had indeed produced fatty acids thirty years before Tilghman’s invention, would it be fair for Tilghman to enjoin such use just because he was the first to discover how the fatty acids were actually produced?

In addition, the Court in *Tilghman* essentially promulgated a highly questionable, “subjective appreciation” test—whether the prior user (the operator) herself had understood the invention.<sup>140</sup> A subjective appreciation test would lead to great controversies and uncertainties. The patentability of many inventions would depend on the mental states and credibility of prior users. So even if we were to adopt a rule that requires prior appreciation, at minimum, the test should be objective, as the Federal Circuit in *Continental Can* articulated: the undisclosed feature should be “recognized by *persons of ordinary skill*.”<sup>141</sup>

*Schering*, on the other hand, reflected the Federal Circuit’s desire to strictly enforce the essence of the § 102 novelty requirement: non-removal of public domain subject matters.<sup>142</sup> Instead of harmonizing *Atlas Powder* and *Continental Can* on the “physical structure versus law of nature” distinction (as suggested in *EMI Group*), the court took a bright-line position that inherent anticipation does not require appreciation or recognition in prior art, as long as the disclosure is a “necessary and inevitable” consequence of the prior disclosures.<sup>143</sup> The outcome of *Schering* is consistent with the notion that after the expiration of a patent monopoly, the “discoveries embodied in them shall become a part of the public stock of knowledge.”<sup>144</sup> When Schering’s loratidine patent expired in 2002, it became public knowledge and other pharmaceutical companies should be free to make generic versions of Claritin. Had the Federal Circuit decided otherwise and held Schering’s DCL claim valid, all

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139. 167 F. 977, 980 (3d Cir. 1909) (emphasis added).

140. *Tilghman v. Proctor*, 102 U.S. 707, 711-12 (1881).

141. *Cont’l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (emphasis added).

142. See 35 U.S.C. § 102(a) (2000).

143. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1378-80 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

144. See *Beidler v. United States*, 253 U.S. 447, 453 (1920).

generic versions of Claritin would have inevitably infringed the DCL patent since (1) all patients taking generic loratidine will naturally produce DCL in their bodies as a metabolite, and (2) Schering's DCL claim is broad enough to encompass DCL in all forms, including metabolites produced in human bodies.<sup>145</sup> This would have effectively taken the expired loratidine patent out of the public domain and extended the patent term of loratidine until the DCL patent expires. If such practices were allowed, a patentee could potentially identify a series of metabolites of a known drug (for example, A is metabolized into B, then B into C, then C into D, and so on), and then strategically stagger the patent filings of A, B, C, and D, thereby significantly increasing the patent term of the original compound. From this point of view, *Schering* correctly prevented "unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about."<sup>146</sup>

Although the Federal Circuit distinguished *Schering* from *Tilghman* on "accidental" versus "inevitable" grounds,<sup>147</sup> the underlying policy considerations of *Tilghman*—incentives for knowledge accumulation and rewarding ingenuity—were not addressed by the *Schering* court. From this point of view, the two cases are not in complete harmony with each other. The incentive goal and the nonremoval-of-existing-subject-matter goal obviously clashed in *Schering*: denying patent protection on DCL discourages Schering scientists from disclosing a valuable discovery to the public, while granting patent protection on DCL allows Schering to take the expired loratidine patent out of public domain. A fair interpretation of *Schering* is that when the two goals cannot both be served, the need to protect public knowledge trumps the need to encourage beneficial discoveries and disclosures.

## **B. Is *Schering* Unfair to Those Who Discovered the Inherent Information?**

Although the *Schering* outcome may seem harsh to those who discovered an inherent feature of the prior art, it is important to note that not all discoveries enjoy equal rewards in the patent system. Courts have traditionally barred patent protection on certain categories of discoveries based on public policy.

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145. See, e.g., *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997) (holding that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes into the claimed metabolite).

146. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

147. *Schering*, 339 F.3d at 1378.

A classical example is that the discoverer of a new use of an old substance cannot obtain a product patent on the old substance, but only a process patent on the new use.<sup>148</sup> This rule holds true even if no use was previously known for the substance.<sup>149</sup> In *In re Hafner*, an old product (a resin) would have been useless without Hafner's discovery of how to use it;<sup>150</sup> nevertheless, the discovery of a new use did not make the resin patentable even when the prior art did not teach any use of the resin.<sup>151</sup> Some commentators have argued that the "new use patent" rule failed to produce optimal levels of either (1) research into new products or (2) research into new uses for old products because incentives were too great for the former and too weak for the latter.<sup>152</sup> Nevertheless, courts have firmly established the "new use patent" rule,<sup>153</sup> favoring the policy consideration of protecting public domain knowledge over the need to provide optimal incentives for research.<sup>154</sup> One can make a similar argument that after *Schering*, research on second-generation metabolite drugs will be discouraged because patent protection for metabolites is not as broad as the protection for original drugs. However, before a complete solution is found that optimally balances the incentives and the scope of property rights given to pioneering drugs and second-generation improvements, the *Schering* rule at least prevents patentees from manipulating the system to unfairly extend the terms of patent monopolies.

Courts have also traditionally limited patent protection on natural substances.<sup>155</sup> *General Electric Co. v. DeForest Radio Co.* highlights the judiciary reluctance to grant patents on naturally-occurring substances, regardless of the economic value of the discovery.<sup>156</sup> In *DeForest*, the patentee converted tungsten, a naturally-existing yet very brittle material, into "an entirely new metal" that was highly valuable for incandescent

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148. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 392-97 (3d ed. 2002).

149. See *In re Hafner*, 410 F.2d 1403 (C.C.P.A. 1969).

150. *Id.* at 1404-06.

151. *Id.*

152. See MERGES & DUFFY, *supra* note 148, at 393.

153. See, e.g., *Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 17 (1892) (holding that "it is no new invention to use an old machine for a new purpose"); *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (holding that "recitation of a new intended use for an old product does not make a claim to that old product patentable").

154. See MERGES & DUFFY, *supra* note 148, at 392-97.

155. See *id.* at 97.

156. 28 F.2d 641, 642 (3d Cir. 1928).

electric lamps.<sup>157</sup> The Third Circuit acknowledged that there was little doubt that the discovery led to a “tremendous” technological advance.<sup>158</sup> Nevertheless, the court invalidated the product patent on pure tungsten because pure tungsten “existed in nature and doubtless has existed there for centuries.”<sup>159</sup> To some extent, one can argue that the discovery of DCL in *Schering* is similar to the discovery of pure tungsten in *DeForest*. DCL was naturally produced by patients who took Claritin. Although DCL was identified several years after Claritin was marketed, no one can deny that DCL existed as early as the time when the first Claritin pills became available.

Many additional examples can be found in which a discovery, albeit highly valuable and clearly enriching the public knowledge, is denied patent protection.<sup>160</sup> Although sometimes it seems unfair that the patent system rewards some discoverers’ labor and investments but not others’, the ultimate goal of patents is to promote advances in science and art.<sup>161</sup> Therefore, patent protection should be denied if granting a patent will unreasonably stifle competition, extend monopolies, or remove existing knowledge from public use.

### C. Implications of *Schering* for the Pharmaceutical Industry

If a metabolite of a drug indeed works better than the original compound,<sup>162</sup> would *Schering*’s bright-line rule discourage companies like Schering from future metabolite research because they could no longer secure patent protection on inherent subject matter? Or, would other pharmaceutical companies step in so that metabolites would be discovered sooner rather than later because that subject matter is in the public domain? Although the full effect of *Schering* is hard to predict, a reality check of the pharmaceutical industry indicates that *Schering* is unlikely to have any significant impact on metabolite research.

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157. *Id.*

158. *Id.* at 644.

159. *Id.* at 643.

160. See *Parker v. Flook*, 437 U.S. 584, 589 (1978) (holding that a “principle” or “fundamental truth” is unpatentable); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (holding that prohibited categories include phenomena of nature, mental processes, and abstract intellectual concepts). See generally *MERGES & DUFFY*, *supra* note 148, at 77-128 (discussing the bar to patenting “laws of nature, physical phenomena, and abstract ideas”).

161. See U.S. CONST. art. I, § 8, cl. 8.

162. In fact, Schering-Plough regards DCL, marketed as Clarinex®, as a “new and improved version” of Claritin®. See, e.g., Rita Rubin, *Claritin to Go OTC Next Spring, Clarinex to Replace It*, USA TODAY, Apr. 23, 2002, at D11, available at <http://www.usatoday.com/news/health/drugs/2002-04-23-claritin.htm>.

### 1. *Patenting Metabolites of Known Drugs in the Future*

It should be clear that the invalidity of a metabolite patent based on inherency requires a dual footing.<sup>163</sup> First, the prior art compound must necessarily produce the metabolite.<sup>164</sup> Second, the claim must be sufficiently broad to encompass the naturally-produced form of the metabolite.<sup>165</sup> In fact, in an effort to encourage future research on drug products, the *Schering* court went out of its way to provide guidance on obtaining valid metabolite patents.<sup>166</sup>

Most importantly, a metabolite could be claimed in its pure and isolated form.<sup>167</sup> The allowance of purified metabolite claims echoes the “product of nature” doctrine established in *Parke-Davis v. E.K. Mulford Co.*,<sup>168</sup> in which purified adrenaline extracted from adrenal glands was held patentable.<sup>169</sup> Judge Hand concluded in *Parke-Davis* that purified adrenaline did not exist in nature, and was “for every practical purpose a new thing commercially and therapeutically.”<sup>170</sup>

The same rule applies to artificial compounds as well. In *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, the Seventh Circuit held that aspirin purified from a mixture was patentable, even if aspirin was previously known to exist in that mixture.<sup>171</sup> Thus, it is more accurate to say that the *Schering* court did not invalidate all metabolite patents, but instead would only allow a narrower scope of patent protection on metabolites and treat metabolites of known drugs as if they were natural products or previously-existing, unpurified compounds.

The valid metabolite claims suggested by the *Schering* court could all be explained on enablement grounds. An enabling disclosure is necessary for inherent anticipation.<sup>172</sup> While naturally-produced DCL within the human body was enabled by the earlier loratidine patent (merely by taking Claritin pills), the purified form of DCL or the method of administration were clearly unanticipated since DCL was not even discovered when the

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163. *Schering Corp. v. Geneva Pharms, Inc.*, 339 F.3d 1373, 1376, 1379-80 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

164. *Id.* at 1380.

165. *Id.* at 1376, 1380.

166. *Id.* at 1381.

167. *Id.*

168. 189 F. 95, 102-04 (S.D.N.Y. 1911).

169. *Id.* at 103.

170. *Id.*

171. 179 F. 701, 704-05 (7th Cir. 1910).

172. *Schering Corp. v. Geneva Pharms, Inc.*, 339 F.3d 1373, 1376, 1379-80 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

loratidine patent was filed. Therefore, although the Federal Circuit dropped the recognition requirement in *Schering*, most metabolite patent claims that require deliberate human intervention (such as purification steps or method of administration) will not be invalidated by inherency.<sup>173</sup> Thus, as a result of the enablement requirement of inherency, metabolite drugs will still enjoy a wide range of patent protection; in most cases, only the naturally-produced forms found in the human body cannot be protected.

## 2. *Potential Impact on Research Incentives for Metabolites of Existing Pharmaceutical Drugs*

Considering that it takes on average twelve to fifteen years to discover and develop a new medicine,<sup>174</sup> including approximately eight and a half years to obtain the Food and Drug Administration (FDA) approval,<sup>175</sup> it is still advantageous for a brand-name drug company to engage in metabolite research. The FDA approval process for new drugs involves three clinical trial phases and a period of FDA review.<sup>176</sup> On average, brand-name manufacturers spend \$400 million to \$500 million on each drug that survives the approval process.<sup>177</sup> In contrast, second-generation metabolite drugs are significantly cheaper to bring to the market since the FDA approval process is shorter and the patentee has already accumulated large amounts of research and clinical trial data from the original pioneer drug.<sup>178</sup> A 2002 National Institute for Health Care Management (“NIHCM”) study shows that from 1989 to 2000, highly innovative drugs

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173. In addition, merely naming a compound in a prior art reference, without more, does not satisfy the enablement requirement of an anticipatory reference under 35 U.S.C. § 102. See *In re Wiggins*, 488 F.2d 538, 543 (C.C.P.A. 1973) (holding that a list of compounds by name “constituted nothing more than speculation about their potential or theoretical existence” because naming a compound alone was not enough to enable one skilled in the art to make the compound).

174. PHARM. RESEARCH & MFRS. OF AM., WHY DO PRESCRIPTION DRUGS COST SO MUCH . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINES 2-3 (2000), at <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf>.

175. Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 96-98 (2002).

176. *Id.* at 92-98.

177. *Id.* at 98, 103. The entry barrier for a new drug is incredibly high. Brand-name companies once stated that every year, scientists screen more than 126,000 chemicals for potential drug development, while only sixteen will ever make it through the regulatory process and eventually appear in the pharmacy. *Id.* at 103.

178. See, e.g., Martha Slud, *New Tricks for Old Drugs? Pharmaceutical Makers Study How to Extend the Life of Blockbuster Drugs*, CNNMONEY.COM, Nov. 8, 2000, at <http://money.cnn.com/2000/11/08/companies/olddrugs>.

comprised only 15 percent of the pharmaceutical drugs approved by the FDA, while the vast majority of approved drugs were in fact modified versions of existing drugs.<sup>179</sup> Therefore, despite the weaker patent protection on metabolite drugs, companies still have a strong incentive to engage in second-generation drug research. In fact, Schering's Clarinex® (with DCL as the active ingredient) accounted for \$600 million in sales in 2002.<sup>180</sup>

Nevertheless, some commentators argued that after *Schering* metabolite patents may no longer have significant value.<sup>181</sup> For example, one commentator stated:

[A]ssume a pioneer company is developing compound A, a compound that is metabolized in the body to form active compound B. . . . [The *Schering*] outcome raises the real risk that a competitor could design a novel, non-obvious parent compound, for example compound C, that is also metabolized to form active compound B; this could be done even during the patent term of compound A. Before *Schering*, such design around activity could have been prevented by the filing of patents covering active metabolites.<sup>182</sup>

This scenario will probably be extremely rare for several reasons. First, with the Research and Development (R&D) data accumulated from compound A and metabolite B, the brand-name company is in a better position to identify and market the hypothetical compound C than its competitors. Second, competitors might be reluctant to risk R&D resources searching for compound C because a prolonged and expensive lawsuit is almost inevitable. Finally, identifying a "novel, non-obvious" compound C might not be as easy as it appears in the above example. Some minor changes in chemical structure could significantly change the pharmaceutical property of a drug. For example, although D-Amino Acids and L-Amino Acids are almost identical,<sup>183</sup> the human body can only utilize L-Amino Acids. Making a "non-obvious" modification from B to C

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179. *Pricey Copycat Drugs Bring Big Profits, Not New Cures*, USA TODAY, May 31, 2002, at A11, available at <http://www.usatoday.com/usatoday/20020531/4156073s.htm>.

180. Zeke Ashton, *Schering-Plough's Tough Row*, Motley Fool, Sept. 12, 2003, at <http://www.fool.com/news/commentary/2003/commentary030912za.htm>.

181. *Schering Corp. v. Geneva Pharm. et al.*, Mayer, Brown, Rowe & Maw LLP, at [http://www.ipcounsel.com/recent/schering\\_v\\_geneva.html](http://www.ipcounsel.com/recent/schering_v_geneva.html) (last visited Mar. 8, 2005).

182. *Id.*

183. D-Amino Acid and L-Amino Acid are identical in atom composition, but are mirror-images of each other, just like left and right hands. See generally LUBERT STRYER, *BIOCHEMISTRY* 18-23 (4th ed. 1995).

might render C poorly absorbable, or more toxic, or with a shorter effective time. Treasure hunting for a hypothetical compound C could turn out to be expensive and futile, with resources spent on compounds that never make a profit. Competitors might be better off simply waiting for the compound A patent to expire.<sup>184</sup> Taking all these risk factors into consideration, *Schering* is unlikely to significantly reduce the value of metabolite patents.

#### **D. The “Necessary and Inevitable Consequence” Test Should Be Strictly Applied in Determining Inherent Anticipation**

Although *Schering* has clarified the confusion over the recognition requirement in prior art references and provides clear guidance for future cases, the bright-line rule it promulgates runs the risk of unfairly depriving inventors of their property rights for valuable discoveries. Therefore, the “necessary and inevitable consequence” test should be strictly applied in determining whether a patent claim is inherently anticipated by prior art.

##### *1. Distinguishing Between “Scientific Explanation” and “Structures or Method Steps”*

The Federal Circuit in *EMI Group* articulated an interesting distinction between (1) a structure, compositions of matter, and method steps and (2) theoretical mechanisms or rules of natural law, and suggested that these two categories of inherency cases might be treated differently.<sup>185</sup> Although the *Schering* court ignored this distinction, categorizing inherent features into these two groups may sometimes help courts determine whether the challenged claims satisfy the “necessary and inevitable” test laid out in *Schering*.

When the undisclosed or unrecognized feature is method steps or a structural component of a machine, there is a significant risk that people skilled in the art will not be able to achieve the same result each time. They might miss some steps or fail to utilize the structural component,

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184. The Hatch-Waxman Act, codified in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271(e), has made the FDA approval process easier for generic drugs by creating the Abbreviated New Drug Application (ANDA). Generic drug companies only need to prove that their drug is a bioequivalent to the corresponding brand-name drug, and the active ingredient, dosage form, strength, and route of administration are the same as the FDA-approved brand-name drug. Thus, the approval process is much cheaper, shorter, and less in depth compared with the FDA process of a new chemical. See 21 U.S.C. § 355(j) (2000). See generally Miller, *supra* note 175, at 98-102.

185. *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350-51 (Fed. Cir. 2001).

rendering the results unpredictable. *Tilghman*,<sup>186</sup> *Eibel Process*,<sup>187</sup> and *Continental Can*<sup>188</sup> all fall into this category. In *Tilghman*, the claimed invention was a process patent that produced glycerin and fatty acids.<sup>189</sup> Without recognizing the necessary steps and conditions of the process, it would be impossible to consistently reproduce the result. Similarly in *Eibel Process*, a high-pitched wire was necessary for the improved paper-making machine.<sup>190</sup> Without recognizing the required pitch for the wire, the public would not have been able to derive the benefit of the invention. Finally, in *Continental Can*, an indispensable feature of the invention was the “hollow” support ribs, which rendered the bottles flexible and impact-resistant.<sup>191</sup> With this category of cases, because the unrecognized features could easily be missed by others, the prior art reference should be carefully scrutinized to ensure that it indeed “necessarily and inevitably” anticipates the disputed claims. Recognition of the inherent feature might as well be required in most cases in order to pass the “necessary and inevitable” test.

On the other hand, if a claim merely recites a scientific explanation, a theoretical mechanism, or an unrecognized advantage of a prior art, inherency is usually established. *Titanium Metals*<sup>192</sup> and *Cruciferous*,<sup>193</sup> discussed in Part I, are examples of this category of cases. As early as 1916, the Second Circuit already made a distinction between unappreciated scientific theories and unappreciated processes in *Tilghman*, and held that failing to recognize scientific principles did not “vitate the patent.”<sup>194</sup> Similarly, in *EMI Group*, inherency was established because “vapor-induced explosion” was a scientific explanation of how the prior

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186. *Tilghman v. Proctor*, 102 U.S. 707 (1881).

187. *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923).

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

189. 102 U.S. at 708-09.

190. 261 U.S. at 52, 58.

191. 948 F.2d at 1266.

192. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

193. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002), *cert. denied sub nom.*, *Brassica Prot. Prods. LLC v. Sunrise Farms*, 538 U.S. 907 (2003).

194. *Toch v. Zibell Damp Resisting Paint Co.*, 233 F. 993, 995, 997 (2d. Cir. 1916). The Second Circuit followed *Tilghman*'s ruling, stating that “novelty is not negated by a prior accidental production of the same thing when the operator does not recognize the means by which the accidental result is accomplished, and no knowledge of them, or of the method of their employment, is derived from the prior use by any one.” *Id.* at 995. But, the court distinguished *Toch* from *Tilghman* on the “scientific principle ground”: “[i]t may be that the inventor did not know what the scientific principle was, or that, knowing it, he omitted, from accident or design, to set it forth. That does not vitiate the patent.” *Id.* at 997 (citation and internal quotation marks omitted).

art fuses were blown.<sup>195</sup> Likewise, in *Cruciferous*, the anti-cancer activity was a scientific explanation of the result of eating the sprouts.<sup>196</sup> Other cases have also established that certain properties, such as solubility and melting points of chemical compounds<sup>197</sup> and overall capacitance of semiconductor circuitry,<sup>198</sup> are inherent physical characteristics of prior inventions.

In *Eli Lilly & Co. v. Barr Laboratories*, the Federal Circuit invalidated an anxiety-treatment claim because it was “a natural biological activity” upon the administration of the medicine.<sup>199</sup> Here, the prior art reference was a method claim for “treating anxiety in a human by administering an effective amount of fluoxetine hydrochloride,” and the disputed claim covered a method of “blocking the uptake of serotonin by brain neurons . . . by administering the compound fluoxetine hydrochloride.”<sup>200</sup> The panel found that because inhibition of serotonin uptake by the brain naturally occurs in the human body upon taking fluoxetine hydrochloride, the latter claim merely described how fluoxetine hydrochloride would physically act on patients who received the drug.<sup>201</sup> Therefore, the latter claim was invalid.<sup>202</sup>

The above examples illustrate that when an inherent feature is a scientific explanation, a theoretical mechanism, or an unrecognized advantage of a prior invention, those of ordinary skill in the art can practice the invention and reach the same result without understanding the scientific theory behind the invention. A person taking aspirin will get pain relief whether she understands the pain relieving mechanism or not, so it does not make any sense to grant a new patent on “a pain relieving method by taking aspirin through X mechanism.”<sup>203</sup> Therefore, in this line of cases, recognition of the inherent feature (that is, the scientific theory

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195. *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349-50 (Fed. Cir. 2001).

196. 301 F.3d at 1345-47.

197. *In re Donohue*, 766 F.2d 531, 534 (Fed. Cir. 1985) (holding that solubility characteristics and melting point range are inherent).

198. *Hazani v. United States Int'l Trade Comm'n*, 126 F.3d 1473, 1477 (Fed. Cir. 1997) (holding that a device, although not termed as “capacitor,” inherently performs capacitor function).

199. 251 F.3d 955, 968-70 (Fed. Cir. 2001).

200. *Id.* at 968-69.

201. *Id.* at 970-71.

202. *Id.* at 971.

203. *See Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1234 (Fed. Cir. 1994) (Lourie, J., dissenting-in-part). This example was cited by the majority in *Eli Lilly*, 251 F.3d at 971.

explaining the invention) is usually not needed to pass the “necessary and inevitable consequence” test.

It is conceivable that many cases fall in between and are neither clear-cut “missing steps or physical structures” cases nor “missing scientific explanation” cases.<sup>204</sup> It is unnecessary to pigeonhole each and every inherency case into one of the two categories since the purpose of distinguishing one line from the other is to facilitate courts in determining whether the disputed invention is an inevitable result of prior art. The ultimate test still rests on whether the inherent feature “necessarily and inevitably” existed before, not whether it is a scientific explanation or a structural component. In cases where the alleged inherent information is difficult to characterize, inherent anticipation should only be found when there is an absolute certainty that the missing feature was present in prior art.

## 2. *Cases Following Schering Generally Applied the “Necessary and Inevitable Consequence” Test Strictly*

Since the *Schering* decision in August 2003, several cases have followed the inherency doctrine established in *Schering*.<sup>205</sup> A quick review of these recent cases shows that courts have generally applied the “necessary and inevitable consequence” test strictly, indicating that even if *Schering* indeed creates some disincentives for inventors, its impact is rather limited.

In *Glaxo Group v. Teva Pharmaceuticals USA, Inc.*, the district court held that treating migraines with a compound called ondansertron did not inherently anticipate treating nausea and vomiting by the same drug.<sup>206</sup> The court found that although nausea and vomiting were the most common symptoms of migraines, the record showed that only ninety

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204. For example, it is hard to characterize the inherent feature in *Atlas Powder*. On its face, the missing ingredient in the prior art references (entrapped air) fits into the “missing physical component” category. However, the court found the entrapped air inherent based on a calculation of the percentage of the water-in-oil emulsion and the solid constituent. With 40% emulsion and 60% solid constituent, the air must have been entrapped. This calculation seems closer to a “scientific theory.” See *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d, 1342, 1348-49 (Fed. Cir. 1999).

205. See *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004); *Glaxo Group Ltd. v. Teva Pharms. USA, Inc.*, No. C.A. 02-219 GMS, 2004 WL 1875017, at \*19 (D. Del. Aug. 20, 2004); *AstraZeneca AB v. Mut. Pharm. Co.*, 278 F. Supp. 2d 491, 515 (E.D. Pa. 2003), *aff’d-in-part, rev’d-in-part, and remanded*, 384 F.3d 1333 (Fed. Cir. 2004); *Oakwood Labs., L.L.C. v. Tap Pharm. Prods.*, No. 01 C 7631, 2003 WL 22400759, at \*23 (N.D. Ill. Oct. 21, 2003).

206. *Glaxo*, 2004 WL 1875017, at \*18-\*20.

percent of migraine patients also suffered from nausea.<sup>207</sup> Because the other ten percent of migraine sufferers did not experience nausea and vomiting, the court found that the relief for nausea and vomiting was not a necessary consequence of the administration of ondansetron to treat migraines.<sup>208</sup>

Additionally, in *Toro Co. v. Deere & Co.*, the Federal Circuit held that the defendant Deere failed to make the requisite factual showing for summary judgment of inherent anticipation, because the evidence was insufficient to show that a prior art embodiment “necessarily” performed the claimed function.<sup>209</sup> The patent in dispute in *Toro* covered technology for lifting and fracturing soil to encourage turf growth by injecting incompressible liquid into the soil at a jet pressure.<sup>210</sup> Although the prior art embodiments and the claimed invention had several overlapping parameters, the court found that Deere failed to raise a genuine issue of material fact regarding whether the prior art embodiment always performed the function of “lifting and fracturing soil to encourage turf growth.”<sup>211</sup> Therefore, inherency was not established.<sup>212</sup>

These recent decisions indicate that although the Federal Circuit adopted a bright-line rule after *Schering*, the “necessary and inevitable” bar significantly limits any potential chilling effect on further research of existing technologies.

#### IV. CONCLUSION

*Schering* resolved a split within the Federal Circuit and held that inherent anticipation does not require recognition in prior art references.<sup>213</sup> The decision, that an inherent feature of a prior art always anticipates even if the inherent feature was unappreciated by those skilled in the art, denies patent protection on new discoveries that merely spell out or explain what had implicitly existed in prior art.<sup>214</sup> The inherency doctrine established in *Schering* is probably not in complete harmony with earlier Supreme Court decisions in *Tilghman*<sup>215</sup> and *Eibel Process*,<sup>216</sup> which focused on

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207. *Id.* at \*19.

208. *Id.*

209. 355 F.3d 1313, 1320 (Fed. Cir. 2004).

210. *Id.* at 1314.

211. *Id.* at 1320.

212. *Id.*

213. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1371, 1378-80 (Fed. Cir.), *review en banc denied*, 348 F.3d 992 (Fed. Cir. 2003).

214. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

215. *Tilghman v. Proctor*, 102 U.S. 707, 711-12 (1881).

“secur[ing] to the inventor the reward he deserves” if the invention had advanced the art.<sup>217</sup> Nevertheless, to preserve the bargain carefully established by the patent system, the Federal Circuit expanded the inherency doctrine in *Schering* by eliminating the recognition requirement, ensuring that knowledge already in the public domain “remain[s] there for the free use of the public.”<sup>218</sup> In reality, the *Schering* decision is unlikely to have a significant impact on metabolite research because of the high cost of developing new drugs in the pharmaceutical industry.<sup>219</sup> Outside the pharmaceutical setting, it is possible that *Schering* discourages knowledge accumulation on existing technologies to some extent. However, as long as courts strictly apply the “necessary and inevitable consequence” test, the chilling effect of *Schering* on research and development should be quite limited. In most cases, inherent anticipation would only invalidate claims that merely recite scientific explanations of preexisting subject matters.

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216. *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 66 (1923).

217. *Id.* at 63.

218. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979).

219. *See Miller*, *supra* note 175, at 96-98.

