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## THE ACCIDENTAL AND INHERENT ANTICIPATION DOCTRINES: WHERE DO WE STAND AND WHERE ARE WE GOING?

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### ABSTRACT

It is often unclear when a prior occurrence or disclosure of a claimed invention falls under the patent law doctrines of inherent or accidental anticipation. Courts have applied various tests in determining whether anticipation is inherent or accidental, and the cases are difficult to reconcile. Tests seemingly dispositive to establish an accident in one case may also appear dispositive to establish inherency. As a result of our analysis, we have developed a two-step test that can be used to reconcile the two doctrines and determine whether a product or process anticipates. The first prong is concerned with whether the prior process or composition was useful in the art. If the answer to the first prong is no, then the anticipation is accidental; if the answer is yes, the second prong is whether the process or composition occurred under unusual conditions or occasionally. If the answer to the second prong is no, then the anticipation is inherent; if the answer is yes, then the anticipation is accidental. This test helps resolve the confusion about inherent and accidental anticipation while remaining consistent with Supreme Court, Federal Circuit and CCPA decisions.

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THE ACCIDENTAL AND INHERENT ANTICIPATION DOCTRINES:  
WHERE DO WE STAND AND WHERE ARE WE GOING?

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INTRODUCTION

It is well-known in patent law that a prior reference can defeat patentability under 35 U.S.C. § 102 by expressly disclosing all of the elements of a claimed invention. It is also well-known that a prior reference can defeat patentability under the statute without having to expressly disclose all of the elements in the claim.<sup>1</sup> The elements may simply inhere in a disclosed composition or process. This latter type of reference is said to anticipate the claimed invention under the doctrine of “inherent anticipation.”<sup>2</sup>

The prior occurrence of a process or composition can anticipate a claim under this doctrine because of elements that simply inhere in the process or composition even if these elements were not recognized at the time of the prior occurrence. Inherent elements include components or properties of a composition and steps, mechanisms of action, or results of a process. To establish a case of inherent anticipation, the process or composition or element thereof must have existed or occurred to a certainty (i.e., not possibility or probability).<sup>3</sup>

There have been instances, however, in which a prior process or composition inherently met all of the limitations of a claim, but where a court decided that the doctrine of inherent anticipation did not apply (i.e., the claim was not anticipated). In these cases, the courts have rationalized the prior art as “accidental.” This has come to be known among patent practitioners as the doctrine of “accidental anticipation.” “Accidental anticipation” is somewhat of a misnomer because under this doctrine the prior art does not, in fact, anticipate under 35 U.S.C. § 102.

As demonstrated by the recent Federal Circuit cases *Schering Corp. v. Geneva Pharmaceuticals, Inc.*<sup>4</sup> and *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research*,<sup>5</sup> it is often unclear when an inherent prior occurrence or disclosure falls under the doctrines of inherent anticipation or accidental anticipation. Courts have not clearly defined what constitutes “accident.” Instead, courts seem to have relied on specific factual criteria. Additionally, courts have applied various tests in determining whether anticipation is inherent or

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<sup>1</sup> See *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”).

<sup>2</sup> *Verdegaal Brothers*, 814 F.2d at 631.

<sup>3</sup> *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999).

<sup>4</sup> 339 F.3d 1373 (Fed. Cir. 2003).

<sup>5</sup> 346 F.3d 1051 (Fed. Cir. 2003).

accidental, and the cases are difficult to reconcile. Tests seemingly dispositive to establish an accident in one case may also appear dispositive to establish inherency.

In this paper, we propose a way to decide which of the two doctrines applies when all of the limitations of a claim inhere in a prior composition or process. We organized various cases on the basis of the outcome: if the court found that the invention was not anticipated, the case was placed under the “Accidental Anticipation” rubric; if the court found that the invention was anticipated, the case was placed under the “Inherent Anticipation” rubric. After each case description, potential tests (explicit and implicit) are distilled. The tests are then applied to each discussed case to ascertain whether any of the tests apply to one doctrine but not the other.

As a result of our analysis, we have developed a two-step test that can be used to reconcile the two doctrines and determine whether a product or process anticipates. The first question is whether the prior product or process was useful for any purpose. If not, the process or product does not anticipate. If the product was useful, the second question is whether the product was obtained or the process occurred under unusual conditions. If the answer is yes, then the prior process or product does not anticipate. We believe that this test helps resolve the confusion about inherent and accidental anticipation while remaining consistent with Supreme Court, Federal Circuit and CCPA decisions.

## I. TESTS APPLIED BY COURTS

Courts have applied multiple tests in their anticipation analyses under varying fact patterns. Prior to discussing the various tests and the current direction of the Federal Circuit, a brief analysis of the cases and potential tests must be undertaken. In the following sections, cases where a process was at issue are discussed first, and then followed by cases dealing with compositions of matter. Each of these sections is subdivided into accidental and inherent anticipation sections.

### *A. Processes*

#### *1. Accidental Anticipation*

##### *a. Tilghman v. Proctor*

*Tilghman* is the seminal case for accidental anticipation. The invention was a process for producing free fatty acids by subjecting triglycerides to high heat and pressure in the presence of water, which resulted in a glycerin backbone and undamaged free fatty acids.<sup>6</sup> The defendants sought to invalidate the patent by submitting evidence of the method’s existence prior to the patentee’s discovery.<sup>7</sup> The

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<sup>6</sup>Tilghman v. Proctor, 102 U.S. 707, 712–13 (1880).

<sup>7</sup>*Id.* at 711–12.

prior process was a method for lubricating a piston with fat in a steam engine.<sup>8</sup> During operation of the steam engine, the process for producing free fatty acids was accidentally performed because fat, containing triglycerides, was subjected to high heat and pressure in the presence of water.<sup>9</sup> The defendants argued that free fatty acids would necessarily be produced and the patent in question must be anticipated.<sup>10</sup> The Supreme Court, however, found no anticipation.

In explaining why the prior existence of the process would not constitute anticipation, the Court assumed, for the sake of argument, free fatty acids were accidentally produced and the claimed process was accidentally performed in the prior art.<sup>11</sup> Notwithstanding the existence of the process, the Court reasoned that the process did not anticipate:

We do not regard the accidental formation of fat acid in Perkin's steam cylinder from the tallow introduced to lubricate the piston (if the scum which rose on the water issuing from the injection pipe was fat acid) as of any consequence in this inquiry. What the process was by which it was generated or formed was never fully understood. Those 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.<sup>12</sup>

The following potential accidental anticipation tests are derived from *Tilghman*:

- (1) The claimed process was unintended in the prior art
- (2) The claimed process was (assumed to be) a necessary consequence of an intentional act
- (3) The claimed process was unrecognized in the prior art
- (4) The prior art had a different purpose
- (5) The claimed process was not useful in the prior art

*b. In re Marshall*

In *Marshall*, the claims at issue were directed to a process for achieving weight loss by periodically administering an anesthetic prior to eating so as to contact nerve

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<sup>8</sup> *Id.* at 711.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 712.

<sup>11</sup> *Id.* at 711.

<sup>12</sup> *Id.* at 711–12.

endings that release pancreatic hormones necessary for digestion.<sup>13</sup> The following dependent claim is directed to the anesthetic oxethazaine: “A weight control process as claimed in claim 2 wherein: said anesthetic means is oxethazaine.”<sup>14</sup>

The prior art was the Physician’s Desk Reference, which prescribed oxethazaine to treat colitis, ulcers and other gastro-intestinal problems by dosing periodically prior to eating and at bedtime.<sup>15</sup> The court found no anticipation, reasoning as follows: “Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings, it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation.”<sup>16</sup>

The following potential accidental anticipation tests are distilled from *Marshall*:

- (1) The claimed process was intended in the prior art
- (2) The result of the claimed process was unintended in the prior art
- (3) The claimed process was recognized in the prior art
- (4) The result of the claimed process was not recognized in the prior art
- (5) The prior art had a different purpose
- (6) The claimed process was useful in the prior art

However, it should be noted that *Marshall* was cited only once by the Federal Circuit in connection with an accidental anticipation analysis, and the court’s reliance upon *Marshall* is unclear.<sup>17</sup>

### c. MEHL/Biophile International Corp. v. Milgraum

The claims at issue in *MEHL/Biophile* were directed to a process for hair removal by using a laser. The process destroys the papilla, the germ cells from which hair grows, thus inhibiting further hair growth.<sup>18</sup> The laser utilizes a wavelength absorbed by melanin (found in melanosomes at the root of hair follicles) and an exposure long enough to damage hair follicle papillae (where melanosomes are found) but not the surrounding skin.<sup>19</sup> The sole independent claim provides:

A method of hair depilation, comprising the steps of:

- a) aligning a laser light applicator substantially vertically over a hair follicle opening, said applicator having an aperture of sufficient area to surround a hair follicle and overlie its papilla;

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<sup>13</sup> *In re Marshall*, 578 F.2d 301, 302–03 (C.C.P.A. 1978).

<sup>14</sup> *Id.* at 302.

<sup>15</sup> *Id.* at 303.

<sup>16</sup> *Id.* at 304 (citing *In re Felton*, 484 F.2d 495, 500 (C.C.P.A. 1973)).

<sup>17</sup> *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

<sup>18</sup> *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1363, 1364 (Fed. Cir. 1999).

<sup>19</sup> *Id.*

b) applying through said aperture to the hair follicle a pulse of laser energy of a wavelength which is readily absorbed by the melanin of the papilla and having a radiant exposure dose of sufficient energy and duration to damage its papilla so that hair regrowth is prevented and scarring of the surrounding skin is avoided.<sup>20</sup>

To prove anticipation, the defendants introduced a laser instruction manual teaching tattoo removal.<sup>21</sup> Despite the defendants' argument that the manual inherently disclosed the claimed process, the court found no anticipation.<sup>22</sup>

The court stated that to anticipate, the reference would have to teach, either expressly or inherently, aligning the laser "substantially vertically" over hair follicles.<sup>23</sup> The court continued, noting that it is possible, or even probable, that a laser would be substantially vertically aligned over a hair follicle in the process of removing a tattoo.<sup>24</sup> However, the court concluded if something happens only occasionally it is not grounds for anticipation because "occasional results are not inherent."<sup>25</sup>

The following potential accidental anticipation tests are derived from *MEHL/Biophile*:

- (1) The claimed process occurred occasionally in the prior art
- (2) The claimed process was intended in the prior art
- (3) The result of the claimed process was unintended in the prior art
- (4) The claimed process was recognized in the prior art
- (5) The result of the claimed process was not recognized in the prior art
- (6) The prior art had a different purpose
- (7) The claimed process was useful in the prior art

## 2. Inherent Anticipation

### a. *Verdegaal Brothers, Inc. v. Union Oil Company of California*

In *Verdegaal Brothers*, the invention at issue was a process for making liquid fertilizer from urea and sulfuric acid.<sup>26</sup> Claim 1 is representative:

In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:

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<sup>20</sup> *Id.*

<sup>21</sup> *Id.* A second reference asserted by the defendants is discussed *infra* Part I.A.2.b.

<sup>22</sup> *Id.* at 1365.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

- (a) providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
- (b) adding water to the heat sink in an amount not greater than 15% of the end product,
- (c) adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
- (d) adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.<sup>27</sup>

The prior art clearly disclosed elements (b)-(d) of the above claim, and added all the components of (b)-(d) to previously reacted fertilizer in amounts that were inherently at least 5% of the end product.<sup>28</sup> However, Verdegaal argued that the prior art did not refer to, or recognize, the totally reacted fertilizer as a “heat sink” (element (a)).<sup>29</sup> The prior art used the totally reacted fertilizer for convenience – so it would not have to remove the old fertilizer – not to dissipate heat as the patentee suggested.<sup>30</sup> The court found that the claims were anticipated, stating:

In essence, Verdegaal maintains that because [the prior art] did not recognize the “inventive concept” that the heel functioned as a heat sink, [the prior art’s] process cannot anticipate. This argument is wrong as a matter of fact and law....Even assuming [the prior art] did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention.<sup>31</sup>

*Verdegaal Brothers* presents the following potential inherent anticipation tests:

- (1) A species of the claimed process was intended in the prior art
- (2) A species of the claimed process was recognized in the prior art
- (3) The prior art had the same purpose
- (4) The claimed process was useful in the prior art
- (5) A property of one of the components of the process was not recognized in the prior art

*b. MEHL/Biophile International Corp. v. Milgraum*

As discussed above, the claims at issue in *MEHL/Biophile* were directed to a process for hair removal using a laser. The laser destroys the papilla, germ cells from which hair grows, thus inhibiting further hair growth, but does not damage the

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<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 632.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* The court relied on column 7 of the specification of the Stoller prior art patent, U.S. Patent No. 4,315,763, beginning at line 30. *Id.*

<sup>31</sup> *Id.* at 633 (citing *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981); *In re Swinehart*, 439 F.2d 210, 212–13 (C.C.P.A. 1971)).

surrounding skin.<sup>32</sup> The defendants presented a reference disclosing studies of laser-induced damage to melanosome cells in Guinea pig skin.<sup>33</sup> The reference described using a laser to analyze the nature and extent of pigment cell injury and found that melanosomes were a primary target.<sup>34</sup> Based on the reference, which included a description of circular apertures resulting from laser pulses, the court stated, “the record shows that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings.”<sup>35</sup> The court reasoned hair follicles are inherently exposed to perpendicular application of the laser because Guinea pigs have so much hair.<sup>36</sup>

Therefore, the prior art necessarily practiced the limitations of the claims although it did not recognize the result, i.e., hair removal. The court took the position that hair removal occurred inherently, thus, the reference anticipated the claims.<sup>37</sup> The result was a necessary consequence of what was deliberately intended (melanosome destruction).<sup>38</sup>

The following potential tests are derived from the inherent anticipation analysis of *MEHL/Biophile*:

- (1) The claimed process was intended in the prior art
- (2) The result of the claimed process was unintended in the prior art
- (3) The claimed process was recognized in the prior art
- (4) The result of the claimed process was not recognized in the prior art
- (5) The prior art had a different purpose
- (6) The claimed process was useful in the prior art

*c. In re Cruciferous Sprout Litigation*

The claims at issue in *Cruciferous Sprout* were directed to a method for preparing food rich in glucosinolates by germinating the seeds of specific crucifers that when harvested before the two-leaf stage contain high levels of glucosinolates.<sup>39</sup> One of the claims reads, “A method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.”<sup>40</sup>

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<sup>32</sup> *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1364 (Fed. Cir. 1999); *see also supra* Part I.A.1.c.

<sup>33</sup> *Id.* at 1366.

<sup>34</sup> *Id.* at 1364.

<sup>35</sup> *Id.* at 1366.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 1367.

<sup>38</sup> *Id.* at 1366–67.

<sup>39</sup> *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1345 (Fed. Cir. 2002). The food was used to prevent cancer. *Id.*

<sup>40</sup> *Id.*

The prior art showed sprouts prepared from the claimed crucifers had been eaten for years.<sup>41</sup> However, it did not recognize the presence of glucosinolates.<sup>42</sup> The Federal Circuit noted the district court's explanation that "a plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature."<sup>43</sup> In finding the claims inherently anticipated, the Federal Circuit stated, "[w]hile [Plaintiff] may have recognized something quite interesting about those sprouts, it simply has not invented anything new."<sup>44</sup>

The court further stated that all the sprouts identified in the patent were in the public domain.<sup>45</sup> "The public remains 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>46</sup> The court quoted *MEHL/Biophile* for the principle that "[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art...[and] artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."<sup>47</sup>

*Cruciferous Sprout* presents the following potential inherent anticipation tests:

- (1) The claimed process was intended in the prior art
- (2) The claimed process was recognized in the prior art
- (3) The claimed property was not recognized in the prior art
- (4) The prior art had a different purpose
- (5) The claimed process was useful in the prior art

## *B. Compositions of Matter*

### *1. Accidental Anticipation*

#### *a. Eibel Process Co. v. Minnesota and Ontario Paper Co.*

The claims at issue in *Eibel Process* were directed to a machine for making paper.<sup>48</sup> Claim one reads:

A Fourdrinier machine, having [the end of the mesh] maintained at a substantial elevation above the level, whereby the stock is caused to travel

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<sup>41</sup> *Id.* at 1346.

<sup>42</sup> *See id.* at 1349–50.

<sup>43</sup> *Cruciferous Sprout*, 301 F.3d at 1351.

<sup>44</sup> *Id.* at 1346.

<sup>45</sup> *Id.* at 1351.

<sup>46</sup> *Id.* (quoting *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999)).

<sup>47</sup> *Cruciferous Sprout*, 301 F.3d at 1349.

<sup>48</sup> *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 46 (1923).

by gravity, rapidly in the direction of movement of the wire, and at a speed approximately equal to the speed of the wire, substantially as described.<sup>49</sup>

In the paper making machine, a mesh material formed a continuous treadmill around a set of rollers.<sup>50</sup> The wood-pulp slurry was fed at one end and moved along the mesh.<sup>51</sup> Liquid drained through the mesh, and then the ultimate paper precursor was delivered from the mesh rollers.<sup>52</sup> A problem with this process was that the paper precursor material contained ripples when it came off the mesh.<sup>53</sup> The patentees discovered that elevating the apparatus, such that the wire mesh was on an incline, equalized the pulp gravity flow with the roller speed.<sup>54</sup> This adjustment minimized ripples in the slurry.<sup>55</sup> The examples in the patent showed a substantial elevation.<sup>56</sup>

The prior art disclosed the same type of paper making machine having a somewhat elevated mesh.<sup>57</sup> However, the mesh was elevated in the prior art to improve drainage, not to minimize ripples.<sup>58</sup> The defendants pointed out that the thickness of the pulp could vary.<sup>59</sup> Therefore, to achieve equal pulp flow and roller speeds, the elevation would have to vary depending on the thickness of the pulp.<sup>60</sup> This meant that in some instances (e.g., thin pulp), achieving the desired results required utilizing a slight elevation, such as that in the prior art.<sup>61</sup>

The Court held the claims were not anticipated:

In administering the patent law the court first looks into the art, to find what the real merit of the alleged discovery or invention is and whether it has advanced the art substantially...In the case before us, for the reasons we have already reviewed, we think that Eibel made a very useful discovery, which has substantially advanced the art.<sup>62</sup>

. . . [I]n the first place we find no evidence that any pitch of the wire, used before Eibel, had brought about such a result as that sought by him, and in the second place, if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.<sup>63</sup>

From *Eibel Process*, the following potential tests are derived for accidental anticipation:

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<sup>49</sup> *Id.* at 50.

<sup>50</sup> *Id.* at 47.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 52.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 49–50.

<sup>57</sup> *Id.* at 58.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 59.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 63.

<sup>63</sup> *Id.* at 66 (citations omitted).

- (1) The claimed composition was intended in the prior art
- (2) The result the composition could achieve was unintended in the prior art
- (3) The claimed composition was recognized in the prior art
- (4) The result the composition could achieve was not recognized in the prior art
- (5) The prior art had a different purpose
- (6) The claimed composition was useful in the prior art
- (7) The composition of the prior art was an unusual embodiment of the claimed invention

*b. In re Seaborg*

The claims at issue in *Seaborg* were directed to Element 95, now known as Americium.<sup>64</sup> The inventors discovered this element and attempted to patent it.<sup>65</sup> The art applied against the claims was the Fermi process for producing uranium in a reactor, which inherently produces Americium.<sup>66</sup>

The Federal Circuit held there was no anticipation.<sup>67</sup> The court agreed with Appellant-Seaborg that the reactor could not have produced any more than “a billionth of a gram [of Americium],” which “would have been distributed throughout forty tons of intensively radioactive uranium reactor fuel.”<sup>68</sup> As Seaborg successfully argued, “this amount of an unknown unconcentrated isotope, if present, would have been undetectable.”<sup>69</sup>

If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation.<sup>70</sup>

*Seaborg* presents the following potential accidental anticipation tests:

- (1) The claimed composition was unintended in the prior art
- (2) The claimed composition was a necessary consequence of an intentional act
- (3) The claimed composition was not recognized in the prior art
- (4) The prior art had a different purpose
- (5) The claimed composition was not useful in the prior art

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<sup>64</sup> *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964).

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 996–97.

<sup>67</sup> *Id.* at 999.

<sup>68</sup> *Id.* at 997.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* (quoting *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 989 (2d Cir. 1942)).

c. *In re Felton*

The invention in *Felton* was a dropper/stirrer combination for testing blood samples.<sup>71</sup> The dropper/stirrer was constructed so it would take-up and dispense only one drop of liquid.<sup>72</sup> It could then be turned around by the handler and used as a stirrer.<sup>73</sup> Accordingly, it was a cylindrical item with an opening at one end and a flattened structure at the other end.<sup>74</sup> The circumference of the opening could vary to accommodate more or less viscous drops.<sup>75</sup> The prior art taught a medicine dispenser for insertion into a body cavity with a basic cylindrical structure containing a medicament, with one end sealed with wax and the other end flattened and scored to break off so that medication could be dispensed.<sup>76</sup>

The argument for invalidating the claim was that before the prior art medicine dispenser was sealed with wax and prior to scoring, it had an open end and a flattened end.<sup>77</sup> Therefore, this intermediate would be the same as some embodiments of the dropper/stirrer (for example, the dropper/stirrer used to dispense a viscous liquid).<sup>78</sup> In view of the purpose of the art, the prior art may have had an intermediate with a dropper size similar to the dropper size of the patented device.<sup>79</sup> The court found no anticipation, stating:

[W]e do not disagree with the Board's apparent conclusion that an intermediate structure made for the [prior art] could possess the characteristics called for in these claims. However, in view of the purpose for which the [prior art] was intended, it is apparent that it requires no critical dimension which would lead to a structure inherently having those characteristics. Therefore, it would be mere happenstance if any structure made according to [the prior art] met the limitations of the claims. An accidental or unwitting duplication of an invention cannot constitute an anticipation.<sup>80</sup>

From *Felton*, the following potential tests for accidental anticipation are derived:

- (1) The claimed composition was intended in the prior art
- (2) The result the composition could achieve was not intended in the prior art
- (3) The claimed composition was recognized in the prior art
- (4) The result the composition could achieve was not recognized in the prior art

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<sup>71</sup> *In re Felton*, 484 F.2d 495, 497 (C.C.P.A. 1973).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 498.

<sup>74</sup> *Id.* at 497.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 498.

<sup>77</sup> *See id.* at 500.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 499–500 (citing *Tilghman v. Proctor*, 102 U.S. 707 (1880); *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923)).

- (5) The prior art had a different purpose
- (6) The claimed composition was useful in the prior art
- (7) The composition of the prior art was an unusual embodiment of the claimed invention

## 2. *Inherent Anticipation*

### a. *Continental Can Co. U.S.A. v. Monsanto Co.*

The claims at issue in *Continental Can* were directed to a container with several specific features. Claim 1 is representative:

A container having a sidewall and a bottom structure closing the container at an end portion of the sidewall,  
the outer surface of the bottom structure comprising a central concavity, a convex heel surrounding the concavity and merging therewith and with the sidewall end portion, the lowermost points of the heel lying in a common plane,  
and a plurality of ribs interrupting the outer surface of the concavity and distributed in a symmetrical array,  
each rib extending longitudinally in the direction of the heel and downwardly from an inner portion of the concavity, whereby the outer end portion of each rib is lower than the inner portion thereof,  
*characterized by the feature that the ribs are hollow.*<sup>81</sup>

The limitation at issue is a bottom concavity of the container with an array of *hollow ribs* around the concavity.<sup>82</sup> The prior art taught the same limitation, except the ribs were not disclosed to be hollow.<sup>83</sup> However, one of the inventors of the prior art testified that because the ribs were made by the process of injection blow molding, they inherently would be hollow.<sup>84</sup>

The Federal Circuit vacated the summary judgment of anticipation and remanded so the district court could ascertain whether the ribs were hollow.<sup>85</sup> There was no decision on anticipation because of the factual dispute about whether the prior art process necessarily produced “hollow” ribs.<sup>86</sup> Nevertheless, the Federal Circuit noted that the reference would anticipate only if hollow ribs were necessarily present *and* a person of ordinary skill in the art would have recognized that the ribs were hollow.<sup>87</sup>

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<sup>81</sup> *Cont'l Can Co. U.S.A. v. Monsanto Co.*, 948 F.2d 124, 1266 (Fed. Cir. 1991) (emphasis added).

<sup>82</sup> *Id.* at 1267.

<sup>83</sup> *Id.* at 1268.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 1269.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.<sup>88</sup>

*Continental Can* suggests the following potential tests for inherent anticipation:

- (1) The claimed composition was intended in the prior art
- (2) The prior art recognized the claimed composition
- (3) The prior art had the same purpose
- (4) The claimed composition was useful in the prior art
- (5) The prior art may not have recognized a property of one of the components

*b. Atlas Powder Co. v. Ireco, Inc.*

The claims at issue in *Atlas Powder* are directed to a blasting composition with various components:

A blasting composition consisting essentially of 10 to 40% by weight of a greasy water-in-oil emulsion and 60 to 90% of a substantially undissolved particulate solid oxidizer salt constituent, wherein the emulsion comprises about 3 to 15% by weight of water, about 2 to 15% of oil, 70 to 90% of powerful oxidizer salt comprising ammonium nitrate which may include other powerful oxidizer salts, wherein the solid constituent comprises ammonium nitrate and in which sufficient aeration is entrapped to enhance sensitivity to a substantial degree, and wherein the emulsion component is emulsified by inclusion of 0.1 to 5% by weight, based on the total composition, of an [oil-in-water] water-in-oil emulsifier to hold the aqueous content in the disperse or internal phase.<sup>89</sup>

The limitation at issue is a composition with sufficient aeration (i.e., interstitial air) entrapped to enhance sensitivity (detonability) to a substantial degree.<sup>90</sup>

The prior art disclosed a blasting composition but did not recognize the presence of interstitial air, instead, advising to eliminate it.<sup>91</sup> However, there actually was sufficient interstitial air to meet the claim limitation of the allegedly infringed patent.<sup>92</sup> The court found the requirement of sufficient aeration was inherent in the prior art because the compositions described necessarily contained a sufficient

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<sup>88</sup> *Id.* at 1268.

<sup>89</sup> *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1344 (Fed. Cir. 1999).

<sup>90</sup> *Id.* at 1345.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 1346.

amount of air.<sup>93</sup> The court believed it was irrelevant that the prior art did not recognize that air may act as the sole sensitizer of the explosive composition.<sup>94</sup> Thus, the Federal Circuit held that the claims were anticipated.<sup>95</sup> In an extensive discussion on the rules of inherency, the court noted:

Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.<sup>96</sup>

The court analogized this case to *Titanium Metals Corp. v. Banner*.<sup>97</sup> There, the invention was a titanium alloy containing various ranges of nickel, molybdenum, iron and titanium, characterized by good corrosion resistance in hot brine environments.<sup>98</sup> The prior art reference disclosed the alloy but not the corrosion-resistant property.<sup>99</sup> The court affirmed that discovery of an inherent property of the alloy did not confer novelty to the alloy.<sup>100</sup> In *Atlas Powder*, the court reached a similar conclusion, maintaining the same reasoning would hold true when an ingredient, rather than a property, is inherently contained in the prior art.<sup>101</sup> The court also noted:

The public remains 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. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.<sup>102</sup>

From *Atlas Powder*, the following potential tests for inherent anticipation may be derived:

- (1) The claimed composition was intended in the prior art
- (2) The claimed composition was recognized in the prior art
- (3) The prior art had the same purpose
- (4) The claimed composition was useful in the prior art
- (5) The prior art did not recognize a property of one of the components of the composition

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<sup>93</sup> *Id.* at 1345.

<sup>94</sup> *Id.* at 1348.

<sup>95</sup> *Id.* at 1349.

<sup>96</sup> *Id.* at 1347 (citations omitted).

<sup>97</sup> 778 F.2d 775 (Fed. Cir. 1985).

<sup>98</sup> *Id.* at 776.

<sup>99</sup> *Id.* at 777.

<sup>100</sup> *Id.* at 782.

<sup>101</sup> *Atlas Powder*, 190 F.3d at 1348.

<sup>102</sup> *Id.*

c. Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research

i. *Original Opinion, Later Vacated*<sup>103</sup>

In August 2002, the Federal Circuit issued an opinion by Judge Newman regarding inherent anticipation that seemed to re-inject the requirement of recognition of the allegedly anticipating compound or process by the prior art.<sup>104</sup> This decision was later vacated and a substitute opinion issued.<sup>105</sup>

The *Elan* cases involved amyloid precursor proteins (APP), which are now known to be broken down in the body into three fragments: a larger amino terminal fragment (ATF-betaAPP), a smaller beta AP fragment, and the remainder of the APP.<sup>106</sup> Beta AP has been implicated in Alzheimer's Disease because it is found in plaques in Alzheimer's patients.<sup>107</sup> The APP gene can have a mutation known as the Swedish mutation, which affects the cleavability of the APP so that ATF-betaAPP is formed.<sup>108</sup>

Elan's patents, U.S. Patent No. 5,612,486 (the '486 patent) and U.S. Patent No. 5,850,003 (the '003 patent), claimed a transgenic animal with human DNA containing the Swedish mutation.<sup>109</sup> Claim 1 of the '486 patent was directed to a transgenic rodent with the Swedish mutation where ATF-betaAPP is detectable in brain homogenates:

A transgenic rodent comprising  
a diploid genome comprising a transgene encoding a heterologous APP polypeptide having the Swedish mutation wherein the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively,  
wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation,  
and wherein said polypeptide is processed to ATF-betaAPP in a sufficient amount to be detectable in a brain homogenate of said transgenic rodent.<sup>110</sup>

The prior art cited against the claims, U.S. Patent No. 5,455,169 (the '169 patent), suggested introducing a Swedish mutated human gene into a mouse.<sup>111</sup> The inventors of the '169 patent did not reduce production of the transgenic mouse to

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<sup>103</sup> *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221 (Fed. Cir. 2002) (hereinafter *Elan I*), *vacated and reh'g granted*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc), *substituted opinion*, 346 F.3d 1051 (Fed. Cir. 2003) (hereinafter *Elan II*).

<sup>104</sup> *Elan I*, 304 F.3d at 1230.

<sup>105</sup> *Elan II*, 346 F.3d at 1051.

<sup>106</sup> *Elan I*, 304 F.3d at 1224.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 1226.

<sup>109</sup> *Id.* at 1223.

<sup>110</sup> *Id.* at 1226.

<sup>111</sup> *Id.* at 1225.

practice.<sup>112</sup> Furthermore, the '169 patent did not recognize the formation of ATF-betaAPP.<sup>113</sup>

Although the '169 patent does not mention the formation of ATF-betaApp, the district court found formation was inherent in the suggestion of transgenic mice with the Swedish mutation.<sup>114</sup> The Federal Circuit reversed and explained:

When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown that the undisclosed information was known to be present in the subject matter of the reference.<sup>115</sup>

Mayo argues, and the district court found, that this claim limitation is "inherent" in [the prior art] because a successful transgenic procedure and ensuing enzymatic cleavage will produce ATF-betaAPP. However, this was not shown by [the prior art], and there was no evidence that the formation and detection of ATF-betaAPP in the transgenic mouse brain with the Swedish mutation was known to persons of ordinary skill in the field of the invention. Inherency cannot be based on the knowledge of the inventor; facts asserted to be inherent in the prior art must be shown by evidence from the prior art. The purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field.<sup>116</sup>

Based on this reasoning, the Federal Circuit concluded that, because a person of ordinary skill in the art would not have known that the ATF-betaAPP fragment existed, the mere suggestion of a transgenic mouse, even if enabled and even if it produced the metabolite in detectable amounts, would not anticipate.<sup>117</sup>

#### *ii. Substituted Opinion*<sup>118</sup>

On December 18, 2002, the Federal Circuit, acting en banc, vacated the prior opinion without stating a reason.<sup>119</sup> On October 2, 2003, the original panel issued another opinion. This time, the court did not address the question of inherency, but instead characterized the anticipatory reference as non-enabling:

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<sup>112</sup> *Id.* at 1226, 1230.

<sup>113</sup> *Id.* at 1227.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at 1228 (citing *Cont'l Can Co. U.S.A. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991)).

<sup>116</sup> *Elan I*, 304 F.3d at 1229 (citations omitted).

<sup>117</sup> *Id.* at 1228–29.

<sup>118</sup> *Elan Pharms., Inc., v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051 (Fed. Cir. 2003).

<sup>119</sup> *Elan Pharms., Inc., v. Mayo Found. for Med. Educ. & Research*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc).

In response to the questions raised in the petitions for reconsideration, we clarify that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference....Applying this rule, we remand for determination of whether the [prior art] was an enabling disclosure.<sup>120</sup>

Thus, the court appears to simplify the case to one in which enablement has not been shown. The law is clear that to anticipate, the prior art must be enabling.<sup>121</sup> This reduces the matter to a clear issue: whether a prophetic invention is enabled. Thus, a prophetic disclosure of an entire invention should be sufficient to establish inherency. This was confirmed by the next case.

From *Elan*, the following potential inherent anticipation tests are derived:

- (1) The claimed composition was intended in the prior art
- (2) The claimed composition was a necessary consequence of an intended act
- (3) An inherent property of the claimed composition was not recognized
- (4) The prior art had the same purpose
- (5) The claimed composition was useful

*d. Schering Corp. v. Geneva Pharmaceuticals, Inc.*

*Schering* is noteworthy for several reasons. It is the first case where the doctrine of inherent anticipation was directly applied to the entire invention and not just a characteristic, component, function, or property of a previously disclosed invention.<sup>122</sup> Second, in its novelty analysis, *Schering* removes the requirement that a person of ordinary skill in the art recognize anything about the invention, including its existence.<sup>123</sup> Third, the invention need not actually have occurred; it can be prophetic.<sup>124</sup> Lastly, the invention can be the unknown result of a prior process.<sup>125</sup>

Schering had two patents. The earlier patent, U.S. Patent No. 4,282,233 (the '233 patent), is directed to the anti-histamine loratadine (Claritin™), and the later patent, U.S. Patent No. 4,659,716 (the '716 patent), is directed to a metabolite of loratadine, DCL (Clarinex™).<sup>126</sup> The defendants sought to produce generic loratadine, as the '233 patent expired in 2001.<sup>127</sup> Schering brought an infringement suit for the '716 patent asserting the defendants induced infringement of the metabolite that would be formed *in vivo* when loratadine is administered to a patient.<sup>128</sup>

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<sup>120</sup> *Elan II*, 346 F.3d at 1052.

<sup>121</sup> *Id.* at 1054.

<sup>122</sup> *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379–80 (Fed. Cir. 2003).

<sup>123</sup> *Id.* at 1377.

<sup>124</sup> *Id.* at 1380.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.* at 1374–76.

<sup>127</sup> *Id.* at 1375–76.

<sup>128</sup> *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d. 534, 539 (D.N.J. 2002).

The earlier '233 patent did not expressly disclose DCL and did not refer to any metabolite of loratadine.<sup>129</sup> Instead, it merely disclosed the administration of loratadine.<sup>130</sup> Nevertheless, the defendants argued the '233 patent inherently anticipated the '716 patent because DCL would inevitably be formed upon administering loratadine.<sup>131</sup> Schering asserted that the claims to DCL were valid because the existence of DCL was not recognized in the prior art.<sup>132</sup> In doing so, Schering relied on the vacated *Elan* opinion.<sup>133</sup>

The claims at issue in *Schering* are directed to “[a] compound of the formula [diagram of DCL] or pharmaceutically acceptable salt thereof....”<sup>134</sup> The district court found inherent anticipation on the grounds that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the earlier patent, namely disclosure to administer loratadine to a patient.<sup>135</sup> The Federal Circuit affirmed the district court in an opinion by Judge Rader.<sup>136</sup>

Judge Rader stated that inherent anticipation can apply to an entire invention.<sup>137</sup> This solidifies the position in *Elan*. Previously, we discussed the fact that accident cases were directed to the pre-existence of the product or process per se (i.e., the entire claimed invention) while inherency cases were directed to pre-existing parts, properties, results, etc., of the entire claimed invention.<sup>138</sup> We proposed that this distinction may form a basis to distinguish accident from inherency. *Schering* completely changes the potential of this approach because *Schering* is directed to the inherent pre-existence of the entire invention.

In a detailed discussion, Judge Rader rejected the contention that inherent anticipation requires recognition in the prior art:

Other precedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. *E.g., In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (“Where...the result is a necessary consequence of what was deliberately intended, it is of no import that the article’s authors did not recognize the results .”); *Atlas Powder*, 190 F.3d at 1348-49 (“Because ‘sufficient aeration’ was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of the invention....An inherent structure, composition, or function is not necessarily known.”). Thus, recognition by a person of ordinary skill in the art before the critical date of the '716 patent is not required to show anticipation by inherency. The district court therefore did not err in

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<sup>129</sup> *Schering*, 339 F.3d at 1376.

<sup>130</sup> *Id.*

<sup>131</sup> *Schering*, 275 F. Supp. 2d at 537.

<sup>132</sup> *Schering*, 339 F.3d at 1377.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 1375.

<sup>135</sup> *Schering*, 275 F. Supp. 2d at 542.

<sup>136</sup> *Schering*, 339 F.3d at 1381.

<sup>137</sup> *Id.* at 1380.

<sup>138</sup> *See supra* INTRODUCTION.

allowing for later recognition of the inherent characteristics of the prior art '233 patent.<sup>139</sup>

The opinion also seems to implicitly take the position that recognition does not distinguish accident from inherency, citing *Eibel Process* and *Tilghman* for support.<sup>140</sup> *Eibel Process* and *Tilghman* are distinguished on the grounds that the prior art only *possibly* produced the claimed subject matter.<sup>141</sup> This is somewhat misleading, however, since in those cases, certainty was not the dispositive issue. Instead, the dispositive issue was that, even if the event had occurred, it was unintended, unappreciated, not recognized, and not useful, and therefore, did not rise to the level of legal anticipation.<sup>142</sup>

The *Schering* court quoted the following *Eibel Process* statement: “We find no evidence that any pitch of the wire...had brought about such a result...and...if it had done so under unusual conditions, accidental results, not intended and not appreciated, did not constitute anticipation.”<sup>143</sup> Thus, the court appeared to imply that these elements still play a role in determining whether anticipation is accidental by stating:

In the context of accidental anticipation, DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients. The record also shows that DCL provides a useful result, because it serves as an active non-drowsy antihistamine. In sum, this court’s precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.<sup>144</sup>

Saying that DCL is “not formed accidentally” begs the question of how an accident would be characterized. While *Schering* did not elaborate on this issue, its approval of *Eibel Process* and *Tilghman*<sup>145</sup> infers that an accident involves the unusual, unintended, or unrecognized product or process.

The opinion also discussed Schering’s contention that *Continental Can* stands for the proposition that an inherent feature of a prior art reference must be perceived as such by the person of ordinary skill in the art.<sup>146</sup> Judge Rader did not squarely address the unequivocal proposition in *Continental Can* that a finding of inherency requires the missing disclosure necessarily be present and recognized by a person of ordinary skill in the art.<sup>147</sup> He concluded that “[i]n *Continental Can*, this court did not require past recognition of the inherent feature, but only allowed recourse to

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<sup>139</sup> *Schering*, 339 F.3d at 1377.

<sup>140</sup> *Id.* at 1378.

<sup>141</sup> *Id.*

<sup>142</sup> See *supra* Parts I.A.1.a. & I.B.1.a.

<sup>143</sup> *Schering*, 339 F.3d at 1378 (quoting *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923)).

<sup>144</sup> *Schering*, 339 F.3d at 1378.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 1377.

<sup>147</sup> See *supra* Part I.B.2.a. (discussing of *Continental Can*).

opinions of skilled artisans to determine the scope of the prior art reference.”<sup>148</sup> This interpretation appears inconsistent with Judge Newman’s explicit statement in *Continental Can*.<sup>149</sup>

In addition, *Schering* distinguished *In re Seaborg* on the grounds that the isotope would have been produced at undetectable amounts, whereas DCL forms in readily detectable amounts.<sup>150</sup> Judge Rader approvingly cited the following potential test for anticipation: “Where the result is a necessary consequence of what was deliberately intended, it is of no import that the authors of the prior art did not appreciate the results.”<sup>151</sup>

The following potential tests for inherent anticipation are derived from *Schering*:

- (1) The claimed composition was not intended in the prior art
- (2) The claimed composition was a necessary consequence of an intentional act
- (3) The claimed composition was not recognized in the prior art
- (4) The prior art had the same purpose
- (5) The claimed composition was useful

### *C. Summary Chart*

Courts have articulated various tests to rationalize the choice of inherent or accidental anticipation. To help in an analysis of which potential tests are consistently dispositive, we have constructed a chart correlating the tests with the cases. The vertical columns refer to accidental (A) and inherent (I) anticipation cases. The horizontal rows refer to the following potential tests and the presence or absence of them in each case:

- (1) Was the claimed composition or process recognized in the prior art?
- (2) Did the prior art recognize the claimed result of the process or claimed function of the composition?
- (3) Was the invention per se intended?
- (4) Was the claimed invention a necessary consequence of an intentional act?
- (5) Was the claimed composition or process useful in the prior art?
- (6) Was the claimed process performed occasionally or under unusual conditions in the prior art or was the claimed composition formed occasionally or under unusual conditions?

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<sup>148</sup> *Schering*, 339 F.3d at 1377.

<sup>149</sup> Compare *Schering*, 339 F.3d at 1377, with *Cont’l Can*, 948 F.2d at 1269.

<sup>150</sup> *Id.* at 1379.

<sup>151</sup> *Id.* at 1377 (citing *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999)).

	A	A	A	A	A	A
Case:	<i>Tilghman</i>	<i>Eibel Process</i>	<i>Seaborg</i>	<i>Felton</i>	<i>Marshall</i>	<i>MEHL</i> (Tattoo-removal aspect)
(1) Recognition of Invention per se	No	Yes	No	Yes	Yes	Yes
(2) Recognition of Property of Invention	N/A	No	N/A	No	No	No
(3) Invention per se intended	No	Yes	No	Yes	Yes	Yes
(4) Invention Necessary Consequence of Intentional Act	Yes	N/A	Yes	N/A	N/A	N/A
(5) Invention Useful	No	Yes	No	Yes	Yes	Yes
(6) Invention Unusual/Occasional	N/D	Yes	N/D	Yes	N/D	Yes

N/A = not applicable  
A = Accident

N/D = not discussed in opinion  
I = Inherent Anticipation

	I	I	I	I	I	I
Case:	<i>Atlas Powder</i>	<i>Verdegaal Brothers</i>	<i>MEHL</i> (Pigment cell damage aspect)	<i>Cruciferous Sprout</i>	<i>Elan</i>	<i>Schering</i>
(1) Recognition of Invention per se	Yes	Yes	Yes	Yes	Yes	No
(2) Recognition of Property of Invention	No	No	No	No	No	N/A
(3) Invention per se intended	Yes	Yes	Yes	Yes	Yes	No
(4) Invention Necessary Consequence of Intentional Act	N/A	N/A	N/A	N/A	N/A	Yes
(5) Invention Useful	Yes	Yes	Yes	Yes	Yes	Yes
(6) Invention Unusual/Occasional	No	No	No	No	No	No

N/A = not applicable  
A = Accident

N/D = not discussed in opinion  
I = Inherent Anticipation

### *1. Analyzing the Table*

We analyzed each of the potential tests to determine whether any consistently apply to accidental anticipation but not inherent anticipation, and vice versa. With the possible exception of the “unusual/occasional results” test, we did not find any one test sufficient to distinguish the two doctrines. However, a combination of two specific tests, the “useful” and “unusual/occasional” tests, may provide a helpful framework for deciding whether the facts of a case constitute accidental or inherent anticipation.

#### *a. Recognition of Invention per se*

The “prior art recognition of the claimed process or composition” test fails as an across the board test for both accidental and inherent anticipation. In *Schering*, DCL was not recognized by the art, yet the court found inherent anticipation. On the other hand, in *Eibel Process*, *Felton*, and *MEHL* (tattoo removal), allegedly anticipating compositions or processes were recognized, yet found to be accidental. Therefore, recognition alone (or lack of recognition) of the invention or a property thereof is not dispositive.

#### *b. Recognition of a Property of the Invention*

Recognition of a property of an invention is negative in all the accident cases, but is also negative in several inherency cases, such as *MEHL* and *Cruciferous Sprout*. Similarly, in *Elan I* the prior art did not recognize the formation of ATF-betaAPP. It is possible for the prior art to inherently anticipate even if the prior art does not recognize the claimed result of the process or the claimed function of the composition. Therefore, this parameter alone cannot distinguish accidental anticipation from inherent anticipation.

#### *c. Invention per se Intended*

The “prior art intention to make the claimed invention per se” test fails as an across the board test for both accidental and inherent anticipation. In *Schering*, DCL was not intended, yet the court found inherent anticipation. On the other hand, in *Eibel Process*, *Felton*, and *MEHL* (tattoo removal), even though allegedly anticipating compositions or processes were intended, they were deemed accidental. Therefore, intent to achieve the claimed process or product alone is not dispositive.

#### *d. Invention Necessary Consequence of Intentional Act*

This test only applies to three cases, however, it is not dispositive to distinguish between accidental and inherent anticipation. The fact patterns for *Seaborg*, *Tilghman*, and *Schering* all exemplify the situation where a claimed invention is a

necessary consequence of an intentional act. In *Seaborg*, the invention was necessarily produced by the intentional application of the Fermi process. In *Tilghman*, the claimed process was necessarily achieved during intentional application of the lubrication process. In *Schering*, DCL would have been produced as a consequence of administration of loratadine.

*e. Usefulness*

For inherency, all of the processes or compositions in the cases examined were considered useful. This test alone is not dispositive, however, because in three of the accident cases, the compositions or processes were also useful. For example, the *Eibel Process* prior art composition was useful, yet the Supreme Court found the anticipation was accidental.

In a sense, neither *Tilghman* nor *Seaborg* represent a discrete doctrine of “accidental anticipation.” Had these cases been litigated today, they both could have been decided strictly based on enablement (similar to *Elan II*). To be enabled, the art must teach how to make and *use* the invention.<sup>152</sup> The prior process in *Tilghman* and the prior composition in *Seaborg* were not useful; thus, they were not enabled. It is a well-established rule that to anticipate, a product or process must be enabled.<sup>153</sup> On this basis alone, there would be no anticipation.

*f. Unusual/Occasional*

This parameter was not discussed except in three of the accidental anticipation cases. Where the occurrence of the claimed invention was unusual or occasional, the anticipation was deemed accidental.<sup>154</sup> Therefore, this parameter, in some cases, may be dispositive by itself. If the occurrence of the prior art process or composition was not unusual or occasional, then the claimed process or composition should be inherently anticipated. If the occurrence was occasional or unusual, then anticipation is accidental.

Courts have not specified which criteria are considered in deciding what constitutes “unusual” or “occasional.” At this point, the most useful approach would be to extrapolate the fact patterns of *Eibel Process*, *Felton*, and *MEHL* to one’s own specific fact pattern.

*g. Combination of the Tests*

From the chart, it is evident that for all the inherency cases, the inventions were useful. As mentioned above, this alone is not dispositive because the inventions were also useful in four of the accident cases. However, where the invention was useful

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<sup>152</sup> *Bristol-Myers Squibb v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374 (Fed. Cir. 2001).

<sup>153</sup> *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

<sup>154</sup> *See supra* Parts I.A.1.c., I.B.1.a. & I.B.1.c.

and unusual or occasional, the court found accidental anticipation but not inherent anticipation. Furthermore, none of the inherency cases are directed to an invention that is unusual/occasional. Thus, when the parameter of usefulness is combined with the parameter “unusual/occasional,” a pattern emerges. Wherever a process or composition is considered useful, but only occurs under unusual conditions or occasionally, a court should find that the anticipation was accidental.

Therefore, we suggest a two-prong test. The first prong is concerned with whether the prior process or composition was useful in the art. If the answer to the first prong is no, then the anticipation is accidental; if the answer is yes, the second prong is whether the process or composition occurred under unusual conditions or occasionally. If the answer to the second prong is no, then the anticipation is inherent; if the answer is yes, then the anticipation is accidental.

## 2. *Summary of the Conclusions*

Accordingly, the following conclusions can be drawn:

- (1) Recognition of an entire invention or property of invention is not dispositive.
- (2) Intent to achieve the claimed product or process is not dispositive.
- (3) If a prior composition or process is not useful, it will not inherently anticipate.
- (4) If a process occurs only occasionally or under unusual conditions, or if a composition is formed only occasionally or under unusual conditions, anticipation is accidental even if the process was intentionally performed or the composition intentionally made, regardless of whether the process or composition was recognized and whether the composition or process was useful.

## II. WHAT IS THE FUTURE FOR ACCIDENTAL ANTICIPATION? – ACCIDENTAL INFRINGEMENT UNDER *SMITHKLINE BEECHAM CORP. V. APOTEX CORP.*

Although this recent case discusses accidental and inherent anticipation only in dicta, it is important because it suggests that even an undetectable and unintentional amount of patented subject matter may result in infringement.

### *A. Facts*

Plaintiff SmithKline accused Defendant Apotex of infringing its patent, U.S. Patent No. 4,721,723 (the ‘723 patent), directed to a hemihydrous form of Paroxetine hydrochloride (“PHC”).<sup>155</sup> PHC is an antidepressant originally patented in its anhydrous form in the late 1970s.<sup>156</sup> In 1985, scientists at SmithKline created a new,

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<sup>155</sup> SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1309 (Fed. Cir. 2004).

<sup>156</sup> *Id.* at 1308.

hemihydrous form of PHC, which was claimed in the '723 patent.<sup>157</sup> Claim 1 of the '723 patent recites “[c]rystalline paroxetine hydrochloride hemihydrate.”<sup>158</sup>

Starting in 1993, SmithKline marketed the PHC hemihydrate under the name Paxil ®.<sup>159</sup> In 1998, Apotex filed an Abbreviated New Drug Application (ANDA) to market its generic version of PHC antidepressant.<sup>160</sup> In the ANDA, Apotex specified that it would market an anhydrate form of PHC and, thus, not infringe the '723 patent.<sup>161</sup> Nevertheless, SmithKline asserted that Apotex would infringe the '723 patent because Apotex would inevitably produce trace amounts of PHC hemihydrate in the process of making PHC anhydrate.<sup>162</sup>

### *B. Claim Construction & Infringement*

The claims at issue were construed to cover trace or undetectable amounts of hemihydrous PHC.<sup>163</sup> In arguing for infringement, SmithKline relied on the “disappearing polymorph” theory.<sup>164</sup> According to this theory, once the hemihydrous form of PHC was created, it contaminated the environment and resulted in the conversion of the anhydrate to the more stable patented hemihydrate.<sup>165</sup> Because the hemihydrate form is more stable, the anhydrate form converts to hemihydrate through “seeding,” making it no longer possible to produce uncontaminated anhydrate.<sup>166</sup> Therefore, SmithKline argued that Apotex’s tablets of anhydrous PHC would inevitably contain at least trace amounts of hemihydrous PHC, which may be undetectable.<sup>167</sup> Both the district court and the Federal Circuit found the record supported SmithKline’s theory.<sup>168</sup>

### *C. Anticipation*

Having construed the claims to cover even the undetectable amounts of PHC hemihydrate, the court turned to the anticipation analysis.<sup>169</sup> It found that while the prior art (trace amounts of PHC hemihydrate) would have anticipated the '723 patent had the prior art existed before the filing, it did not exist at that time.<sup>170</sup> Both the district court and the Federal Circuit accepted SmithKline’s theory that the hemihydrate form did not exist before 1985.<sup>171</sup> Therefore, a somewhat anomalous

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<sup>157</sup> *Id.* at 1309.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Id.* at 1312.

<sup>164</sup> *Id.* at 1310.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 1310, 1312.

<sup>169</sup> *Id.* at 1315.

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

situation was created; while the prior art infringes now, it did not inherently anticipate the '723 patent simply because it did not exist at that time.

This aspect of the Federal Circuit's analysis has far-ranging implications for the doctrine of accidental anticipation. It has long been recognized that "that which would literally infringe if later in time anticipates if earlier."<sup>172</sup> Accordingly, because even undetectable and unintended amounts of PHC hemihydrate infringe the '723 patent, it inescapably follows that undetectable and unintended PHC hemihydrate would have anticipated the '723 patent.<sup>173</sup> In other words, if it was known that the hemihydrate form existed before the filing date of the '723 patent, it would have anticipated. SmithKline was saved because Apotex could not prove by clear and convincing evidence that the hemihydrate existed before the filing date of the '723 patent.

It is interesting to apply our proposed two-step test to this fact pattern, assuming that undetectable hemihydrate existed before the filing date of the '723 patent. The first question is whether undetectable hemihydrate was useful for any purpose. The answer must be "no" because hemihydrate was an unrecognized by-product of the process of making PHC anhydrate. Our test, therefore, would end at this point and would lead to a finding of no anticipation. In contrast, the logic of *SmithKline* would lead to the opposite result. If there is an infringement by this undetectable hemihydrate, it must anticipate if it existed earlier in time. Otherwise, the patentee would be able to prevent the public from practicing prior art, which is never true.

Additionally, it appears that under the *SmithKline* logic, *In re Seaborg*<sup>174</sup> would have been decided differently. As discussed earlier in this article, Seaborg's claims to Americium were upheld despite the fact that some small and undetectable amounts of Americium were inherently produced in the prior art as a by-product of a different process. The C.C.P.A. stated that the undetectable isotope did not enrich "the store of common knowledge" and was not an anticipation. However, if the *SmithKline* rationale is applied, practicing the prior art process of producing minuscule amounts of Americium as a by-product would infringe the patent to Americium, and the patent to Americium must be anticipated by these tiny undetected amounts of Americium.

#### *D. Conclusion*

The discussion of anticipation in *SmithKline* is dictum. The Federal Circuit ultimately relied on the "public use" bar of §102(b) to hold claim 1 of the '723 patent invalid.<sup>175</sup> Moreover, it was not entirely clear from the record whether the hemihydrate form of PHC existed before the filing date of the '723 patent.<sup>176</sup>

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<sup>172</sup> *Id.* (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)).

<sup>173</sup> *SmithKline*, 365 F.3d at 1315.

<sup>174</sup> *See supra* Part I.B.1.b.

<sup>175</sup> *SmithKline*, 365 F.3d at 1321.

<sup>176</sup> *Id.* at 1315.

Therefore, the discussion of what would happen if the hemihydrate existed in the prior art is not the basis of the court's holding and is dictum.

Nevertheless, based on the court's rationale, infringement by accident is still infringement. Infringement and anticipation go hand in hand: if something infringes if later in time, then it anticipates if earlier in time.<sup>177</sup> Therefore, had trace or undetectable amounts of the hemihydrate existed in the prior art, they should have anticipated. On the other hand, it would appear that trace or undetectable amounts of hemihydrate are useless. Thus, if the court's dicta ultimately become law, this is the first instance where a useless prior composition would inherently anticipate. Hence, the first prong of our test would fail to distinguish accident and inherency. In that situation, the only remaining test would be the second prong, whether a prior art process occurred under unusual conditions or a prior art composition was obtained under unusual conditions.

### III. CONCLUSION

As our analysis demonstrates, courts do not seem to apply consistent standards when faced with accidental or inherent anticipation. Since *Tilghman*, most courts recognize that even when a claimed composition or process was present in the prior art, under certain circumstances, anticipation may have been accidental. The difficulty lies in determining exactly what such circumstances are as different courts stress different reasons for finding or not finding anticipation.

Having analyzed various accidental and inherent anticipation cases, we propose a decision tree consisting of the following two questions:

- (1) Was the allegedly anticipating prior art product or process useful; and
- (2) Was the product obtained under unusual conditions or did the process occur under unusual conditions?

If the answer to the first question is no, then the anticipation is accidental; if the answer is yes, then the second question must be answered. If the answer to whether the composition was formed or process occurred under unusual condition is yes, then the anticipation is accidental; otherwise, it is inherent.

If the rationale of the recent Federal Circuit decision in *SmithKline v. Apotex* becomes the law, it would appear to abolish the first prong of our test, i.e., whether the prior composition or process was useful. Since that panel of the Federal Circuit virtually eliminated the concept of accidental infringement, it would appear that accidental anticipation is also virtually abolished. Remembering the axiom of patent law that "that which infringes if later in time anticipates if earlier,"<sup>178</sup> even if an allegedly anticipating composition was a useless by-product, it may still anticipate. It remains to be seen if the Federal Circuit extends the *SmithKline* analysis to

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<sup>177</sup> *Bristol-Myers*, 246 F.3d at 1378.

<sup>178</sup> *Id.*

accidental anticipation cases or if it limits it to the unusual *SmithKline* fact pattern.<sup>179</sup>

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<sup>179</sup> Also worth noting is that the rationale in *SmithKline* seems to conflict with *In re Seaborg*. In *Schering*, the court stated that *In re Seaborg* was distinguished because the by-product was undetectable. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). In *SmithKline*, however, the conclusion appears to be that an undetectable contaminant can still anticipate. See *SmithKline*, 365 F.3d at 1315 (implying that had the defendant “present[ed] clear and convincing evidence of inherent anticipation” at trial, the defendant’s prior art product—which was found to contain only trace amounts of the compound covered by the plaintiff’s patent—may have anticipated the claim at issue). In view of the above considerations, it appears that if the *SmithKline* rationale becomes law, then the only remaining test for accidental anticipation would be whether the prior composition or process was occasional or unusual, as exemplified by *Eibel Process*, *Felton*, and *MEHL* (tattoo removal aspect).