# 4 Tex. Intell. Prop. L.J. 303

# Texas Intellectual Property Law Journal Winter, 1996

# Recent Develpment

# RECENT DEVELOPMENTS IN PATENT LAW

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#### \*304 I. Introduction

This article reviews patent cases reported in the September through December 1995 advance sheets of the United States Patent Quarterly, 35 U.S.P.Q.2d 1577-1864 and 36 U.S.P.Q.2d 1001-1864.

The cases are reviewed by subject matter and where a case has points of interest under more than one heading, the first reference to the case contains the full discussion of that case. The headings are necessarily arbitrary and were chosen to aid the review of the cases.

#### **II. Construction of Claims**

The after-shock of *Markman*<sup>1</sup> was clearly present in several reported cases.

## A. Exxon Chemical Patents, Inc. v. Lubrizol Corp.<sup>2</sup>

The district court entered a judgment of willful infringement based on the jury verdict, though only literal infringement was put to the jury.<sup>3</sup> The Federal Circuit reversed.<sup>4</sup>

The district court erroneously believed it had to adopt the claim construction offered by one or other of the parties.<sup>5</sup> The Federal Circuit held that the trial judge has an independent duty to determine the meaning of claims and to instruct the jury accordingly.<sup>6</sup> In this case, each party's proposed construction was partly right and partly wrong. If the correct interpretation of the claim had been included in the charge, no reasonable jury could have found infringement.<sup>7</sup>

The claims at issue were product claims. Exxon contended that the claim was a recipe so that a combination of the listed ingredients caused infringement, even if the finished product did not contain all elements.<sup>8</sup>

\*305 The Federal Circuit held that the correct issue is whether defendant's products at some time contained each of the claimed recipe ingredients in the claimed amounts. In particular, the question was whether Lubrizol's products at some time contained an ashless dispersant in the amount claimed. Exxon adduced no evidence that Lubrizol's products ever contained all of the claimed ingredients in the claimed amount. Therefore, infringement was not established. On the claimed ingredients in the claimed amount.

The dissent argued that Exxon proved Lubrizol used the claimed ingredients in the claimed amounts when making its product and that this was enough to establish literal infringement, despite argument that in its final product some reaction or

combination of the ingredients may have altered the amounts of each ingredient.11

## B. Laitram Corp. v. NEC Corp. 12

The Federal Circuit applied its *Markman* de novo review of claim construction.<sup>13</sup> The jury found the claim infringed, but the district court entered judgment as a matter of law, holding no infringement.<sup>14</sup> The Federal Circuit reversed and remanded for reinstatement of the jury's verdict, holding that the trial court correctly decided that the claim allowed "strobed" operation of the LED's, but then wrongly held no infringement.<sup>15</sup> There was "substantial evidence" supporting the jury's verdict of infringement.<sup>16</sup> The patent described both continuous and strobed activation of the LED's.<sup>17</sup> The accused device used strobed activation of the LED's, each strobe of a fixed duration.<sup>18</sup> The trial court's construction of the claims which did not cover fixed-time strobed activation during variable periods of activation was wrong, based on the prosecution history and prior art.<sup>19</sup>

#### III. Infringement

Infringement is a fact issue, to be determined by a jury if any question remains after the court's construction of the claim. In an evenhanded way the Federal Circuit, \*306 having taken the duty of claim construction from the jury in *Markman*, handed to the jury the issue of infringement under the doctrine of equivalents and decreed that the doctrine be applied in every case in *Hilton Davis*.<sup>20</sup>

#### A. Infringement Under 35 U.S.C. § 271(e)(2)(A)21

Section 271(e)(2)(A) provides that it is an infringement of a patent to file an Abbreviated New Drug Application (ANDA) seeking FDA approval to manufacture, use, or sell a drug before the expiration of a patent on that drug.<sup>22</sup>

# 1. DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.<sup>23</sup>

This declaratory judgment action involved an alleged conflict between the Hatch-Waxman Act,<sup>24</sup> intended to speed up FDA approval of generic drug manufacture after the expiration of a patent, and the extension of patent term under the Uruguay Round Agreements Act<sup>25</sup> (URAA).<sup>26</sup> Under the URAA, there are limited remedies for infringement that occurs during the "Delta period," the period between the original expiration date of the patent and the URAA extended expiration date.<sup>27</sup> DuPont Merck purported to find a conflict between the safe harbor that the URAA provides for a manufacturer, which had made substantial preparation towards marketing the patented product before the original patent expiration date, and the combined effect of 35 U.S.C. § 271(c) and the FDA procedure, 21 U.S.C. § 355(j), which effectively allow a patentee to put a halt to a generic drug manufacturer's ANDA by filing an infringement suit.<sup>28</sup>

Bristol-Myers' patent on Capoten, a captopril heart drug, should have expired August 8, 1995, but was extended through February 13, 1996, under the URAA.29 An ANDA must contain either a Paragraph III certificate (date when patent will expire) or a Paragraph IV certificate (that patent is invalid or will not be infringed by the generic drug).30 DuPont Merck had filed an ANDA with a Paragraph III \*307 certificate prior to June 8, 1995, relying on the August 8, 1995 expiration date.31 The FDA required under its procedure that if the term of the patent was extended under URAA, the ANDA must be amended to include a Paragraph IV certification.<sup>32</sup> A Paragraph IV certification also requires the applicant to give notice to the patentee and to state detailed reasons why the patent was either not infringed or was invalid.<sup>33</sup> If the patentee then sued the applicant for patent infringement within 45 days, the FDA approval would not occur until the expiration of the patent, judicial resolution of the infringement suit, or 30 months from the patentee's receipt of notice.<sup>34</sup> Under the Hatch-Waxman Act, to "make, use, offer to sell or selling ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs,"35 is not an infringement of the patent. A generic drug manufacturer infringes when it files an ANDA to obtain FDA approval to market the generic drug product before the expiration of the drug patent.<sup>36</sup> DuPont declined to amend its ANDA to include a Paragraph IV certificate, but instead filed this action, seeking a declaration that because of the URAA safe harbor provisions, its manufacture and sale of a generic version of captopril during the extended life of the patent would not be an infringement.37

The Federal Circuit first considered whether there was an "actual controversy" giving a federal court jurisdiction to hear a declaratory judgment action.<sup>38</sup> This requires determining if the acts of the defendant indicated an intent to enforce the patent, and whether the plaintiff engaged in an actual making, selling, using, or making meaningful preparations for such activity.<sup>39</sup> It found this test satisfied.<sup>40</sup> The court then considered the effect of the URAA on Hatch-Waxman and held that it was an infringement to apply for an ANDA to sell a drug before the patent expires.<sup>41</sup> The URAA had no impact on the provisions of section 355(j)(4)(b)(iii) so the FDA \*308 was correct to insist on the Paragraph IV amendment, even though that would give

the patentee the opportunity to block the ANDA by filing an infringement action.<sup>42</sup>

#### IV. Damages

# A. King Instrument Corp. v. Perego<sup>43</sup>

The district court found that one of three patents on loading audio and video tapes into closed cassettes was valid and literally infringed and that two were not infringed either literally or under the doctrine of equivalents.<sup>44</sup> The Federal Circuit affirmed.<sup>45</sup>

The plaintiff sought lost profits damages, even though its competing machine did not include the '461 invention.<sup>46</sup> Following *Rite-Hite*,<sup>47</sup> the court affirmed an award of lost profits on sales of the plaintiff's product.<sup>48</sup> Exploitation of the patent by an infringement plaintiff is not a prerequisite for damages because a patent is a right to exclude others, not to exploit the invention oneself.<sup>49</sup>

To recover damages, a patentee is required to show "but for" causation. There is no prescribed method of proving causation. To obtain reversal on this issue an appellant must show an abuse of discretion by the trial court, for example, a clearly erroneous factual finding, legal error, or manifest error of judgment. 51

The Federal Circuit approved the district court's damage award calculation that determined a figure based on the number of lost sales, gross receipts from those lost sales, cost of sales to be deducted from gross receipts, and the profit on those lost sales, and then factored in the patentee's market share and the existence of noninfringing alternatives.<sup>52</sup>

#### \*309 V. Invalidity

#### A. Lack of Novelty

In all but one of the cases in which lack of novelty under section 102, as opposed to obviousness under section 103, was an issue, the question was whether an otherwise invalidating prior use could be excused as experimental.

#### 1. Allied Colloids v. American Cyanamid Co.53

The trial court granted judgment as a matter of law that the patent was invalid under the public use bar based on section 102(b), holding that the use, although experimental, was "commercially motivated" and hence anticipating.<sup>54</sup>

The Federal Circuit held this wrong as a matter of law.<sup>55</sup> Evidence showed that *in situ* testing in Detroit sewage was necessary, that only the patentee's employees had access to tests, and that no payment was received for the tests.<sup>56</sup> All of these tended to establish that the use was experimental. The absence of a written confidentiality agreement was not controlling. On this record, there was evidence from which a reasonable jury could have found the use "experimental," so the judgment as a matter of law was vacated.<sup>57</sup>

#### 2. In re Graves<sup>58</sup>

Graves appealed from two decisions of the Board of Patent Appeals and Interferences (BPAI). The first rejection was decided by the BPAI on September 30, affirming the examiner's final rejection of the claims of Graves' patent application. The second decision denied Graves' request that the BPAI reverse its September 30 decision.<sup>59</sup> Graves filed a notice of appeal after filing a Rule 197(d) request for reconsideration with the BPAI and before the BPAI had rendered a decision on that request.<sup>60</sup> The Federal Circuit held that the BPAI had jurisdiction to hear a request for reconsideration of its earlier decision upholding the examiner's final rejection of claims of a patent application, even though notice of appeal was filed before the BPAI \*310 entered its reconsideration decision.<sup>61</sup> Graves filed his notice of appeal to Federal Circuit more than two months after the BPAI had issued its September 30, 1994 decision.<sup>62</sup> Thus, the decision was no longer an "appealable decision."<sup>63</sup>

The Federal Circuit determined that the notice of appeal could refer only to the January 20 decision.<sup>64</sup> The court was required to determine whether it had jurisdiction, given that the notice of appeal was filed over two weeks before the decision it appealed. The Federal Circuit held that it had jurisdiction because its jurisdiction to hear the appeal was, in effect, suspended until the BPAI acted upon the request for consideration, and the notice of appeal thus ripened into an effective appeal on the date the BPAI acted upon the reconsideration request.<sup>65</sup> The Federal Circuit held that there is no clear legislative command as to the date before which an applicant may not file an effective notice of appeal to the Federal Circuit, and the Federal Circuit

would thus not deny an applicant the right to appeal based on the facts of this case. 66

On the merits, the Federal Circuit upheld the BPAI's determination that the only claims remaining in the application, independent claims 4, 5, and 6, were anticipated by prior patents.<sup>67</sup> Anticipation under section 102(b) is a factual determination which is reviewed under the clearly erroneous standard.<sup>68</sup> The BPAI found that a prior patent anticipated claims 4 and 6, despite ambiguity regarding whether the claims required simultaneous monitoring of each multiple connection point or simultaneous monitoring of input and output points, but not necessarily the simultaneous monitoring of an input point and multiple output points.<sup>69</sup> The Federal Circuit held that the BPAI's construction of the claims to mean the latter was proper, in that it gave claim 4 as broad a meaning as possible that was not inconsistent with the applicant's disclosure.<sup>70</sup> Even if claim 4 did not expressly disclose simultaneous monitoring of the output points, the claim was anticipated if simultaneous or parallel monitoring is within the knowledge of a skilled artisan. Thus, the Federal Circuit upheld the BPAI's construction of the claim as reasonable and its determination that \*311 claims 4 and 6 were anticipated as not clearly erroneous.<sup>71</sup> The Federal Circuit similarly upheld the Board's decision that a prior patent anticipated claim 5.<sup>72</sup>

### **B.** Inequitable Conduct

Many cases included an allegation that a patent was unenforceable because of inequitable conduct. Generally the attacks met with little success.

### 1. Hydranautics v. FilmTec Corp. 73

The Ninth Circuit reversed the district court's dismissal of a complaint in which Hydranautics alleged that Film Tec improperly obtained a patent on a reverse osmosis membrane. Hill While employed at a nonprofit institution, Cadotte conceived of three new types of membranes for reverse osmosis desalinization. The research contract required that the benefits of the research were to be dedicated to the general public and were not to be owned by the researchers. Cadotte and others at the nonprofit institution left and created a for-profit corporation. Cadotte then duplicated his experiment with a slight refinement and obtained a patent, assigned to FilmTec, on the reverse osmosis membranes. When Hydranautics began manufacturing similar membranes, FilmTec unsuccessfully sued Hydranautics for patent infringement. Hydranautics then sued FilmTec under the Clayton and Sherman Acts alleging "predatory" patent litigation in a separate lawsuit. The district court dismissed Hydranautics' antitrust complaint. The Ninth Circuit held that it was permissible for Hydranautics to delay suing FilmTec for predatory patent litigation until it had defeated the infringement case. Thus, the predatory patent litigation claims were not compulsory counterclaims in the prior patent infringement case as the evidence on patent infringement and antitrust damages may differ considerably and Congress has \*312 provided different appellate paths for the two kinds of claims. Ultimately, the two types of claims do not arise out of the same transaction or occurrence.

The Ninth Circuit then reached FilmTec's assertion that it was immune from Hydranautics' antitrust action under the *Noerr-Pennington* doctrine, which immunizes litigation from antitrust claims unless it is a sham.<sup>85</sup> The Ninth Circuit held that, in this case, FilmTec's patent infringement action was objectively baseless because the fraudulently obtained patent was obtained by intentional fraud and not "technical fraud."<sup>86</sup> A fraudulently obtained patent is a "nullity because of the underlying fraud" and is thus not able to immunize predatory behavior from antitrust liability.<sup>87</sup>

# C. Broadening a Claim During Re-Examination

# 1. Quantum Corp. v. Rodime PLC88

The issue in this declaratory judgment action was whether the claims were broadened during re-examination, and if so, what the legal effect of that was.

The patent related to disk drives--all the originally issued claims were limited to a track density of "at least 600 consecutive tracks per inch." On re-examination this limitation was amended to read "at least *approximately* 600" t.p.i. The patentee argued that the amendment was mere clarification for the original claim, and when properly construed, meant "approximately 600." The Federal Circuit found that "at least," absent a definition in the patent or the prosecution history, or evidence of special meaning in the art, means "as the minimum," the dictionary definition. Therefore the claim had been broadened. The interesting issue was whether this broadening resulted in the entire claim being invalid, or only the broadened part? This is not addressed by the statute.

\*313 The court held that the claim is totally invalid, otherwise there would be no incentive *not* to broaden a claim during re-examination: Section 282 (which references the section 251 restriction on broadening re-issue patents, but not the section 305 restriction on broadening re-examined patents) is not an *exclusive* list of patent invalidity defenses.<sup>94</sup>

#### D. Failure to Renew and Intervening Rights

#### 1. Haden Schweitzer Corp. v. Arthur B. Myr Indus. 95

In April 1989, the patentee wrongly paid a small entity renewal fee. After discovering the mistake and petitioning the commissioner, it paid the correct fee in May 1994. In September 1994 an infringement suit was filed. The defendant claimed that the accused act was completed between June 9 and December 1, 1989, and raised an "intervening rights" defense. The patentee argued that this defense was not available because the defendant did not know of, and therefore did not *rely on,* an intervening right.

The court compared the intervening rights provision of section 41(c)(2) with intervening rights under a reissue patent, section 252. <sup>101</sup> Under section 252 there is an absolute right, without proof of reliance, to continue to sell or use a specific product made, purchased, or sold before the reissue if that product did not infringe a valid claim in the original patent. <sup>102</sup> In addition, there is an equitable right, requiring proof of reliance, to continue to manufacture, use, and sell additional products after the reissue of the patent. <sup>103</sup> By analogy to section 252, the court held that if the infringing act was completed after the six month grace period for payment of the proper renewal fee, but before acceptance of the late maintenance fee, then the use is protected from the claim of infringement without proof of reliance. <sup>104</sup> Thus, to \*314 establish the defense, the act of alleged infringement must have occurred within the period afforded to intervening rights. Did preparation work that occurred within the grace period for late payment of the renewal fee prevent the application of intervening rights? Because the product in question, an oven, was completed within the intervening rights "window," the court granted defendant's partial summary judgment motion. <sup>105</sup>

### VI. Litigation--Procedure

#### A. Venue

#### 1. Square D Co. v. Medar Inc. 106

In a patent action involving three patents, the plaintiff alleged that the defendant had sold the accused products to a customer in Delaware.<sup>107</sup> Neither the plaintiff nor the defendant had business establishments in Delaware.<sup>108</sup> In addition to the instant action, Square D had filed a second patent infringement action in the Eastern District of Michigan alleging infringement of two other Square D patents.<sup>109</sup> Defendant Medar had most of its relevant technical personnel and documents in the Eastern District of Michigan.<sup>110</sup> The defendant moved to transfer the Delaware case to Michigan, arguing that this would be in the interest of justice and that it would be more convenient, in balance, for the parties.<sup>111</sup>

The court held that Michigan was the more convenient forum to Medar and its witnesses. <sup>112</sup> Furthermore, given the location of Square D's facilities and witnesses, Delaware was at least as convenient a forum for Square D as is Michigan. <sup>113</sup> The balance of convenience to the witnesses and parties, they argued, weighs in favor of transfer to Michigan. <sup>114</sup>

The court, however, found that due to modern technology in the field of transportation and data transference, the convenience factors are of minimal \*315 significance, and the movant now has to show that the interests of justice weigh strongly in favor of transferring the case out of the jurisdiction chosen by the plaintiff.<sup>115</sup> In the present case, because the plaintiff-patentee represented that the two cases do not involve the same products, while the defendant strongly argued that they were closely related, the court held that the movant had not demonstrated that the interests of justice weighed *strongly* in favor of transfer.<sup>116</sup> The motion was accordingly denied with the proviso that if it transpired that the plaintiff's representations that the two cases would not involve the same product lines was inaccurate, the court would entertain a renewed motion to transfer at the close of discovery.<sup>117</sup>

### 2. Novo Nordisk of North America, Inc. v. Genentech, Inc. 118

This case involved a motion under section 1404(a) to stay or transfer a declaratory judgment action.<sup>119</sup> The patentee sought transfer to the district in which a later filed infringement suit was pending, the declaratory judgment action having been filed one day before the substantive infringement action.<sup>120</sup> The general rule is "first filed takes priority" and an exception will be

made only in "special circumstances." Special circumstances include the situation in which the choice of forum was based solely on forum shopping, if the balance of convenience is in favor of the second forum, or if the first action is against the customer and the seller is the defendant in the second action. 122

The court held that because the action was filed in the state in which plaintiff had its principal place of business, the choice of New York was not *pure* forum shopping (forum had a connection with case) and that the balance of convenience was even. 123

### \*316 B. Standing to Sue

## 1. University of Colorado Foundation, Inc. v. American Cyanamid<sup>124</sup>

At American Cyanamid's (Cyanamid) request and expense, researchers at the University of Colorado Health Science Center (Researchers) conducted a comparative study of the iron absorption of Cyanamid's Materna multi-vitamin and a competitive product because of concern that the formulation with calcium carbonate interfered with iron absorption. <sup>125</sup> Researchers found both formulations provided insufficient iron for pregnant women. <sup>126</sup> Subsequently, Researchers, allegedly independently, conducted studies as to the reason for the reduced absorption and established the reason and a reformulation of Materna that had improved iron absorption. <sup>127</sup> Cyanamid then paid Researchers to carry out further comparative tests, including tests on the reformulated Materna. <sup>128</sup> These showed that reducing the calcium carbonate and magnesium oxide components improved iron absorption. <sup>129</sup>

Cyanamid obtained a patent on the reformulation, naming its employee as the sole inventor.<sup>130</sup> The University claimed conversion, fraud, wrongful naming of inventor, copyright infringement, misappropriation, patent infringement, breach of confidential obligation and unjust enrichment.<sup>131</sup>

On the motion to dismiss the infringement claim because the University was not the legal owner of patent, the court held that the University had no basis for recovery of legal damages for infringement because only the owner of the legal title can obtain damages. The university, however, could recover equitable relief if it could show itself the owner of equitable title to the patent. Accordingly, Cyanamid's motion to dismiss the patent infringement claim was denied. Accordingly, Cyanamid's motion to dismiss the patent infringement claim was denied.

\*317 The University also asked the court to substitute Researchers as the inventors under section 256 (application to correct error in inventorship). 135 However, the court ruled that section 256 cannot be used where there is an allegation that the naming of the original inventor was fraudulent. 136 Cyanamid's motion to dismiss, as to the cause of action to correct the wrongful naming of the inventor, was granted. 137

## C. Wrongful Naming of Inventor

## 1. Stark v. Advanced Magnetics 138

Dr. David Stark, a physician, claims to have invented techniques of using superparamagnetic, biodegradable materials as MRI contrast agents. <sup>139</sup> Stark claims that he collaborated with Advanced Magnetics (Advanced) in various studies that relate to the patented subject matter and that he disclosed his techniques to Advanced during the course of these studies. <sup>140</sup> Without naming Stark as inventor, Advanced prosecuted and obtained six patents covering the inventions of which Stark claims he is a sole or joint inventor. <sup>141</sup>

Stark filed a complaint against Advanced for correction of the inventor named in the patents pursuant to 35 U.S.C. § 256 and for damages and injunctive relief under state tort and contract law.<sup>142</sup> In a procedurally complex posture, the issue in this case was whether a claim for correction of patent inventorship under 35 U.S.C. § 256 is barred by allegations of fraud asserted in state law claims in the same complaint.<sup>143</sup> Ultimately, the court held that the 35 U.S.C. § 256 claim is not barred by allegations of fraud asserted in the same complaint.<sup>144</sup>

This result relied heavily on the law of the case doctrine and an implied holding of the Federal Circuit on appeal from the district court's prior ruling on summary judgment (*Stark I*). On remand, the Massachusetts district court held that, since the Federal Circuit explicitly stated in *Stark I* that on remand the federal \*318 district court must determine the merits of the plaintiff's inventorship claims, and because defendants addressed the issue of fraud allegations on appeal to the Federal Circuit, the result that Advanced was not entitled to summary judgment as a matter of law on the section 256 claim was implicit in and necessary to the Federal Circuit's decision to vacate and remand for further proceedings. Of Thus, following

the law of the case doctrine and the mandate rule, the district court held that the Federal Circuit mandate on remand barred the district court from revisiting the argument that Stark removed himself from the remedial scope of section 256 by alleging deceptive intention on the part of Advanced. The court went on to hold that a 35 U.S.C. § 256 claim clearly requires that before a patent may be amended, it must be found that the name of the true inventor was omitted from the application as a result of mistake and not as a result of deception, and that the test applies to both the actual inventor and the named inventor. Thus, section 256 claims and plaintiff's state law claims alleging unfair and deceptive conduct and fraud by defendants are mutually exclusive. Thus, Stark will have to choose one of the mutually exclusive claims either through election of remedies or the jury through deliberation.

### D. Term of Patents

#### 1. Merck and Co. v. Kessler<sup>151</sup>

Merck and other drug manufacturers sought a declaratory judgment as to the term of patents that have been allowed extension or restoration rights under 35 U.S.C. § 156 (Waxman-Hatch Act), following the general change in the patent term to twenty years from application date brought about by the Uruguay Round Agreements Act. Do June 7, 1995, the PTO published a final determination that the holder of such patent must choose between a term of seventeen years from the grant of the patent plus a restoration period, or a term of twenty years from the filing date without the restoration period. Although the URAA is silent as to the application of regulatory review extensions to the twenty year term, the court held that the purpose of the URAA was to bring U.S. patent law into closer harmony with the laws of other developed nations. Unpersuaded by the Food and Drug Administration's arguments, the court granted summary judgment for plaintiffs and directed that the eleven patents at issue in the case had expiration dates calculated by adding the previously granted extension to the twenty year term under the URAA.

#### Footnotes

Id.

Id. at 1557, 35 U.S.P.Q.2d at 1804.

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Strasburger & Price, L.L.P., Dallas, Texas.

Strasburger & Price, L.L.P., Dallas, Texas.

Strasburger & Price, L.L.P., Dallas, Texas.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 34 U.S.P.Q.2d (BNA) 1321 (Fed. Cir.), cert. granted 116 S. Ct. 40 (1995).

44 F.3d 1553, 35 U.S.P.Q.2d (BNA) 1801 (Fed. Cir. 1995).

Id. at 1555 n.1, 35 U.S.P.Q.2d at 1802 n.1.

Id. at 1555, 35 U.S.P.Q.2d at 1802.

Id.

Id.
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- 9 *Id.* at 1558, 35 U.S.P.Q.2d at 1805.
- 10 Id. at 1560-61, 35 U.S.P.Q.2d at 1807.
- 11 Id. at 1565, 35 U.S.P.Q.2d at 1810.
- <sup>12</sup> 62 F.3d 1388, 36 U.S.P.Q.2d (BNA) 1206 (Fed. Cir. 1995).
- 13 Id. at 1392, 36 U.S.P.Q.2d at 1208.
- <sup>14</sup> *Id*.
- 15 *Id.* at 1394-95, 36 U.S.P.Q.2d at 1210-11.
- 16 Id. at 1395, 36 U.S.P.Q.2d at 1211.
- 17 Id. at 1394, 36 U.S.P.Q.2d at 1210.
- 18 *Id.* at 1392, 36 U.S.P.Q.2d at 1208-09.
- 19 *Id.* at 1394, 36 U.S.P.Q.2d at 1210.
- <sup>20</sup> 62 F.3d 1512, 35 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1995).
- <sup>21</sup> 35 U.S.C. § 271(e)(2)(A) (1994).
- <sup>22</sup> *Id*.
- <sup>23</sup> 62 F.3d 1397, 35 U.S.P.Q.2d (BNA) 1718 (Fed. Cir. 1995).
- <sup>24</sup> *Id.* at 1399, 35 U.S.P.Q.2d at 1720 (citing 21 U.S.C. § 355(j) (1995)).
- <sup>25</sup> *Id.*, 35 U.S.P.Q.2d at 1719-20 (citing 35 U.S.C. § 154(c)(1) (1994)).
- *Id.* at 1398-1401, 35 U.S.P.Q.2d at 1719-21.
- <sup>27</sup> *Id.* at 1399, 35 U.S.P.Q.2d at 1719-20 (citing 35 U.S.C. § 154 (1994)).

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        Id. at 1399-1400, 35 U.S.P.Q.2d at 1720.
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        Id. at 1400, 35 U.S.P.Q.2d at 1720 (quoting 35 U.S.C. § 271(e)(1) (1994)) (alteration in original).
        Id, 35 U.S.P.Q.2d at 1720-21 (citing 35 U.S.C.A. [sic] § 271(e)(1-2) (1994)).
        Id., 35 U.S.P.Q.2d at 1721.
        Id. at 1401, 35 U.S.P.Q.2d at 1721.
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        65 F.3d 941, 36 U.S.P.Q.2d (BNA) 1129 (Fed. Cir. 1995).
44
        Id. at 945, 36 U.S.P.Q.2d at 1131.
        Id. at 944, 36 U.S.P.Q.2d at 1130.
        Id. at 947, 36 U.S.P.Q.2d at 1132-33.
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- <sup>48</sup> King, 65 F.3d at 947, 36 U.S.P.Q.2d at 1133.
- *Id.* at 949, 36 U.S.P.Q.2d at 1135.
- 50 *Id.* at 952, 36 U.S.P.Q.2d at 1137.
- <sup>51</sup> *Id.*
- <sup>52</sup> *Id.* at 953, 36 U.S.P.Q.2d at 1137-38.
- <sup>53</sup> 64 F.3d 1570, 35 U.S.P.Q.2d (BNA) 1840 (Fed. Cir. 1995).
- <sup>54</sup> *Id.* at 1573-74, 35 U.S.P.Q.2d at 1842.
- <sup>55</sup> *Id.* at 1575, 35 U.S.P.Q.2d at 1843.
- *Id.* at 1575-76, 35 U.S.P.Q.2d at 1843-44.
- 57 *Id.* at 1577, 35 U.S.P.Q.2d at 1845.
- <sup>58</sup> 69 F.3d 1147, 36 U.S.P.Q.2d (BNA) 1697 (Fed. Cir. 1995).
- <sup>59</sup> *Id.* at 1148-49, 36 U.S.P.Q.2d at 1698.
- 60 *Id.* at 1149, 36 U.S.P.Q.2d at 1698.
- 61 *Id.* at 1150, 36 U.S.P.Q.2d at 1699.
- 62 *Id.*, 36 U.S.P.Q.2d at 1699.
- <sup>63</sup> *Id*.
- 64 *Id.*, 36 U.S.P.Q.2d at 1699-1700.
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- 67 *Id.* at 1153, 36 U.S.P.Q.2d at 1701.

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        Id. at 1579, 36 U.S.P.Q.2d at 1163.
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