

## Observations on Recent Patent Decisions: The Year in Review

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### Introduction

The past twelve months have included a large number of interesting patent law developments.<sup>1</sup> The Federal Circuit has issued a number of significant opinions over this period covering most areas of patent law. One of the most notable is the Federal Circuit recent en banc opinion on claim interpretation, *Phillips v. AWH Corp.*<sup>2</sup> However, the twelve month period also witnessed the Supreme Court playing an increasing role in patent law. For example, the Supreme Court issued its opinion in *Merck v. Integra Lifesciences I, Ltd.* on the experimental safe harbor of 35 U.S.C. § 271(e)(1).<sup>3</sup>

This Article will review this past year in patent law. While in no way comprehensive, the paper will discuss the significant legal developments in seven main areas of patent law: claim interpretation; utility and patentable subject matter; anticipation; obviousness; infringement; inequitable conduct; and antitrust. This discussion will include cases from the Supreme Court, the Federal Circuit, and the Board of Patent Appeals and Interferences ("Board"). Along the way, some observations will be made about these recent developments and what, if any, insight they have on legal changes to come.

### I. Claim Interpretation

#### A. *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)

An en banc Federal Circuit, in *Phillips v. AWH Corporation*, held that it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims."<sup>4</sup> The en banc court, in turn, disavowed claim interpretation methodologies that "placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias."<sup>5</sup>

Edward H. Phillips is the named inventor on a patent concerning modular wall panels that are load-bearing and resistant to fire, sound, and impact.<sup>6</sup> These patented modular panels are used to construct detention facilities, such as jails, as well as vaults or

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<sup>1</sup> The twelve month period referenced is from November 2004 to October 2005.

<sup>2</sup> 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

<sup>3</sup> 125 S.Ct. 2372 (2005).

<sup>4</sup> 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) ("Phillips III").

<sup>5</sup> *Id.* at 1320.

<sup>6</sup> *Id.* at 1309. The patent at issue is U.S. Patent No. 4,677,798. *Id.*

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safety barriers.<sup>7</sup> Mr. Phillips sued AWH Corporation for patent infringement for selling modular panels allegedly covered by Mr. Phillips's patent.<sup>8</sup> AWH's modular panels included interior baffles angled at ninety degrees with respect to the two exterior walls.<sup>9</sup> The district court construed the asserted claims to exclude baffles at a ninety degree orientation and, thus, granted summary judgment of non-infringement.<sup>10</sup>

In a divided panel opinion, the Federal Circuit initially affirmed the district court's judgment.<sup>11</sup> The majority construed the claim term "baffles" to exclude baffles at a ninety degree angle from the exterior walls.<sup>12</sup> The court reached this conclusion because while "[i]t is true that claims with the non-restrictive term 'baffles' were allowed . . . the patent specification is intended to support and inform the claims, and here it makes it unmistakably clear that the invention involves baffles angled at other than 90°."<sup>13</sup> The dissent, authored by Judge Dyk, came to the opposite conclusion, defining "baffles" to include all baffles, regardless of their angular orientation.<sup>14</sup> The dissent focused on the dictionary definition of "baffles," concluding that "[s]ince there is no argument here that one of skill in the art would ascribe a specialized meaning to the term baffles, and there has been no disclaimer in the specification or prosecution history, the general purpose dictionary definition, 'something for deflecting, checking, or otherwise regulating flow,' *Webster's* at 162, applies."<sup>15</sup>

The Federal Circuit vacated the panel opinion in *Phillips* and granted a rehearing en banc.<sup>16</sup> The vacating order invited the parties and amicus to submit briefs directed to seven questions centered on the use of intrinsic and extrinsic evidence in claim interpretation, the interrelationship between validity and claim interpretation, and the degree of deference that should be given to district court interpretations.<sup>17</sup>

On July 12, 2005, the en banc opinion was issued, with the majority authored by Judge Bryson and joined in full by Chief Judge Michel and Judge Clevenger, Rader, Schall, Gajarsa, Linn, Dyk, and Prost.<sup>18</sup> The Federal Circuit set out to "restat[e]" and "reaffirm" the already established "basic principles of claim construction" with regards to the specification.<sup>19</sup> The court also wanted to "clarif[y]" "the use of dictionaries in claim construction."<sup>20</sup>

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<sup>7</sup> *Id.*

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

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

<sup>10</sup> *Id.* The district court also dismissed Mr. Phillips's trade secret claim as barred by the applicable statute of limitations. *Id.*

<sup>11</sup> *Phillips v. AWH Corp.*, 363 F.3d 1207, 1214 (Fed. Cir. 2004), vacated by en banc order, 376 F.3d 1382.

<sup>12</sup> *Id.* at 1212-14.

<sup>13</sup> *Id.*

<sup>14</sup> *Phillips*, 363 F.3d at 1216-18 (Dyk, J., dissenting-in-part). Judge Dyk agreed with the majority that the trade secret claim was properly dismissed. *Id.* (Dyk, J., dissenting-in-part).

<sup>15</sup> *Id.* (Dyk, J., dissenting-in-part).

<sup>16</sup> *Phillips v. AWH Corp.*, 376 F.3d 1382 (Fed. Cir. 2004) (en banc) ("Phillips II").

<sup>17</sup> *Id.* at 1383.

<sup>18</sup> *Phillips III*, 415 F.3d at 1308-09.

<sup>19</sup> *Id.* at 1312.

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

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The en banc opinion emphasized the importance of the specification's role in claim interpretation. The court initially reiterated the primacy of the claim language and its ordinary and customary meaning—particularly its meaning "to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."<sup>21</sup> The claim language, however must be read "in context of the entire patent, including the specification."<sup>22</sup> This "importance of the specification in claim construction derives from its statutory role," specifically the requirement that the specification must describe the claimed invention.<sup>23</sup> In addition, the specification must be referenced because it "may reveal a specification definition given to a claim term by the patentee that differs from the meaning [the claim] would otherwise possess."<sup>24</sup> The primary role of the specification during interpretation is also supported by the USPTO's reliance on it during examination to interpret the claims.<sup>25</sup>

The court, in turn, clarified the use of extrinsic evidence in claim interpretation. Specifically, the court disavowed the line of cases emphasizing dictionary use, starting with *Texas Digital Systems, Inc. v. Telegenix, Inc.*<sup>26</sup> Such an emphasis improperly "placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history."<sup>27</sup> "The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of claim terms within the context of the patent."<sup>28</sup> "[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."<sup>29</sup>

The court stated, however, that it did "not intend to preclude the appropriate use of dictionaries."<sup>30</sup> Dictionaries are "useful to assist in understanding the commonly understood meaning of the words."<sup>31</sup>

The court also addressed the problem of improperly reading limitations from the specification into the patent claims.<sup>32</sup> The court warned against limiting the claims to specific embodiments.<sup>33</sup> In order to avoid this improper narrowing, "it is important to keep in mind that the purposes of the specification are to teach and enable those of skill

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<sup>21</sup> *Id.* at 1312-14.

<sup>22</sup> *Id.* at 1313.

<sup>23</sup> *Id.* at 1316.

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

<sup>25</sup> *Id.* at 1316-17 (noting that examiners must interpret patent claims in light of the specification). The court also noted the relevance of prosecution history to construe claims. *Id.* at 1317.

<sup>26</sup> *Id.* at 1319-23 (discussing *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002)).

<sup>27</sup> *Id.* at 1320.

<sup>28</sup> *Id.* at 1321.

<sup>29</sup> *Id.* at 1319.

<sup>30</sup> *Id.* at 1322.

<sup>31</sup> *Id.* (noting that the Supreme Court has relied on dictionary definitions to interpret patent claims).

<sup>32</sup> *Id.* at 1323-24.

<sup>33</sup> *Id.* at 1323.

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in the art to make and use the invention and to provide a best mode for doing so."<sup>34</sup> The court did recognize, however, that "it will be hard," in some cases, "to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature."<sup>35</sup> The court concluded that it believed "that attempting to result the problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification."<sup>36</sup>

The court also addressed the principles that "claims should be construed, if possible, as to sustain their validity."<sup>37</sup> The court limited the application of this principle to cases where "the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous."<sup>38</sup> The reason for limited application is the belief that the USPTO only issues valid claims.<sup>39</sup>

The court then turned to construing the claim term at issue—"baffles."<sup>40</sup> The court initially referenced the patent, including the patent's claims and specification.<sup>41</sup> The claims did not specifically restrict the claimed baffles placement to any particular angle.<sup>42</sup> The court then turned to the patent's specification to determine how a person of ordinary skill in the art would understand the claimed "baffles."<sup>43</sup> The court found that the specification "set forth multiple objectives to be served by the baffles recited in the claims."<sup>44</sup> Since the disclosed invention went beyond including baffles just to deflect projectiles, the invention did not require the claimed baffles to always be at acute or obtuse angles.<sup>45</sup> The court concluded that, because the disclosed invention was not limited to include baffles at only angles other than ninety degrees, the claim term "baffles" should not be so limited.<sup>46</sup> The en banc court therefore vacated the district court's grant of summary judgment and remanded the case.<sup>47</sup>

Judge Lourie, joined by Judge Newman, concurred in part and dissented in part.<sup>48</sup> Judge Lourie agreed with the majority's analysis "resolving the relative weights of specification and dictionaries in interpreting patent claims, in favor of the specification."<sup>49</sup> Judge Lourie, however, took issue with the majority's application of the

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

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

<sup>36</sup> *Id.* at 1323-24.

<sup>37</sup> *Id.* at 1327-28 (quoting *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999)).

<sup>38</sup> *Id.* at 1327 (quoting *Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004))

<sup>39</sup> *Id.* at 1327-28.

<sup>40</sup> *Id.* at 1324-27.

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

<sup>42</sup> *Id.* at 1325.

<sup>43</sup> *Id.* at 1325-36.

<sup>44</sup> *Id.* at 1326-27.

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

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 1328.

<sup>48</sup> *Phillips III*, 415 F.3d at 1328-30 (Lourie, J., concurring-in-part and dissenting-in-part).

<sup>49</sup> *Id.* at 1328 (Lourie, J., concurring-in-part and dissenting-in-part).

law to the claim term at issue. Instead, he stayed true to his analysis in the panel opinion, finding that the specification "contains no disclosure of baffles at right angles," and thus the claims cannot be construed to include such subject matter.<sup>50</sup> Judge Lourie also believed that the court took the case to "resolve the claim construction issue," not to differ with the panel on the specific claim interpretation in this case.<sup>51</sup>

Finally, Judge Mayer, joined by Judge Newman, dissented because the majority did not address whether it was proper to frame claim interpretation as a pure question of law.<sup>52</sup> Judge Mayer criticized the majority for failing to introduce any predictability and uniformity to the field.<sup>53</sup> The majority improperly focused on establishing standards of interpretation instead of recognizing the "factual component of the task."<sup>54</sup> Judge Mayer emphasized the factual nature of claim interpretation and the need for deference to these underlying factual findings of the district court during claim interpretation.<sup>55</sup> Judge Mayer characterized the "court's opinion today [as] akin to rearranging the deck chairs on the Titanic—the orchestra is playing as if nothing is amiss, but the ship is still heading for Davey Jones' locker."<sup>56</sup>

The biggest question surrounding the en banc *Phillips* opinion is whether it changes the current law of claim interpretation. As the majority indicates, the opinion "restates" the law of claim interpretation.<sup>57</sup> However, the opinion does more—although maybe not as much as patent observers would have hoped. *Phillips* clearly erases all of the dictionary-focused case law starting from *Texas Digital* going forward.<sup>58</sup> In a way, the opinion produces a "back to the future" effect, taking patent law to the pre-*Texas Digital*, *Vitronics* era of claim interpretation.<sup>59</sup> It is easy to see how this, while definitely changing the law, does not necessarily advance the ball in a crucial area of patent jurisprudence.<sup>60</sup>

But the court does more than just turn back the clock. The majority opinion specifically clarifies the part validity plays in claim interpretation—very little.<sup>61</sup> *Phillips* also provides further evidence of the court's increasing focus on the patent disclosure and

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<sup>50</sup> *Id.* at 1329-30 (Lourie, J., concurring-in-part and dissenting-in-part).

<sup>51</sup> *Id.* at 1329 (Lourie, J., concurring-in-part and dissenting-in-part).

<sup>52</sup> *Phillips III*, 415 F.3d at 1330-35 (Mayer, J., dissenting).

<sup>53</sup> *Id.* at 1330 (Mayer, J., dissenting).

<sup>54</sup> *Id.* at 1330-31 (Mayer, J., dissenting).

<sup>55</sup> *Id.* at 1333-34 (Mayer, J., dissenting).

<sup>56</sup> *Id.* at 1334-35 (Mayer, J., dissenting).

<sup>57</sup> *Phillips III*, 415 F.3d at 1312.

<sup>58</sup> *Id.* at 1319-23.

<sup>59</sup> See generally *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996); John N. Romary & Arie M. Michelsohn, *Claim Interpretation After Markman: How the Federal Circuit Interprets Claims*, 46 Am. U. L. Rev. 1887 (1997).

<sup>60</sup> This conclusion is obviously dependent on whether one believes that the *Vitronics* approach to claim interpretation needed fixing.

<sup>61</sup> *Phillips III*, 415 F.3d at 1327-28. (cite claim interpretation article)

inventive activity.<sup>62</sup> More and more, the § 112 requirements and what the inventor actually invented is becoming the focus of Federal Circuit doctrine. Furthermore, the contrast between the majority and the dissent further emphasize the recurring battleground in this area of law—the law/fact distinction surrounding document interpretation.

**B. Claim Interpretation Cases Issued After Phillips**

Shortly after Phillips, the Federal Circuit issued two precedential panel opinions applying the court's ruling in Phillips.<sup>63</sup> Both opinions emphasized the use of the specification during claim interpretation, but neither completely disavowed usage of external definitional sources.

In *CollegeNet, Inc. v. ApplyYourself, Inc.*, the Federal Circuit focused on interpreting the claim terms to give them their ordinary and accustomed meaning as understood by those of ordinary skill in the relevant art at the time of the invention.<sup>64</sup> The court confirmed its understanding of this customary meaning of the claim term "format" by examining how the specification and claims used the term.<sup>65</sup> The opinion included no discussion of external definitional source.

The court did, however, address the use of dictionaries after Phillips in *Terlep v. Brinkmann Corp.*<sup>66</sup> The court initially cited Phillips for the proposition that "[t]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."<sup>67</sup> The court then focused on the specification's teachings about the disputed claim term "clear."<sup>68</sup> The court also discussed the prosecution history. Finally, the court addressed the parties' citation of several dictionaries. The court noted that Phillips authorized district courts to rely on such extrinsic evidence, but they must "attached appropriate weight" by putting them "in the context of the intrinsic evidence."<sup>69</sup> The district court, in this case, did attach the proper weight, especially because the dictionaries' distinction between definitions of "clear" conformed to the use of the claim term in the claims and the specification.<sup>70</sup>

While the opinion in *CollegeNet* provides little guidance for the post-Phillips age of claim interpretation, the *Terlep* opinion's approach will most likely be the norm. The

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<sup>62</sup> See Christopher A. Cotropia, *Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms*, 47 Wm. & Mary L. Rev. 49 (2005) (explaining how this specification focused approach to interpretation focuses on inventive activities).

<sup>63</sup> *Terlep v. Brinkmann Corp.*, No. 04-1337, 2005 WL 1950186 (Fed. Cir. Aug. 16, 2005); *CollegeNet, Inc. v. ApplyYourself, Inc.*, Nos. 04-1202, 04-1222, 04-1251, 2005 WL 1803665 (Fed. Cir. Aug. 2, 2005).

<sup>64</sup> *CollegeNet*, 2005 WL 1803665 (citing *Phillips III* for this proposition).

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

<sup>66</sup> *Terlep*, 2005 WL 1950186.

<sup>67</sup> *Id.* (quoting *Phillips III*).

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

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

<sup>70</sup> *Id.*

specification and other intrinsic evidence will be the focus of the interpretation analysis. However, dictionaries and other extrinsic evidence will still play a role, albeit secondary to the patent document. Thus, patent practitioners just need to readjust their interpretation arguments, stressing intrinsic evidence first. But everyone should hold onto their dictionaries—they still play a part after *Phillips*.

## II. Utility/Patentable Subject Matter

### A. *In re Fisher* – 421 F.3d 1365 (Fed. Cir. 2005)

A divided panel of the Federal Circuit in *In re Fisher* held that claims covering expressed sequence tags ("ESTs") encoding proteins and protein fragments in maize plants did not meet the utility or enablement requirement.<sup>71</sup>

Daniel K. Fisher and Raghunath Lalgudi filed a patent application claiming "five purified nucleic acid sequences [ESTs] that encode proteins and protein fragments in maize plants."<sup>72</sup> The application was ultimately rejected by the USPTO for lack of utility under 35 U.S.C. § 101 and lack of enablement under 35 U.S.C. § 112, ¶ 1.<sup>73</sup> The Board upheld these two rejections and the case was appealed to the Federal Circuit.<sup>74</sup>

To begin its analysis, the Federal Circuit described the two utility requirements at issue: substantial and specific utility. Substantial utility requires "an asserted use must show that that claimed invention has significant and presently available benefit to the public."<sup>75</sup> Specific utility requires "an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public."<sup>76</sup> The court found that the applied for claims failed to meet both requirements.

The court concluded that the claimed ESTs "act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes."<sup>77</sup> The applicants noted seven specific uses for the claimed ESTs at the time of filing, but the underlying genes the ESTs encode for "have no known function."<sup>78</sup> This failure to "correlate" the claimed EST "to an underlying gene of known function" means that the claims do not meet the "standard for utility intended by Congress."<sup>79</sup> The claimed ESTs "have not been researched and understood to the point of providing an immediate, well-defined, real

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<sup>71</sup> 421 F.3d 1365, 1378-79 (Fed. Cir. 2005).

<sup>72</sup> *Id.* at 1367. The application was Serial No. 09/619,643.

<sup>73</sup> *Id.* at 1368.

<sup>74</sup> *Id.* at 1368-69.

<sup>75</sup> *Id.* at 1371.

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

<sup>77</sup> *Id.* at 1373.

<sup>78</sup> *Id.* The court contrasted the claimed invention with a microscope, noting that while both are research tools—the microscope has a "specific benefit of optically magnifying an object to immediately reveal its structure." *Id.*

<sup>79</sup> *Id.* at 1374.

world benefit to the public meriting the grant of a patent."<sup>80</sup> The court went on to specifically note that it did not take into consideration statements by amici and the government that granting patents to ESTs would "delay scientific discovery, and thwart progress in the 'useful Arts' and 'Science'" because such policy determinations is a job for Congress, not the court.<sup>81</sup>

For the same reasons the applied for claims failed to meet the utility requirement, they also failed to meet the enablement requirement.<sup>82</sup> The enablement prong of § 112 "incorporates the utility requirement of § 101."<sup>83</sup> "Here, in light of [the Federal Circuit's] conclusion that the Board's decision with respect to utility applied the correct legal standard and was supported by substantial evidence, [the court] conclude[d] that Fisher failed to satisfy the enablement requirement."<sup>84</sup>

Judge Rader dissented, concluding that the claimed ESTs meet the utility requirement.<sup>85</sup> The claimed ESTs were the same as any other patentable research tool and enhanced research.<sup>86</sup> The invention is beneficial because it both helps isolate the underlying gene it encodes for and "can serve as a probe introduced into a sample tissue to confirm" that a gene corresponding to the EST is being expressed."<sup>87</sup> Judge Rader viewed the claimed ESTs as being the same as a microscope—"tak[ing] a researcher one step closer to identifying and understanding a previously unknown and invisible structure."<sup>88</sup> The Board, thus, failed to overcome the presumption of utility applied to all applications.<sup>89</sup> Judge Rader concluded that policy concerns with such inventions are better addressed through the nonobviousness doctrine—a doctrine that has been handicapped in this technological area by the *In re Deuel* decision.<sup>90</sup>

One of the main questions presented by the *Fisher* opinion is whether it invalidates all patent claims directed to ESTs. Some amicus in the case suggested that this would be the case. Such an absolute conclusion does not, however, follow from the reasoning of the opinion. Utility is a question of fact, and thus, with each claim to an EST, the factual question will be presented whether there was a substantial and specific

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<sup>80</sup> *Id.* at 1376. Commercial success of the database of ESTs, by itself, did not evidence a substantial and specific utility. *Id.* at 1377-78.

<sup>81</sup> *Id.* at 1378. In contrast, however, the court did cite these same amicus briefs earlier in the opinion for the fact that the claimed uses in the application "are nothing more than a 'laundry list' of research plans, each general and speculative, non providing a specific and substantial benefit in currently available form." *Id.* at 1370. Amicus from industry should continue to provide the court with this type of information in these cases where it is quite clear that policy decisions are embedded in the very language of the statute. See *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

<sup>82</sup> *Id.* at 1378-79.

<sup>83</sup> *Id.* at 1378.

<sup>84</sup> *Id.* at 1379.

<sup>85</sup> *Fisher*, 421 F.3d at 1379-82 (Rader, J., dissenting).

<sup>86</sup> *Id.* at 1379 (Rader, J., dissenting).

<sup>87</sup> *Id.* (Rader, J., dissenting) (citing the majority's opinion).

<sup>88</sup> *Id.* at 1380 (Rader, J., dissenting).

<sup>89</sup> *Id.* at 1381 (Rader, J., dissenting).

<sup>90</sup> *Id.* at 1381-81 (Rader, J., dissenting) (citing *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)).

utility when the application was filed.<sup>91</sup> *Fisher* provides guidance as to what facts an applicant or patentee must prove to establish utility—a specific function for the gene the EST identifies. And, for already issued patents, it may be easier for litigants to establish such proof in the patent litigation setting. However, utility must still be established at the time of filing, not the time of the litigation.<sup>92</sup> Furthermore, the court is very clear the evidence of commercial success of EST databases in general is not enough to establish utility.<sup>93</sup>

Finally, the issues presented in *Fisher* will likely be addressed by the Supreme Court in a case it recently granted certiorari, *Lab. Corp. of Am. v. Metabolite Labs.*<sup>94</sup> The Court grant of cert is limited to the third question presented by petitioner—"[w]hether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."<sup>95</sup> This question presented prompts similar utility questions as those addressed in *Fisher*.

**B. *Ex Parte Lundgren*, No. 2003-2088 (Bd. Pat. App. & Int. 2005) (precedential)**

In *Ex Parte Lundgren*, a divided Board ruled, in a precedential opinion, that there is no support for a "technological arts" patentability test under 35 U.S.C. § 101.<sup>96</sup>

Carl A. Lundgren filed an application directed towards a business method for compensating a business manager. Claim 1 of the application described the invention as "[a] method of compensating a manager who exercises administrative control over operations of a privately owned primary firm . . . ."<sup>97</sup> All of the claims of the application were eventually rejected because "both the invention and the practical application to which it is directed [is] outside the technological arts, namely an economic theory expressed as a mathematical algorithm without the disclosure or suggestion of computer, automated means, apparatus of any kind."<sup>98</sup> Thus, the examiner found "the invention as claimed . . . non-statutory."<sup>99</sup> This is the so-called "technological arts" test under § 101.<sup>100</sup>

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<sup>91</sup> *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993).

<sup>92</sup> *Fisher*, 421 F.3d at 1373-74.

<sup>93</sup> *Id.* at 1377-78. This would presumably be extended to evidence of the commercial success of a database containing the specific EST claimed. The key is what people are doing with that information—are they identifying a gene with a known function—and whether this was taking place at the time of the application's filing.

<sup>94</sup> No. 04-607 (U.S. Oct. 31, 2005).

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

<sup>96</sup> No. 2003-2088 (Bd. Pat. App. & Int. 2005) (precedential).

<sup>97</sup> *Id.* at 1. (quoting Application No. 08/093,516).

<sup>98</sup> *Id.* at 4. (quoting the examiner's rejection)

<sup>99</sup> *Id.* (quoting the examiner's rejection)

<sup>100</sup> *Id.* at 5-6. These rejections are, allegedly, currently quite prevalent.

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Upon a request for reconsideration and rehearing, the Board evaluated the propriety of the examiners rejection.<sup>101</sup> A majority of the Board concluded that no such technological arts test existed.<sup>102</sup> Specifically the Board noted that the patentable subject matter test requires a process claim "produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle, on its face within comfortably falls within the scope of § 101."<sup>103</sup> There is no support for a separate patentable subject matter test.<sup>104</sup> The Board specifically noted that it had rejected a technological arts test theory before and found *Ex Parte Bowman*, a previous Board opinion, unpersuasive because it was not precedential.<sup>105</sup> Finally, the Board pointed to the Supreme Court's decision in *Gottschalk v. Benson* as evidence that the Court was aware of such a test and had not adopted it.<sup>106</sup>

Administrative Patent Judge Jerry Smith dissented, concluding that a technological arts test was constitutionally mandated.<sup>107</sup> The term "Science" in the Constitution "should be interpreted to mean based on scientific principles."<sup>108</sup> Administrative Patent Judge Barrett wrote an in-depth concurrence-in-part and dissent-in-part concluding that the Board should enter a new ground of rejection under § 101.<sup>109</sup>

The opinion in *Lundgren* is a great example of how the USPTO can set patent policy and how its actions can go unreviewed for sometime. While the Board indicated that it was following Federal Circuit case law, it clearly was making a policy choice as to the scope of subject matter allowed under 35 U.S.C. § 101. Since it found the patent claims patentable, the issues it addressed in *Lundgren* are virtually non-reviewable by the Federal Circuit or the Supreme Court. Not until a business method patent claim is challenged on the same grounds in a patent infringement litigation or a third party reexamination will the Federal Circuit have an opportunity to opine on this issue. The issues discussed, however, may be touched by the Supreme Court in the upcoming *Metabolite* case.<sup>110</sup>

Contrasting the decision in *Lundgren* with that in *Fisher* highlights the industry specific nature of the § 101 requirement. While the amount of eligible subject matter in the biotechnology area is arguably shrinking, *Lundgren* signals an opposite direction in the computer software and business method fields. These cases provide further evidence of the policy levers available to courts and the USPTO to tune patent policy depending on the industry and science at issue

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<sup>101</sup> *Id.* at 3.

<sup>102</sup> *Id.* at 5-9.

<sup>103</sup> *Id.* at 5 (quoting *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1358 (Fed. Cir. 1999)). The Board, and even the examiner, concluded that the claims meet this patentable subject matter test. *Id.* at 4-5.

<sup>104</sup> *Id.* at 5-9.

<sup>105</sup> *Id.* at 6-8 (citing *Ex Parte Bowman*, 61 USPQ2d 1669 (Bd. Pat. App. & Int. 2001) (non-precedential)).

<sup>106</sup> *Id.* at 8-9 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

<sup>107</sup> *Lundgren*, No. 2003-2088, at 10-15 (Bd. Pat. App. & Int. 2005) (Smith, APJ, dissenting).

<sup>108</sup> *Id.* at 10 (Smith, APJ, dissenting).

<sup>109</sup> *Lundgren*, No. 2003-2088, at 16-92 (Bd. Pat. App. & Int. 2005) (Barrett, APJ, concurring-in-part and dissenting-in-part).

<sup>110</sup> *Lab. Corp. of Am. v. Metabolite Labs.*, No. 04-607 (U.S. Oct. 31, 2005).

**III. Anticipation -- *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005)**

Upon rehearing en banc, a divided panel of the Federal Circuit in *SmithKline Beecham Corp. v. Apotex Corp.* held, in part, that inherent anticipation can be found when the prior art produces trace amounts of the patented invention and those skilled in the art at the time did not have knowledge of these trace amounts.<sup>111</sup>

In the late 1970s, Ferrosan developed crystalline paroxetine hydrochloride ("PHC") in anhydrate form—without water—and was awarded a patent on the compound.<sup>112</sup> SmithKline licensed the patent from Ferrosan and then developed PHC in a hemihydrate form—with a water molecule—and was awarded a patent in the late 1980s claiming only the hemihydrate form of PHC.<sup>113</sup> SmithKline used the patented PHC hemihydrate in its antidepressant drug Paxil.<sup>114</sup> Then, Apotex filed an Abbreviated New Drug Application ("ANDA") seeking approval of its antidepressant drug with its active ingredient being PHC anhydrate.<sup>115</sup> SmithKline sued Apotex for infringement asserting that PHC anhydrate tablets necessarily contained amounts of PHC hemihydrate.<sup>116</sup> Ferrosan's earlier efforts producing PHC anhydrate created an unstable form that "morphed" into the more stable form—PHC hemihydrate.<sup>117</sup> Once PHC hemihydrate was produced, it then "seeded" the general environment with crystals of PHC hemihydrate that convert the anhydrate form into the hemihydrate form.<sup>118</sup> This "disappearing polymorph" and "seeding" phenomena make it impossible to create pure PHC anhydrate because "it changes naturally into the new polymorph, PHC hemihydrate."<sup>119</sup> Judge Posner, sitting by designation as a district court, found no infringement.<sup>120</sup>

In its initial majority opinion issued on April 23, 2004, the Federal Circuit reversed the district court's finding of no infringement, but found the asserted claim under the public use bar of 35 U.S.C. § 102(b).<sup>121</sup> With regards to the public use issue, the court noted that SmithKline used the claimed invention in public clinical trials in the

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<sup>111</sup> 403 F.3d 1331, 1343-46 (Fed. Cir. 2005) ("*SmithKline III*").

<sup>112</sup> *Id.* at 1334. The patent was U.S. Patent No. 4,007,196. *Id.*

<sup>113</sup> *Id.* The patent was U.S. Patent No. 4,721,723. *Id.* Claim 1 of the patent reads: "Crystalline paroxetine hydrochloride hemihydrate." *Id.* at 1339.

<sup>114</sup> *Id.* at 1334.

<sup>115</sup> *Id.* at 1334-35.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 1335.

<sup>118</sup> *Id.* at 1335-36.

<sup>119</sup> *Id.* at 1336.

<sup>120</sup> *Id.* at 1336-37. The district court construed the patent to require "commercially significant" amounts of PHC hemihydrate and found that Apotex only produced trace amounts of the compound. *Id.* at 1337. In the alternative, the district court "create[d] a new equitable defense to infringement" where the patentee "caused the alleged infringement." *Id.*

<sup>121</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1313-15, 1316-21 (Fed. Cir. 2004), vacated by 403 F.3d 1328 (Fed. Cir. 2005) (en banc) ("*SmithKline I*"). The court found the district court's claim construction too narrow and against the plain language of the claim. *Id.* at 1313-14. The court also dismissed the district court new equitable defense. *Id.* at 1315-16.

## Observations on Recent Patent Cases

United States before the critical date.<sup>122</sup> SmithKline asserted that this use was experimental.<sup>123</sup> The Federal Circuit disagreed because the uses were focused on whether the claimed compound worked as an antidepressant and "[t]he antidepressant properties of the compound are simply not claimed features."<sup>124</sup> Judge Gajarsa concurred, stating that he would invalidate the asserted claim as unpatentable under 35 U.S.C. § 101.<sup>125</sup>

The Federal Circuit, acting en banc, granted SmithKline's petition for rehearing en banc "for the limited purpose of vacating the panel's original opinion addressing the issue of experimental use" and remanded the case to the original panel for further proceedings.<sup>126</sup> The panel then issued an opinion changing its invalidity analysis.<sup>127</sup> The majority, instead of invalidating the composition claim under the public use bar, now found the claim inherently anticipated.<sup>128</sup> The court concluded that PHC hemihydrate was inherent in the earlier disclosures of PHC anhydrate because of the "disappearing polymorph" process that makes the manufacture of PHC anhydrate naturally produce PHC hemihydrate.<sup>129</sup> Thus, the earlier teaching of PHC anhydrate necessarily taught PHC hemihydrate, even if it produced only "trace amounts of PHC hemihydrate."<sup>130</sup>

The majority noted that "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created."<sup>131</sup> As long as all of the elements existed in the prior art, even if they were not detected at that time—the invention is inherently anticipated.<sup>132</sup> This stays true, the court found, to the rationale behind inherent anticipation—"to ensure that '[t]he 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>133</sup>

Judge Gajarsa maintained his concurrence, still focusing on invalidity under 35 U.S.C. § 101 because the claims necessarily encompassed unpatentable subject matter.<sup>134</sup> Judge Gajarsa raised this reason for invalidity *sua sponte* and based it upon the same scientific principles that supported SmithKline's theory of infringement.<sup>135</sup> A claim covering all PHC hemihydrate includes naturally produced compounds, and thus covers

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<sup>122</sup> *Id.* at 1317.

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

<sup>124</sup> *Id.* at 1319-21. The court noted that the "experimental use negation does not extend beyond perfecting claimed features." *Id.* at 1319.

<sup>125</sup> *SmithKline I*, 365 F.3d at 1321 (Gajarsa, J., concurring)..

<sup>126</sup> *SmithKline Beecham Corp. Apotex Corp.*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (en banc) ("*SmithKline II*").

<sup>127</sup> *SmithKline III*, 403 F.3d at 1342-46.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 1344-45.

<sup>130</sup> *Id.* at 1344-46.

<sup>131</sup> *Id.* at 1343 (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

<sup>132</sup> *Id.* at 1344-46.

<sup>133</sup> *Id.* at 1346 (quoting *Atlas Powder Co. v. Hanex Prods., Inc.* 190 F.3d 1342, 1348 (Fed. Cir. 1999)).

<sup>134</sup> *SmithKline III*, 403 F.3d at 1347 (Gajarsa, J., concurring).

<sup>135</sup> *Id.* at 1352-56, 1359-62 (Gajarsa, J., concurring).

unpatentable subject matter.<sup>136</sup> The reason such subject matter is not patentable is because one can infringe even when they want to avoid infringement, vitiating "public notice function of patents."<sup>137</sup>

Judge Newman dissented from the order on the petition for rehearing en banc.<sup>138</sup> Judge Newman asserted that the new majority panel opinion improperly enlarges the doctrine of inherent anticipation.<sup>139</sup> There was no evidence "that the hemihydrate existed at the time the anhydrate patent application was filed, and no evidence that such existence would have been recognized by a person of skill in the field of the invention."<sup>140</sup> PHC hemihydrate was not identified until a decade later after the anhydrate was invented and thus, the disclosure of anhydrate does not "provide retrospective knowledge of this then-unknown compound."<sup>141</sup> Judge Newman noted that anticipation requires the invention to have been "known or its existence would reasonably have been known to a person of ordinary skill of the invention."<sup>142</sup> To hold otherwise would call into question "[t]he patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial components of existing materials."<sup>143</sup>

The legal analysis produced in the multiple opinions in *SmithKline* are the product of the unique factual situation—"patentee induced infringement." Here, the activities of SmithKline made it impossible for anyone practicing the prior art to avoid infringing SmithKline's patent. This unique situation prompted varied responses from judges to avoid a finding of infringement—from a special equitable defense articulated by Judge Posner, to a § 101 basis for invalidity described by Judge Gajarsa, to inherent anticipated articulated by Judge Rader.

Furthermore, the contrast between Judge Rader's new majority in *SmithKline* and the dissent from the petition for rehearing en banc by Judge Newman clearly establishes the current disagreement on the court on the issue of inherent anticipation.<sup>144</sup> Hopefully, the court will eventually take this issue en banc to provide some clarity to an area of law that is, even without the conflict, difficult to comprehend.

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<sup>136</sup> *Id.* at 1359-62 (Gajarsa, J., concurring).

<sup>137</sup> *Id.* at 1359-63 (Gajarsa, J., concurring).

<sup>138</sup> *SmithKline II*, 403 F.3d at 1329-30 (Newman, J., dissenting).

<sup>139</sup> *Id.* at 1329 (Newman, J., dissenting).

<sup>140</sup> *Id.* (Newman, J., dissenting).

<sup>141</sup> *Id.* at 1329-30 (Newman, J., dissenting).

<sup>142</sup> *Id.* at 1330 (Newman, J., dissenting).

<sup>143</sup> *Id.* (Newman, J., dissenting).

<sup>144</sup> *See, e.g.*, *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003), *reh'g denied*, 348 F.3d 992 (Fed. Cir. 2003); *Randy P. Boyer, Schering Corporation v. Geneva Pharmaceuticals, Inc.: Requiem for the Recognition Requirement in the Law of Inherent Anticipation*, 14 Fed. Cir. B. J. 677 (2004).

#### IV. Obviousness

##### A. *Teleflex, Inc. v. KSR Intern. Co.*, No. 04-1152, 119 Fed. Appx. 282 (Fed. Cir. Jan 6, 2005) (unpublished)

In *Teleflex, Inc. v. KSR Intern. Co.*, an unpublished decision, a unanimous panel of the Federal Circuit vacated a summary judgment of obviousness because the district court "applied an incomplete teaching-suggestion-motivation."<sup>145</sup>

Teleflex sued KSR alleging infringement of its patent directed to an adjustable pedal assembly for use with electronic throttle control on automobiles.<sup>146</sup> Specifically, it asserted claim 4 of the patent describing an assembly where the electronic control is mounted to the support bracket of the assembly so as to avoid movement of the electronic control when the pedal's position is adjusted.<sup>147</sup> In due course, the district granted KSR summary judgment of invalidity, concluding that claim 4 is obvious.<sup>148</sup>

On appeal, the Federal Circuit vacated the district court's grant of summary judgment. The court first noted that, while the nature of the problem being solved can provide a suggestion or motivation to combine prior art references, the prior art references must "address the precise problem that the patentee was trying to solve."<sup>149</sup> Here, the prior art was not directed to solving the same problem as the Teleflex's patent—designing a "smaller, less complex, and less expensive electronic pedal assembly."<sup>150</sup> Instead, the art either addressed different problems—solving the "constant ratio problem" or "reducing wire chafing"—suffered from the problem Teleflex's patent solves.<sup>151</sup>

The court also discredited KSR's declaration in support of a finding of obviousness because it did not speak to motivation.<sup>152</sup> Instead, it simply stated that the prior art "could have been" combined to replicated the patented invention.<sup>153</sup> Teleflex also introduced two declarations before the district court supporting a conclusion of non-obviousness—noting that the invention "was simple, elegant, and novel combination of features"—which the Federal Circuit concluded presented, at the least, a genuine issue of material fact.<sup>154</sup>

Even though this is an unpublished decision, there has been significant interest in the case. Specifically, amicus, ranging from twenty-four law professors to large technological companies, have joined KSR in asking the Supreme Court to grant certiorari in the case to address the propriety of the Federal Circuit's "teaching, suggestion, or

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<sup>145</sup> No. 04-1152, 119 Fed. Appx. 282, 288 (Fed. Cir. Jan. 6, 2005).

<sup>146</sup> *Id.* at 283-84. The relevant patent is U.S. Patent No. 6,237,565.

<sup>147</sup> *Id.* at 284.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* at 288.

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

<sup>151</sup> *Id.* at 288-89.

<sup>152</sup> *Id.* at 289.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 289-90.

motivation" test.<sup>155</sup> The amicus assert that Supreme Court case law does not require such a showing to establish obviousness and that this requirement improperly sets the obviousness bar too high.<sup>156</sup> Since these filings, the Supreme Court has asked the United States government to provide briefing on the issue.

The decision in *Teleflex* and response by industry and academy highlights one of the current areas of focus of nonobviousness reform—the Federal Circuit's usage of the suggestion test. The traditional, broad, suggestion test recites three basis for a suggestion or motivation to combine the prior art: (a) the prior art references themselves; (b) the knowledge of those of ordinary skill in the art; and (c) the nature of the problem to be solved.<sup>157</sup> Recent criticism, including a report by the Federal Trade Commission in 2003, has asserted that the Federal Circuit uses a narrow suggestion test that requires any suggestion to come from the prior art—eliminating the other two independent grounds for a suggestion to combine.<sup>158</sup> *Teleflex* provides a good, albeit not perfect, example of an application of the narrow suggestion test, requiring the nature of the problem being solved basis for suggestion to come from the prior art. This application of the suggestion is the reason this unpublished decision has garnered so much attention.

**B. *In re Beasley*, No. 04-1225, 117 Fed. Appx. 739 (Fed. Cir. Dec. 7, 2004) (unpublished)**

A divided panel of the Federal Circuit, in the unpublished decision *In re Beasley*, vacated and remanded a Board decision because it failed to rely on "concrete evidence in the record" to establish a *prima facie* case of obviousness.<sup>159</sup>

Bruce Beasley applied for a patent on January 2, 1991 "directed to the generation of images or markings on a video display screen using a light pen."<sup>160</sup> The patent's independent claims required "mapping the display screen into the memory on a point-by-point basis . . . to provide a one-to-one correspondence" between the points on the screen and the memory locations.<sup>161</sup>

In the examiner's initial office action, he rejected the patent's claims for obviousness in view U.S. Patent No. 3,832,485 ("Pieters") combined with either U.S. Patent No. 3,973,245 ("Belser") or U.S. Patent No. 4,847,604 ("Doyle").<sup>162</sup> Pieters is directed to creating demarcations on images using a light pen, but fails to disclose the

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<sup>155</sup> See Br. of Twenty-Four Intellectual Property Law Professors as *Amici Curiae* in Support of Petitioner; Br. of Cisco Sys. Inc. et al. as *Amici Curiae* in Support of Petitioner; Br. of the Progress & Freedom Foundation as *Amicus Curiae* in Support of Petition for a Writ of Certiorari (May 12, 2005).

<sup>156</sup> See *id.*

<sup>157</sup> Ruiz v. A.B. Chance Co., 234 F.3d 654, 665 (Fed. Cir. 2000).

<sup>158</sup> Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), Chap. 4, at 8-9.

<sup>159</sup> No. 04-1225, 117 Fed. Appx. 739, 743-45 (Fed. Cir. Dec. 5, 2004).

<sup>160</sup> *Id.* at 740. Beasley's application was U.S. Patent Application 07/636,839. *Id.*

<sup>161</sup> *Id.* This limitation was added to the claims in response to an earlier obviousness rejection by the office. *Id.*

<sup>162</sup> *Id.* at 740-41.

point-by-point mapping limitation claimed by the application at issue.<sup>163</sup> The examiner, therefore, relied upon Belser or Doyle as disclosing "a conventional bit map memory mapping a display screen into the memory on a point by point basis."<sup>164</sup> The examiner also concluded that "it would have been obvious to one of ordinary skill in the art to substitute Belser's [or Doyle's] bit map memory" for the memory used in Pieters.<sup>165</sup> The examiner noted that a person of ordinary skill in the art would be motivated to make such a change "because image data stored in the bit map format can be read out rapidly."<sup>166</sup>

Beasley responded, asserting that the examiner failed to establish a *prima facie* case of obviousness.<sup>167</sup> In response, the examiner, in his final office action, maintained his obviousness rejection. The examiner asserted that it was "well known in [the] computer display art to substitute a bit map memory for a conventional memory such as the memory used in Pieters."<sup>168</sup> The examiner further detailed three advantages of the bit map memory disclosed in Belser and Doyle that were "well recognized."<sup>169</sup> In view of these well known advantages, the examiner concluded that "it would have been obvious to one of ordinary skill" to substitute the memory in Belser or Doyle for that disclosed in Pieters, making the invention unpatentable.<sup>170</sup> Beasley appealed to the Board, and the Board maintained the examiner's obviousness rejection.<sup>171</sup>

On appeal, a divided Federal Circuit concluded that there was no substantial evidence to support a *prima facie* case of obviousness. The court first noted that "the advantages of one type of memory over another that had been advanced by the examiner and the Board for the express purpose of showing motivation for the proposed substitution have been set forth without any supporting citations to relevant portions of either Pieters, Belser, Doyle, or any other authority."<sup>172</sup> The court faulted the Board for relying on "the examiner's and its own knowledge as skilled artisans."<sup>173</sup> The court also focused on the lack of "a citation of any relevant, identifiable source of information justifying" the substitution of the Pieters memory with the memory disclosed in Belser or Doyle.<sup>174</sup>

Judge Dyk dissented, finding "no error in the Board's reliance on the PTO's own specialized knowledge."<sup>175</sup> Judge Dyk noted that the Board and examiner "are presumed

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

<sup>164</sup> *Id.* at 740. As the court noted, Belser "concerns a method and apparatus for 'converting information in coded form into a dot matrix or raster form,'" while Doyle "is directed to a system that allows a user to point to a feature on an image and cause descriptive information . . . to appear." *Id.* at 741 n.3 (citing the relevant patents).

<sup>165</sup> *Id.* at 741.

<sup>166</sup> *Id.* (quoting the examiner's office action).

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

<sup>168</sup> *Id.* at 741 (quoting the examiner's office action).

<sup>169</sup> *Id.* (quoting the examiner's office action).

<sup>170</sup> *Id.* (quoting the examiner's office action).

<sup>171</sup> *Id.* at 741-42.

<sup>172</sup> *Id.* at 743.

<sup>173</sup> *Id.* at 743-44.

<sup>174</sup> *Id.* at 744.

<sup>175</sup> *Beasley*, 117 Fed. Appx. at 745 (Dyk, J., dissenting).

to be skilled in the art."<sup>176</sup> And in this case, the examiner articulated his knowledge and placed it on the record, satisfying any evidentiary concerns when knowledge is used to negate a finding of patentability.<sup>177</sup> Under these circumstances, Judge Dyk believed the USPTO established a *prima facie* case of patentability.<sup>178</sup> Finally, Judge Dyk recognized that the new MPEP provision regarding the use of general and common knowledge may "give[] the PTO greater scope to rely on its own expert knowledge," and that the court needs to address the extent of this provision.<sup>179</sup>

The majority opinion in *Beasley* provides the other half of the suggestion test discussion prompted by *Teleflex*. While *Teleflex* demonstrates a narrow suggestion test in the patent litigation context, *Beasley* demonstrates its application in the context of patent examination. Here, the Federal Circuit, relying on its 2002 opinion in *In re Lee*,<sup>180</sup> forces the USPTO to ground its finding of suggestion in a reference—knowledge of in the art or nature of the problem alone, without some grounding, cannot establish a *prima facie* case. Such a finding must be grounded in "concrete evidence," such as the prior art. This application of the narrow suggestion test in USPTO practice has further reaching implications than in the litigation setting, potential lowering the standard for nonobviousness for all patent applications, not just those that reach the litigation stage. Thus, discussions of the suggestion test prompted by the certiorari petition in *Teleflex* will include the way the test affects patent prosecution.

**C. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), request for rehearing en banc denied, 405 F.3d 1338**

A divided panel of the Federal Circuit, in *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, held, in part, that evidence of commercial success is not probative of nonobviousness when others in the market were legally barred, due to patent protection, from combining the teachings of the prior art and implementing the patented invention.<sup>181</sup>

Merck owns a patent directed to "a method of treating and preventing osteoporosis through less-than-daily administration of bisphosphonate," and markets the patented drug under the trade name Fosamax.<sup>182</sup> Teva sought an ANDA for a generic version of Fosamax.<sup>183</sup> Merck then filed suit against Teva, alleging that Teva's filing of the ANDA was an act of infringement of its Fosamax patent.<sup>184</sup> The district court rejected Teva's arguments that Merck's patent was invalid as anticipated and obviousness and, as a result, enjoined Teva.<sup>185</sup>

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<sup>176</sup> *Id.* (Dyk, J., dissenting) (citing *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002)).

<sup>177</sup> *Beasley*, 117 Fed. Appx. at 745 (Dyk, J., dissenting).

<sup>178</sup> *Id.* (Dyk, J., dissenting).

<sup>179</sup> *Id.* at 745-46 (Dyk, J., dissenting) (citing MPEP 2144.03 (8th ed., rev. 2, 2004)).

<sup>180</sup> 277 F.3d 1338 (Fed. Cir. 2002).

<sup>181</sup> 395 F.3d 1364, 1376-77 (Fed. Cir. 2005).

<sup>182</sup> *Id.* at 1365-66. The patent is U.S. Patent No. 5,994,329. *Id.* at 1365.

<sup>183</sup> *Id.* at 1367.

<sup>184</sup> *Id.*

<sup>185</sup> *Id.* at 1368.

## Observations on Recent Patent Cases

On appeal, the Federal Circuit affirmed the district court's finding of invalidity. In addition to other issues,<sup>186</sup> the Federal Circuit addressed Merck's argument regarding commercial success as a secondary consideration of non-obviousness.<sup>187</sup> The Federal Circuit noted that "[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to the market sooner, in response to market forces, had the idea been obvious to persons skilled in the art."<sup>188</sup> This rationale, the court concluded, had "no force in this case" because others were "legally barred from commercially testing" the invention.<sup>189</sup> Merck owned another, earlier base patent that precluded others from practicing the patented invention at issue.<sup>190</sup> "Because market entry by others was precluded on those bases, the inference of non-obviousness . . . from evidence of commercial success, is weak."<sup>191</sup>

The Federal Circuit then denied Merck's petition for rehearing and rehearing en banc.<sup>192</sup> A poll of the judges was taken and Judge Lourie, joined by Chief Judge Michel and Judge Newman, wrote a dissent from the order denying the rehearing en banc.<sup>193</sup> The dissent focused on the panel's discussion of commercial success.<sup>194</sup> The dissent asserted that the probative nature of commercial success "is not negated by any inability by others to test various formulations because of the existence of another patent."<sup>195</sup> For this secondary consideration, "[s]uccess is success."<sup>196</sup> The dissent also clarified that commercial success is "independent" of the "failure of others," which is a secondary consideration of its own.<sup>197</sup> Finally, the dissent took issue with the panel's ruling "because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention."<sup>198</sup>

*Merck* complements the other nonobviousness opinions in *Teleflex* and *Beasley* by highlighting the other aspect of nonobviousness that has been the focus of recent reform efforts—secondary considerations and, more specifically, commercial success. In addition to targeting the suggestion test, recent reports on the patent system have noted

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<sup>186</sup> An additional issue of particular note was the proper construction of the claim term "about." The majority concluded that the district court erred in interpreting "about" to mean "exactly," and instead should be given its ordinary meaning of "approximately." *Id.* at 1369-72. In his dissent, Judge Rader agreed with the district court's construction, concluding that the patentee had acted as his own lexicographer in the patent's specification. *Merck*, 395 F.3d at 1377-80 (Rader, J., dissenting). Judge Rader also stated that the Federal Circuit, particularly in close cases of construction such as this one, should give deference to the lower court's decision. *Id.* at 1380-81 (Rader, J., dissenting).

<sup>187</sup> *Id.* at 1376-77. The court found that Teva had established a prima face case of obviousness. *Id.* at 1372-76.

<sup>188</sup> *Id.* at 1376.

<sup>189</sup> *Id.* at 1376-77.

<sup>190</sup> *Id.* at 1377. That patent is U.S. Patent No. 4,621,077.

<sup>191</sup> *Id.*

<sup>192</sup> *Merck & Co. v. Teva Pharm. U.S.A., Inc.*, 405 F.3d 1338, 1338 (en banc).

<sup>193</sup> *Id.* at 1338-39.

<sup>194</sup> *Id.* at 1339.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

the importance of secondary considerations to a proper nonobviousness analysis.<sup>199</sup> The attempt by the court to further define the scope of these considerations, while not conclusive, shows the court's interest in this other significant area of nonobviousness jurisprudence.

## V. Infringement

### A. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372 (2005)

The Supreme Court, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, held that "the use of patented compounds in preclinical studies is protected under [35 U.S.C.] § 271(e)(1) as long as there is a reasonable basis for believing the experiments will produce" information that is relevant to an FDA submission, such as an investigational new drug application ("IND") or new drug application ("NDA").<sup>200</sup>

Integra Lifesciences I., Ltd. ("Integra") owns patents covering the tripeptide sequence Arg-Gly-Asp, identified by the single-letter notation "RGD peptide."<sup>201</sup> The technology "promotes cell adhesion by attaching to  $\alpha_v\beta_3$ " receptors on the surface of cells.<sup>202</sup> Merck used the RGD peptide in its research trying to inhibit angiogenesis—a process that plays a significant role in tumor growth and certain diseases.<sup>203</sup> The peptides were used in *in vitro* and *in vivo* experiments to determine their "efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors."<sup>204</sup> The results of these experiments were then used by Merck to choose the best candidate for clinical development.<sup>205</sup> Merck also used the RGD peptides as "positive controls" to measure the efficacy of organic mimetics designed to inhibit angiogenesis in a similar manner as the RGD peptides.<sup>206</sup> None of these experiments directly supplied information for submission to the United States Food and Drug Administration ("FDA").<sup>207</sup>

Integra became aware of Merck's activities and sued them for infringement of its RGD peptide patents.<sup>208</sup> Merck responded that its activities were exempt from infringement under 35 U.S.C. § 271(e).<sup>209</sup> The issue was submitted to a jury that found

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<sup>199</sup> See FTC, *supra* note 158, at Chap. 4, pgs. 15-19.

<sup>200</sup> 125 S.Ct. 2372, 2383-84 (2005).

<sup>201</sup> *Id.* at 2377. Integra's patents covering RGD peptide include U.S. Patent Nos. 4,988,621; 4,792,525; 5,695,997; 4,879,237; and 4,789,734. *Id.*

<sup>202</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 862 (Fed. Cir. 2004), rev'd by, 125 S.Ct. 2372 (2005).

<sup>203</sup> *Merck*, 125 S.Ct. at 2378. "Angiogenesis is the process by which new blood vessels sprout from existing vessels." *Id.* Merck provided

<sup>204</sup> *Id.*

<sup>205</sup> *Id.* at 2378-79.

<sup>206</sup> *Id.* at 2379.

<sup>207</sup> *Integra*, 331 F.3d at 866. The experimentation was for "only general biomedical research to identify new pharmaceutical compounds. *Id.*

<sup>208</sup> *Merck*, 125 S.Ct. at 2379.

<sup>209</sup> *Id.* Section 271(e)(1) provides that "[i]t shall not be an act of infringement to . . . use . . . or import into the United States a patent invention . . . solely for uses reasonably related to the development and

that Merck infringed and failed to show it fell within the exemption.<sup>210</sup> On appeal, a divided panel of the Federal Circuit concluded that the exemption did not apply because "the [Merck] work sponsored by Integra was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."<sup>211</sup> The Supreme Court took the case to address the breadth of the § 271(e)(1) exemption.<sup>212</sup>

The Supreme Court did not agree with the Federal Circuit's interpretation of the exemption. First, the Court noted that the plain language of § 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Federal Food, Drug and Cosmetic Act]."<sup>213</sup> The Court found nothing in the statute that narrowed the exemption to a particular "phase of research" or "submission" to the FDA.<sup>214</sup> The Court further rejected the argument that, with regards to preclinical data, the exemption is limited to experiments to produce safety information or conducted in conformity with the FDA's good laboratory practices.<sup>215</sup>

The Court then concluded that the § 271(e)(1) simply requires infringing uses to be "reasonably related" to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs" to be eligible for the exception.<sup>216</sup> Experiments do not need to be part of the "submission of information" to the FDA and they can, due to failures for example, never be submitted to the FDA.<sup>217</sup> The experimenter, however, does need a "reasonable basis" to believe that the experiments with the patented compound will produce information relevant to an IND or NDA.<sup>218</sup> The case was then remanded to the Federal Circuit.

The Supreme Court did not address the common-law research exception, even though it was asserted.<sup>219</sup> On remand, however, this issue may be breached. The Federal Circuit recently issued an order asking both parties to file briefs with "particular attention paid to the Supreme Court decision."<sup>220</sup> The DC Bar Association have filed an amicus brief with the Federal Circuit asking the court to simply remand the case back to the district court on the statutory exception and with orders not to address the common-law

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submission of information under a Federal law which regulates the . . . use . . . of drugs." 35 U.S.C. § 271(e)(1).

Merck also asserted the "common-law research exemption" to infringement, but the Supreme Court did not address this issue in its opinion. *Merck*, 125 S.Ct. at 2379.

<sup>210</sup> *Merck*, 125 S.Ct. at 2380.

<sup>211</sup> *Integra*, 331 F.3d at 866. Judge Newman dissented in part, asserting that the majority improperly interpreted the statutory exemption. *Integra*, 331 F.3d at 877 (Newman, J., dissenting).

<sup>212</sup> *Merck*, 125 S.Ct. at 2380.

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

<sup>215</sup> *Id.* at 2380-82.

<sup>216</sup> *Id.* at 2383-84.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.* at 2384 (quoting the United States Amicus brief with approval).

<sup>219</sup> *Id.* at 2379.

<sup>220</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 02-1052, 02-1065, 2005 WL 1965928, \*1 (Fed. Cir. Aug. 17, 2005).

exception. The Glushko-Samuelsan Clinic has filed a brief asking for the very opposite—insisting that Federal Circuit should address the common-law exception. The focus on the common-law research exemption of these two amicus briefs highlight that the real area of contention in this area of the law.

**B. *NTP v. Research in Motion Ltd.*, No. 03-1615, 2005 WL 1806123 (Fed. Cir. Aug. 2, 2005).**

In its revised opinion *NTP, Inc. v. Research in Motion, Ltd.*, a unanimous Federal Circuit panel held, in part, that the location for "uses " under 35 U.S.C. § 271(a) are (a) for system, claims "the place where control of the system is exercised and beneficial use of the system obtained" and (b) for method claims, where "each of the steps is performed."<sup>221</sup>

NTP, Inc. sued Research In Motion, Ltd. ("RIM") alleging that RIM's BlackBerry system infringed five of NTP's patents.<sup>222</sup> The patents claimed systems and methods for "integrating existing electronic mail systems with radio frequency wireless communications networks, to enable a mobile use to receive email over a wireless network."<sup>223</sup> After a jury verdict of infringement and an award of damages and an injunction, RIM appealed to the Federal Circuit.<sup>224</sup>

While reviewing many alleged errors,<sup>225</sup> the Federal Circuit specifically addressed RIM's claim that they could not, as a matter of law, infringe the asserted patents under 35 U.S.C. 271(a).<sup>226</sup> RIM asserted that § 271(a) required all acts of infringement to occur in the United States and one of the infringing components, and one of the infringing steps, was outside the United States, in Canada.<sup>227</sup>

The Federal Circuit, in its initial opinion in the case, concluded that § 271(a) allowed a finding of infringement when (a) "all of the other components of [the] accused system occur in the United States" and (b) "the control and beneficial use of [the] system occur in the United States."<sup>228</sup> In these circumstances, the court found that "the situs of the 'use' for purposes of section 271(a) is the United States."<sup>229</sup>

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<sup>221</sup> No. 03-1615, 2005 WL 1806123, at \*28-\*29 (Fed. Cir. Aug. 2, 2005).

<sup>222</sup> *Id.* at \*4. Specifically, NTP asserted that RIM infringed U.S. Patent Nos. 5,436,390; 5,625,670; 5,819,172; 6,067,451; and 6,317,592. *Id.* at \*1.

<sup>223</sup> *Id.*

<sup>224</sup> *Id.* at \*4-\*5.

<sup>225</sup> These included issues concerning the district court claim construction and evidentiary rulings. *See id.* at \*7-\*22; \*36-\*37.

<sup>226</sup> *Id.* at \*24-\*35.

<sup>227</sup> *Id.* at \*24-\*26. Specifically, RIM's relay switch, which meet the "interface" or "interface switch," is located in Canada. *Id.* at \*25. NTP initially disputed the relay switch's location, but the factual question was resolved in RIM's favor. *Id.* at \*25 n.11.

<sup>228</sup> *NTP, Inc. v. Research in Motion Ltd.*, 392 F.3d 1336, 1368-70 (Fed. Cir. 2004), withdrawn and replaced by, No. 03-1615, 2005 WL 1806123 (Aug. 2, 2005).

<sup>229</sup> *Id.* at 1370.

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However, the court granted rehearing for the "limited purpose of revising portions of the opinion treating Section 271," and then withdrew its prior opinion and replaced it with a new opinion.<sup>230</sup> In the new opinion, the Federal Circuit redrafted its analysis of the § 271(a) question.<sup>231</sup> Initially, the court continued to hold that "[t]he use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, i.e., the place where the control of the system is exercised and beneficial use of the system obtained."<sup>232</sup> In this case, as it previously held, such location is the United States, even though part of the system used was in Canada.<sup>233</sup>

The court, however, came to a different result with regards to the method claims.<sup>234</sup> The court held that the concept of "use" for method claims is different—requiring all steps of the method to be performed in the United States.<sup>235</sup> "[U]nlike use of a system as a whole, in which the components are used collectively," "the use of a process necessarily involves doing or performing each of the steps recited."<sup>236</sup> Thus, RIM could not infringe the method claims because at least one step occurred outside the United States.<sup>237</sup>

The Federal Circuit then addressed whether RIM infringed the method claims under any other theory than use.<sup>238</sup> RIM could not infringe the method claims under the "sells" or "offers to sell" prongs of § 271(a) because the sell or offering to sell of the "handheld device" used in the claimed method "is not, in and of itself, enough."<sup>239</sup> The court did not, however, go as far to hold that a method claim could not be infringed under these prongs.<sup>240</sup> The court dismissed infringement under the "imports into the United States" prong of § 271(a) for similar reasons.<sup>241</sup>

Section 271(f) was not infringed because the providing of handheld devices and related software products to United States customers is "not the statutory 'supply' of any 'component' steps for combination into the" claimed method.<sup>242</sup> Finally, the court held that § 271(g) was not infringed because the email packets RIM transferred into the United

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<sup>230</sup> *NTP*, 2005 WL 1806123, at \*1. The court received multiple amicus briefs requesting a rehearing and rehearing en banc, including a brief filed by the Canadian government. *Id.*

<sup>231</sup> *Id.* at \*24-\*35.

<sup>232</sup> *Id.* at \*28. The court reached this conclusion based on the plain language of § 271(a) and an earlier decision of the Court of Claims, *Decca Ltd. v. United States*, 544 F.2d 1070 (Ct. Cl. 1976). *Id.*

<sup>233</sup> *Id.*

<sup>234</sup> *Id.* at \*29.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.* at \*30-\*35. The court did not need to address these other theories with regards to the system claims because infringement had already been found under a "use" theory. *Id.* at \*30.

<sup>239</sup> *Id.* at \*30-\*32.

<sup>240</sup> *Id.* at \*32. The court did note, however, that "[t]he indication we have from Congress on infringement by selling or offering to sell method claims shows that it believes the beachhead is narrow." *Id.*

<sup>241</sup> *Id.* at \*32. The court did state that "[t]he legislative history cited with respect to the sell and offer to sell provisions indicates that Congress did not consider the 'import' prong of section 271(a) to apply to method claims." *Id.*

<sup>242</sup> *Id.* at \*33-\*34.

States are not "products" for purposes of § 271(g).<sup>243</sup> Section 271(g) requires the product produced by a patented process and imported into the United States to be a "physical product"—something e-mail is not.<sup>244</sup>

The *NTP* decision is just a part of the growing number of cases dealing with the possible extra-territoriality of patent law. A related situation arose in the *Eolas v. Microsoft* case.<sup>245</sup> In *Voda v. Cordis Corp.*, Voda took it a step further, attempting to assert a foreign patent in a U.S. district court.<sup>246</sup> All of these situations stem, in part, from inventions that span across borders, with some of the claimed system or steps in a method occurring outside the United States.<sup>247</sup> At least after *NTP*, it is clear that system claims will fair much better than method claims in capturing infringing activities that cross borders.

## VI. Inequitable Conduct -- *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 410 F.3d 690 (Fed. Cir. 2005)

A unanimous Federal Circuit panel in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.* found statements made by an applicant to be material for purposes of inequitable conduct when the statements (a) were used to distinguish his invention over the prior art and (b) implied experimental results that had been obtained when actually such statements were based on only the inventor's insight.<sup>248</sup>

Purdue produces a controlled release oxycodone pain medication called OxyContin.<sup>249</sup> Purdue also holds patents covering the medication.<sup>250</sup> Purdue sued Endo alleging that Endo's proposed generic version of OxyContin would infringe these patents.<sup>251</sup> The asserted claims required, in part, "[a] controlled release . . . comprising from about 10 to about 40 mg oxycodone" to be administered "every 12 hours . . . ."<sup>252</sup> Each of the asserted patents included the following paragraph in its "Detailed Description" section of the written description:

It has now been *surprisingly discovered* that the presently claimed controlled release oxycodone formulations acceptably control pain over a

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<sup>243</sup> *Id.* at \*34-\*35.

<sup>244</sup> *Id.* at \*35.

<sup>245</sup> *Eolas Techs., Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1338-40 (Fed. Cir. 2005) (discussing the breadth of § 271(f) when the component sent outside the United States is software).

<sup>246</sup> *See Voda v. Cordis Corp.*, No. CIV-03-1512-L, 2004 WL 3392022 (W.D. Okla. Aug. 2, 2004) (granting the plaintiff leave to amend the complaint to allege infringement of foreign patents).

<sup>247</sup> *See, e.g., Mark A. Lemley et. al., Divided Infringement Claims*, 33 AIPLA Q.J. 255 (2005) (discussing theories of, and practical solutions regarding, claims that may include extra-territorial actions to be infringed).

<sup>248</sup> 410 F.3d 690, 699-700 (Fed. Cir. 2005).

<sup>249</sup> *Id.* at 693.

<sup>250</sup> *Id.*

<sup>251</sup> *Id.* Specifically, Purdue asserted that Endo infringed U.S. Patent No. 5,549,912 (the '912 patent) and the '912 patent's continuation-in-part, U.S. Patent No. 5,656,295 and its divisional, U.S. Patent No. 5,508,042. *Id.*

<sup>252</sup> *Id.* at 693-94 (citing claim 1 of the '912 patent).

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substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours-around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.<sup>253</sup>

The written description also describes the "clinical significance" of the claimed four-fold dosage range of the invention over other opioid analgesics, such as morphine.<sup>254</sup>

During prosecution of the applications, Purdue distinguished its claimed controlled release oxycodone formulation from the prior art by emphasizing its "surprising discovery" of claimed four-fold dosage range compared to the eight-fold range for other opioids.<sup>255</sup> Purdue also emphasized that the "in vivo parameters set forth in the claims 'are specifically related to the surprising results obtained by the invention.'"<sup>256</sup> However, the inventor testified at trial that during prosecution of the asserted patents the claimed range was founded on "insight," not any scientific proof or clinical results.<sup>257</sup>

Based on these facts, the Federal Circuit agreed with the district court that Purdue failed to disclose material information during prosecution.<sup>258</sup> Purdue's statements in the asserted patents and to the examiner "clearly" created the inference that they were based on the results of clinical studies.<sup>259</sup> The Federal Circuit also emphasized that these statements were not made to show a "general benefits" of the claimed invention, but "instead relied on . . . to distinguish [Purdue's] invention over" the prior art.<sup>260</sup> The court also clarified that the law does not require inventions to be supported by clinical results—they can be based on only insight—applicants just cannot make material misrepresentations to the USPTO.<sup>261</sup>

Finally, the court affirmed the district court's finding of intent.<sup>262</sup> The finding was properly based on "a clear pattern of misdirection throughout prosecution."<sup>263</sup> The court noted that Purdue had many opportunities to explain it "had no scientific proof of a reduced dosage range, yet Purdue continued to describe its discovery in terms of 'results,' using precise, quantitative, and comparative language."<sup>264</sup>

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<sup>253</sup> *Id.* at 694 (quoting '912 patent, col. 3, ll. 34-41) (emphasis added).

<sup>254</sup> *Id.* at 694 (quoting '912 patent, col. 4, ll. 51-63).

<sup>255</sup> *Id.* at 698. Purdue also made similar statements, and filed an affidavit to the same effect, during the prosecution of the '912 patent's parent, U.S. Patent No. 5,266,331. *Id.* at 697-98.

<sup>256</sup> *Id.* at 698.

<sup>257</sup> *Id.* at 696-97. Purdue did not dispute this testimony. *Id.* at 697.

<sup>258</sup> *Id.* at 698-700.

<sup>259</sup> *Id.* at 698-99.

<sup>260</sup> *Id.* at 699-700

<sup>261</sup> *Id.* (noting this fact in response, in part, to an amicus curiae brief of Guilford Pharmaceuticals).

<sup>262</sup> *Id.* at 700-01.

<sup>263</sup> *Id.* at 700.

<sup>264</sup> *Id.* at 701.

*Purdue* is a significant case because, due to the early nature of patent disclosures, inventors rarely have scientifically, fully established every aspect of their invention. So statements such as those that appear in the written description in *Purdue* are not uncommon. These statements alone, however, are not what the court focuses on to find materiality. It is the reliance on these statements to overcome a rejection. Therefore, *Purdue* is a reminder to the patent prosecutor to communicate with the inventor or inventors throughout the prosecution process and make sure, when relying on something such as unexpected results, that there truly are results upon which to base that argument.

**VII. Antitrust -- *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342 (Fed. Cir. 2005), cert. granted, 125 S.Ct. 2937**

In *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, the Federal Circuit, in a unanimous panel opinion, held that "a rebuttable presumption of market power arises from the possession of a patent over a tying product."<sup>265</sup> On June 20, 2005, the Supreme Court granted certiorari in the case,<sup>266</sup> taking on the question as to whether the existence of a patent implies market power in antitrust cases.

Independent filed suit against Illinois Tool Works ("ITW) in the Central District of California seeking a declaratory judgment of non-infringement and invalidity ITW's patents on ink jet printheads.<sup>267</sup> Independent then amended its complaint to include allegations of illegal tying and monopolization in violation of sections 1 and 2 of the Sherman Act.<sup>268</sup> Independent's antitrust claims alleged that ITW's "standard form licensing agreements . . . grants the right to 'manufacture, use and sell . . . [the patented] ink jet printing devices supplied by Trident' only 'when used in combination with ink and ink supply systems supplied by Trident.'"<sup>269</sup> Both parties moved for summary judgment on Independent's Sherman Act section 1 claim while only ITW moved for summary judgment on the section 2 claim.<sup>270</sup> The district court granted ITW summary judgment on both the section 1 and 2 claims.<sup>271</sup> The parties then settled all remaining claim, including the patent claims.<sup>272</sup> The parties appealed only the antitrust claims to the Federal Circuit.<sup>273</sup>

The court first addressed whether Federal Circuit or Ninth Circuit law governs the Sherman Act claims.<sup>274</sup> The court concluded that it was settled Federal Circuit law that "where an affirmative antitrust claim or antitrust misuse defense is based on 'procuring or enforcing a patent,' the central antitrust question is a matter governed by Federal Circuit

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<sup>265</sup> 396 F.3d 1342, 1344 (Fed. Cir. 2005).

<sup>266</sup> *Illinois Tool Works, Inc. v. Indep. Ink, Inc.*, 125 S.Ct. 2937 (2005).

<sup>267</sup> *See Indep.*, 396 F.3d at 1345.

<sup>268</sup> *Id.*

<sup>269</sup> *Id.* (quoting ITW's standard form licensing agreement).

<sup>270</sup> *Id.*

<sup>271</sup> *Id.*

<sup>272</sup> *Id.* at 1345-46. The patent claims were then dismissed with prejudice and judgment was entered. *Id.*

<sup>273</sup> *Id.* at 1346. The Federal Circuit found appellate jurisdiction because "the complaint originally contained a declaratory judgment of invalidity and non-infringement." *Id.*

<sup>274</sup> *Id.*

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law.<sup>275</sup> The court noted, however, that it "'will continue to apply the law of the appropriate regional circuit to issues involving other elements of antitrust law,' such as defining the relevant market and determining as a factual matter whether power exists within the market."<sup>276</sup>

The court then turned to Independent's section 1 claim--specifically whether patent tying is illegal per se.<sup>277</sup> The court concluded, after reviewing the relevant Supreme Court cases, specifically *International Salt Co. v. United States*<sup>278</sup> and *United States v. Loew's, Inc.*,<sup>279</sup> that "Supreme Court cases in this area squarely establish that patent and copyright tying, unlike other tying cases, do not require an affirmative demonstration of market power."<sup>280</sup> The court noted that "[t]he fundamental error in all of the defendants' arguments is that they ignore the fact that it is the duty of a court of appeals to follow the precedents of the Supreme Court until the Court itself chooses to expressly overrule them."<sup>281</sup>

The court did, however, view this presumption established by the Supreme Court as being rebuttable.<sup>282</sup> In addition, the court did not see the presumption extending to section 2 cases and supporting a finding of monopolization or attempted monopolization over the tied product.<sup>283</sup> Thus, the Federal Circuit reversed the district court's grant of summary judgment as to the Sherman Act section 1 claim but affirmed the grant of summary judgment as to the section 2 claim.<sup>284</sup>

Many amicus filed petitions for writ of certiorari in this case.<sup>285</sup> All of the amicus, and ITW of course, ask the Supreme Court to find no presumption of market

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<sup>275</sup> *Id.* (quoting *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 1067-68 (Fed. Cir. 1998) (en banc in relevant part)).

<sup>276</sup> *Indep. Ink*, 396 F.3d at 1346 (quoting *Nobelpharma*, 141 F.3d at 1068).

<sup>277</sup> *Indep. Ink*, 396 F.3d at 1346-1349.

<sup>278</sup> 332 U.S. 392 (1947).

<sup>279</sup> 371 U.S. 38 (1962).

<sup>280</sup> *Indep. Ink*, 396 F.3d at 1348-49. "Thus, a patent presumptively defines the relevant market as the nationwide market for the patented product itself, and creates a presumption of power within the market." *Id.* at 1352.

<sup>281</sup> *Id.* at 1351.

<sup>282</sup> *Id.* at 1351-52 (noting that once the presumption is established, "it is the defendant's burden to rebut the presumption of market power and consequent illegality that arises from patent tying").

<sup>283</sup> *Id.* at 1353.

<sup>284</sup> *Id.* at 1353-54.

<sup>285</sup> See Br. U.S. as Amicus Curiae Supporting Petitioners, 2005 WL 186093 (Aug. 4, 2005); Br. Am. Bar Ass'n as Amicus Curiae in Support of Petitioners, 2005 WL 1864121 (Aug. 4, 2005); Br. for Verizon Communication as Amicus Curiae in Support of Petitioners, 2005 WL 1865478 (Aug. 4, 2005); Br. Amicus Curiae Intellectual Property Owners Ass'n in Support of Petitioners, 2005 WL 1865479 (Aug. 4, 2005); Br. of the Washington Legal Foundation as Amicus Curiae in Support of Petitioners, 2005 WL 1865480 (Aug. 4, 2005); Br. of New York Intellectual Property Law Ass'n as Amicus Curiae in Support of Petitioners, 2005 WL 1865481 (Aug. 4, 2005); Br. of the Houston Intellectual Property Law Ass'n as Amicus Curiae in Support of Petitioners, 2005 WL 1865482 (Aug. 4, 2005); Br. of Amicus Curiae Bar Ass'n of the District of Columbia – Patent, Trademark & Copyright Section in Support of Petitioner, 2005 WL 1902109 (Aug. 4, 2005); Br. of Amicus Curiae American Intellectual Property Law Ass'n in Support of Neither Party, 2005 WL 1912324 (Aug. 4, 2005); Br. for the Motion Picture Ass'n of Am., Inc. et. al. as Amici Curia Supporting Reversal, 2005 WL 1920933 (Aug. 4, 2005); Br. Amicus Curiae of the Intellectual Property

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power arising from the possession of a patent over a tying product.<sup>286</sup> The case is set for oral argument on November 29, 2005.

All indications are that the Supreme Court took the case to abandon the *per se* rule establishing a presumption of market power in these cases. However, *Independent Ink* will not signal the end of the Supreme Court's focus on antitrust and patent law. The Court recently asked for briefing from the Solicitor General in the petition for certiorari in another patent law and antitrust case, *Fed. Trade Comm'n v. Schering-Plough Corp.*<sup>287</sup>

### Conclusion

This past year in patent law witnessed many significant developments. However, it will most likely be remembered for the foundation it established for legal changes to come. The best example of this is in the area of utility and patentable subject matter, with the Supreme Court already slated to address this area in *Metabolite* and the USPTO continuing to act after its decision in *Lundgren*. Patent observers will need to a watchful eye on cases such as these, and the related cases to come.

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Law Ass'n of Chicago in Support of Petitioners, 2005 WL 1801032 (July 26, 2005); Br. of the American Bar Ass'n as Amicus Curiae in Support of Petitioners, 2005 WL 1397187 (May 5, 2005); Br. of Amicus Curiae of Intellectual Property Owners Ass'n in Support of Certiorari, 2005 WL 1397188 (May 5, 2005); Br. of Amicus Curiae American Intellectual Property Law Ass'n in Support of Petitioners, 2005 WL 1334162 (May 4, 2005).

<sup>286</sup> *Id.*

<sup>287</sup> No. 05-273 (U.S. Oct. 31, 2005)