

DEVELOPMENTS IN PATENT LAW 2004
(COURT DECISIONS)

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A. PATENTABILITY, VALIDITY, AND PROCUREMENT

1. WRITTEN DESCRIPTION

University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004), reh'g denied, July 2, 2004, cert denied, November 29, 2004. The Federal Circuit upheld a district court's ruling that the University of Rochester's patent failed to meet the written description requirement. The patent claimed a method for inhibiting PGHS-2 activity. Rochester sued Pfizer for patent infringement based on Pfizer's CELEBREX and BEXTRA drugs. The district court ruled that Rochester's patent application failed to meet both the written description requirement and the enablement requirement. The Federal Circuit affirmed on the written description ground but did not reach the enablement issue. The court rejected Rochester's argument that there should be no written description requirement separate from the enablement requirement. In a sharply divided vote, the Federal Circuit narrowly rejected Rochester's petition for rehearing on that issue, producing four dissenting votes and five opinions. Judges Linn, Rader and Gajarsa argued that there should be no written description requirement separate from the enablement requirement.

2. ON-SALE BAR

Elan Corp., PLC v. Andrx Pharm., Inc., 366 F.3d 1336 (Fed. Cir. 2004). An offer to enter into a license under a patent for selling the patented product was not an "offer to sell" that invalidated the patent. The Federal Circuit concluded that the letter clearly did not offer to sell the patented tablets but instead offered a license under the patent and the opportunity to become a partner in the clinical testing and marketing of the patented tablets at some future time.

3. PUBLIC USE

Bernhardt, LLC v. Collezione Europa USA, Inc., 386 F.3d 1371 (Fed. Cir. 2004). Bernhardt had conducted a "pre-market" exhibition of its new furniture designs more than one year before filing a design patent application. The exhibition was open to a limited number of attendees who were admitted after a name check; no photographs were permitted; no handouts were provided; but no confidentiality agreements were signed by the attendees. The Federal Circuit overturned the district court's conclusion that this constituted an invalidating public use, because Bernhardt introduced evidence that there was an "industry-wide understanding" that the attendees were to hold in confidence the designs they viewed. This evidence consisted of the testimony of Bernhardt's general manager, who said "it's pretty well understood that confidentiality applies." The Federal Circuit stated that "the presence or absence of a confidentiality agreement is not dispositive of the public use issue, but is one factor to be considered in assessing all the evidence."

4. DEFINITENESS

Novo Indus., L.P. v. Mico Molds Corp., 350 F.3d 1348 (Fed. Cir. 2003). A district court may not interpret a claim in such a way that it corrects an "obvious" error in the claim unless (1) the correction is not subject to reasonable debate and (2) the prosecution history does not suggest a different interpretation of the claims. In this case, a claim was amended during prosecution and issued claiming "stop means formed on a *rotatable with* said support finger." The district court ruled that this was an obvious typographical error, and the phrase should be interpreted to read "stop means formed *on and rotatable with* said support finger." The Federal Circuit reversed, holding that the nature of the error was not evident on the face of the patent, and that the patent owner had itself offered two different possible corrections to this clause, and the prosecution history undermined the patentee's proposed correction. Therefore, the Federal Circuit held that the claim was invalid as indefinite. [Note: this December 2003 decision was decided after last year's summary of cases].

5. ANTICIPATION

In re Ngai, 367 F.3d 1336 (Fed. Cir. 2004). A “kit” including a pre-measured portion of a reagent and instructions for normalizing and amplifying an RNA population according to the inventive method was anticipated by a kit having instructions and a buffer. The only difference between the claim and the prior art were the specific printed instructions provided with the kit. The Federal Circuit ruled that the instructions were not “functionally related” to the rest of the kit, and thus gave no patentable weight to the instructions. Although the applicant was entitled to a patent on the method, no patent could be issued on a kit containing the “novel” instructions.

6. OBVIOUSNESS

Knoll Pharm. Co. v. Teva Pharm. USA, Inc., 367 F.3d 1381 (Fed. Cir. 2004). Evidence developed after a patent was issued can be used to support a nonobviousness determination. The Federal Circuit held that a district court erred by ignoring evidence of unexpected results that were discovered after the patent had issued.

In re Bigio, 381 F.3d 1320 (Fed. Cir. 2004). A toothbrush was held to be in the same “field of endeavor” as the claimed hairbrush invention, and thus rendered it obvious. The Federal Circuit noted that hair was not limited to scalp hair, but could include other types of hair, such as facial hair. The court also agreed with the Board’s characterization of the field of endeavor as hand-held brushes having a handle segment and a bristle substrate segment. Judge Newman dissented, arguing that toothbrushes were not an analogous art to hair brushes, and that facial hair had nothing to do with teeth.

7. INTERFERENCES

In re Sullivan, 362 F.3d 1324 (Fed. Cir. 2004). The Board of Appeals is not obligated to determine questions of patentability in addition to priority. A patent owner involved in an interference with a pending patent application conceded that he could not establish priority, but he wanted the Board to rule on the patentability of the applicant’s invention. The Board terminated the interference and declined to rule on patentability. The Federal Circuit interpreted the statute to permit the Board to have discretion in deciding issues of patentability.

8. EXPERIMENTAL USES

SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004). Clinical trials designed to show the efficacy and safety of a compound for FDA approval (the drug PAXIL) were not “experimental uses” that avoided the public use bar. The claim covered the compound regardless of its use as an antidepressant, which use was not specifically claimed. Therefore, the clinical trials did not involve the claimed features of the invention. The Federal Circuit stated that, “a patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound.”

9. PRINTED PUBLICATIONS

In re Klopfenstein, 380 F.3d 1345 (Fed. Cir. 2004). Printed slides that were pasted on poster boards and displayed for three days at a conference more than a year before a patent applicant’s filing date constituted an invalidating “printed publication” under section 102(b) of the statute. Despite the fact that no copies were distributed to anyone at the conference, and the slides were not cataloged or indexed in any database, the Federal Circuit applied a new test based on factors including (1) the length of time the display was exhibited; (2) the expertise of the target audience; (3) whether there were expectations that the material would not be copied; and (4) the ease with which the materials could have been copied. In a footnote, the court suggested that an entirely oral presentation would not be a “printed publication,” even if transient viewgraphs were displayed.

In re Elsner, 381 F.3d 1125 (Fed. Cir. 2004). A publication that mentioned a new type of plant was held to be enabling (and thus invalidating) when viewed in combination with evidence that the plant had actually been sold in Europe. Although the listing of the plant in the publication was not itself enabling, the Federal Circuit held that the foreign sales put the public in possession of the claimed plants. The court's holding seems to be limited to plant patents, however. The court also stated that the foreign sale must not be an obscure occurrence that would go unnoticed by those of skill in the art. The court remanded to the PTO to determine that question.

10. GOVERNMENT RIGHTS IN PATENTS

Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, ___ F.3d ___, 2004 WL 2535385 (Fed. Cir. Nov. 10, 2004). A government contractor that failed to comply with the strict requirements of the invention disclosure requirements of a U.S. government contract forfeited title to the patent for the invention. Campbell Plastics signed a contract with the Army to develop a protective mask. The contract incorporated numerous clauses from the Federal Acquisition Regulations (FAR), including a requirement that the contractor disclose subject inventions developed under the government contract and provide reports every 12 months concerning inventions. Although Campbell sent various drawings to the Army representative showing a new design that ultimately led to the patentable concept, it failed to notify the Army on the proper form that it had a patentable concept. The Federal Circuit upheld the Army's determination that it, rather than the contractor, owned the patent for failure to follow the proper reporting procedures, even though the Army suffered no harm by Campbell's failure to follow the correct procedures.

11. WAIVER OF ARGUMENTS NOT MADE TO BOARD OF APPEALS

In re Watts, 354 F.3d 1362 (Fed. Cir. 2004). In the Federal Circuit, an applicant was held to have waived an argument that the prior art differed in one respect from the claimed invention, since that exact argument had not been made previously before the Board of Appeals.

B. INTERPRETATION OF PATENTS

1. CLAIM CONSTRUCTION

Novartis Pharm. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306 (Fed. Cir. 2004). The term "hydrosol" in a patent claim was held to exclude hydrosol formed when a pharmaceutical was ingested by a patient. The Federal Circuit relied heavily on a cascading set of dictionary definitions to conclude that "hydrosol" was limited to a medicinal preparation consisting of a dispersion of solid particles formed outside of the body. The dissent argued that the use of dictionaries was improper because the majority's search led it through multiple levels of definitions until it arrived at the "out of the body" limited definition. The majority had first looked to Webster's Dictionary to define "hydrosol" as "a sol in which the liquid is water." It defined "sol" as "a dispersion of solid particles in a liquid colloidal solution." Although there were two different dictionary definitions of "solution," the majority relied on the more limiting definition, which was limited to medicinal preparations.

Searfoss v. Pioneer Consol. Corp., 374 F.3d 1142 (Fed. Cir. 2004). A claim reciting "connecting said tension bail to said extension assembly" was limited to a direct connection and excluded those that were indirectly connected. The Federal Circuit noted that the specification showed direct connections in all the figures. [Practice note: many mechanical and electrical claims contain terms such as "connected," with the intention that they not be limited to direct connections. On possible antidote would be to include a disclaimer in the specification stating that any connections recited in the claims could include indirect rather than direct connections.]

Nystrom v. Trex Co., 374 F.3d 1105 (Fed. Cir. 2004). At issue was whether the word "board" in the claims should be limited to wooden boards. The Federal Circuit noted that although some dictionaries seemed to limit "board" to wooden boards, others did not. Therefore, "giving the term the full range of its ordinary and customary meaning,

consistent with the written description and prosecution history,” the court interpreted “board” to mean an elongated, flat piece of wood or other rigid material. In his dissenting opinion, Judge Gajarsa argued that the written description provided guidance as to which of the dictionary definitions was supported.

Norian Corp. v. Stryker Corp., 363 F.3d 1321 (Fed. Cir. 2004). A claim reciting a kit “consisting of” two chemicals was infringed by a kit that included the two chemicals and a spatula. The majority held that “consisting of” permitted no other chemicals in the kit, but it did not preclude adding a spatula, which was not part of the described invention. Judge Shall dissented, noting that “consisting of” precludes addition of any other components to the claimed structure, and noted that the “consisting of” language was added during prosecution to avoid a prior art reference.

International Rectifier Corp. v. IXYS Corp., 361 F.3d 1363 (Fed. Cir. 2004). The Federal Circuit ruled that the term “polygonal” as used in the claims was limited to a closed plane figure bounded by straight lines, based on a dictionary definition. The district court erred by interpreting “polygonal” to include generally but not perfectly polygonal edges – i.e., slightly rounded corners. Despite the fact that the patent figures showed slightly rounded edges, the Federal Circuit noted that the patent owner could have claimed the regions more broadly but chose to use the word “polygonal.” On another claim construction issue, the Federal Circuit ruled that the claimed “adjoining” was not synonymous with “adjacent,” based on a dictionary usage note that drew a seeming distinction between the two. The Federal Circuit stated that the district court’s claim interpretation disregarded the “usage note” in the dictionary. Had the inventor meant “adjacent,” he could have used that word. Because the defendant’s device did not “touch or bound” another part of the structure, there could be no infringement.

Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004). A claim that recited heating a dough to a temperature in the range of about 400° to 850° was not infringed unless the accused product actually heated the dough to that temperature, even though that interpretation was non-sensical because the dough would become charcoal at that temperature. The Federal Circuit rejected the patent owner’s argument that the claim should be interpreted to cover heating to a temperature at 400°, stating that the claim required “the dough is to be heated to the specified temperature.”

Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295 (Fed. Cir. 2004). There should be no “heavy presumption of ordinary meaning” if a claim term lacks an accepted meaning in the art. Without an accepted meaning in the art, the term should be interpreted only as broadly as provided in the patent specification.

Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333 (Fed. Cir. 2004). A patent specification may “clearly disavow” a particular meaning for a term even if it is not couched in direct negative terms. Based on statements in the specification that “the solubilizers suitable according to the invention are defined below” and “the solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents,” the court ruled that the claims were limited to solubilizers that are surfactants. The court found that this language was a “clear disavowal” of claim scope both for purposes of literal infringement and infringement under the doctrine of equivalents.

Microsoft Corp. v. Multi-Tech. Sys. Inc., 357 F.3d 1340 (Fed. Cir. 2004). The Federal Circuit agreed with the district court’s interpretation of “sending,” “transmitting” and “receiving” of data packets, which were limited to point-to-point communications over a telephone line, and did not include communications over packet-switched networks such as the Internet. The majority relied in part on a “summary of the invention” provided by the applicant during prosecution. Somewhat surprisingly, the Federal Circuit ruled that the statement was applicable not only to the application in which it was made, but also to an earlier-filed parent application – i.e., the statement was held to apply retroactively to an earlier application, which had already issued at the time the statement was made. The court stated that, “any statement of the patentee in the prosecution of a related application as to the scope of the invention would be relevant to claim construction, and the relevance of the statement made in this instance is enhanced by the fact that it was made in an official proceeding in which the patentee had every incentive to exercise care in characterizing the scope of its invention.” Judge Rader dissented, stating that the majority’s opinion was at odds with an earlier decision to the contrary. And the holding of this case may be limited to the situation where statements were made “in connection with

continued prosecution of sibling applications.” See Goldenberg v. Cytogen, Inc., 373 F.3d 1158 (Fed. Cir. 2004).

C.R. Bard Inc. v. U.S. Surgical Corp., ___ F.3d ___, 2004 WL 2414612 (Fed. Cir. October 29, 2004). Because the word “plug” was described in the Summary of the Invention part of the specification as being pleated, the claims were deemed to be limited to a pleated plug. The court stated that, “other things being equal, certain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case-by-case basis.” The court also noted that Bard had pointed to a portion of the specification during prosecution mentioning the pleating, even though the claim did not require pleating.

Phillips v. AWH Corp., 363 F.3d 1207 (Fed. Cir. 2004). The claimed term “baffle” was limited to baffles that were at an angle greater than 90 degrees. Although the dictionary definition for “baffle” was broad, the Federal Circuit concluded that the specification only disclosed an embodiment having baffles with an angle other than 90 degrees. Judge Dyk dissented, noting that the narrow interpretation was contrary to the plain meaning in the dictionary.

Note: The Federal Circuit has ordered that this case be reheard en banc, 376 F.3d 1382 (Fed. Cir. 2004). The en banc rehearing order asked for briefing on the following questions:

- (1) Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee’s use of the term in the specification? If both sources are to be consulted, in what order?
- (2) If dictionaries should serve as the primary source for claim interpretation, should the specification limit the full scope of claim language (as defined by dictionaries) only when the patentee has acted as his own lexicographer or when the specification reflects a clear disclaimer of claim scope? If so, what language in the specification will satisfy those conditions? What use should be made of general as opposed to technical dictionaries? How does the concept of ordinary meaning apply if there are multiple dictionary definitions of the same term? If the dictionary provides multiple potentially applicable definitions for a term, is it appropriate to look to the specification to determine what definition or definitions should apply?
- (3) If the primary source for claim construction should be the specification, what use should be made of dictionaries? Should the range of the ordinary meaning of claim language be limited to the scope of the invention disclosed in the specification, for example, when only a single embodiment is disclosed and no other indications of breadth are disclosed?
- (4) Instead of viewing the claim construction methodologies in the majority and dissent of the now-vacated panel decision as alternative, conflicting approaches, should the two approaches be treated as complementary methodologies such that there is a dual restriction on claim scope, and a patentee must satisfy both limiting methodologies in order to establish the claim coverage it seeks?
- (5) When, if ever, should claim language be narrowly construed for the sole purpose of avoiding invalidity under, e.g., 35 U.S.C. §§ 102, 103 and 112?
- (6) What role should prosecution history and expert testimony by one of ordinary skill in the art play in determining the meaning of the disputed claim terms?
- (7) Consistent with the Supreme Court’s decision in Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), and our en banc decision in Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448 (Fed. Cir. 1998), is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?

(8) [Separate concurring opinion by Judge Rader only]: Is claim construction amenable to resolution by resort to strictly algorithmic rules, e.g., specification first, dictionaries first, etc? Or is claim construction better achieved by using the order or tools relevant in each case to discern the meaning of terms according to the understanding of one of ordinary skill in the art at the time of the invention, thus entrusting trial courts to interpret claims as a contract or statute?

Chief Judge Mayer dissented, arguing that “any attempt to refine the process is future” as long as the court refuses to reconsider the fiction that claim construction is a matter of law.

2. DOCTRINE OF EQUIVALENTS

Gaus v. Conair Corp., 363 F.3d 1284 (Fed. Cir. 2004). Infringement under the doctrine of equivalents was precluded because the specification criticized a prior art feature that was similar to the defendant’s accused structure. The patent owner had argued that Conair’s protective system in its hairdryer was equivalent to the claimed pair of probe networks. According to the Federal Circuit, the inventor’s specification made clear that it was essential that the pair of probe networks be separate from the voltage-carrying components of the appliance. The court stated that Gaus “cannot not reclaim that surrendered claim coverage by invoking the doctrine of equivalents.” [Practice note: this is one more reason to avoid extensive discussion and criticism of the prior art in patent applications.]

PSC Computer Prods., Inc. v. Foxconn Int’l, Inc., 355 F.3d 1353 (Fed. Cir. 2004). An equivalent was “dedicated to the public” because it was indirectly mentioned in the specification as part of the prior art. PSC’s patent claimed a heat sink including a resilient metal strap. The accused defendant sold a device having a plastic strap. The Federal Circuit affirmed the non-infringement ruling under the “dedicated to the public” doctrine of Johnson & Johnston Associates v. R.E. Service Co., 285 F.3d 1046 (Fed. Cir. 2002) (en banc). PSC’s specification stated that “other prior art devices use molded plastic and/or metal parts that must be cast or forged which again are more expensive metal forming operations.” The court held that this statement was sufficient to disclose the use of plastic straps, which PSC failed to claim.

3. PROSECUTION HISTORY ESTOPPEL

Honeywell Int’l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131 (Fed. Cir. 2004) (en banc). Rewriting a dependent claim in independent form coupled with canceling the independent claim constitutes a “narrowing” amendment for the purposes of prosecution history estoppel. During prosecution, the PTO examiner rejected an independent claim but objected to a dependent claim as being allowable if rewritten in independent form. The Federal Circuit stated that the surrendered subject matter is defined by the canceled independent claim lacking a particular limitation and the allowed dependent claim containing the particular limitation. In this case, Honeywell was unable to overcome the Festo presumption created by the amendment. Judge Newman dissented, arguing that the limitation in the dependent claim had never been amended, and thus rewriting the dependent claim into independent form did not change its scope. She also distinguished the court’s earlier Deering and Ranbaxy cases on the ground that in this case, the claimed inlet guide vanes feature in the dependent claim was not present in the independent claim. Note: on November 1, 2004, the U.S. Supreme Court asked the U.S. Government to file a brief in connection with the petition for a writ of certiorari filed in this case.

Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348 (Fed. Cir. 2004). A claim amendment made during prosecution to overcome an enablement rejection gave rise to a presumption of prosecution history estoppel, which the patent owner was unable to rebut. Certain claims were rejected by the PTO examiner for lack of enablement, and Glaxo responded by amending those claims to specifically recite HPMC as a sustained release agent in the claims. (Independent claim 1 had already recited HPMC, and it was not amended). In litigation, the defendant argued that Glaxo was not entitled to any scope of equivalence as to the claimed HPMC, due to the amendments during prosecution. The

Federal Circuit agreed, concluding that an amendment made to overcome an enablement rejection gave rise to prosecution history estoppel, even as to claim 1, which had not been amended. Although Glaxo had not argued that HPMC was critical to enablement, the patent examiner's action gave rise to estoppel. According to the Federal Circuit, "Prosecution history estoppel is not limited to the applicant's own words, but may embrace as well the applicant's responses to the examiner's actions . . . if the patentee does not rebut an examiner's comment or acquiesces to an examiner's request, the patentee's unambiguous acts or omissions can create an estoppel." The Federal Circuit also rejected Glaxo's argument that it could not have amended the claims to cover other non-HPMC compounds because that would have added new matter to the application.

Insituform Tech., Inc. v. CAT Contracting, Inc., 385 F.3d 1360 (Fed. Cir. 2004) (on remand from the U.S. Supreme Court). Because the rationale underlying an amendment narrowing the scope of a claim bore "no more than a tangential relation to the equivalent in question," the patent owner rebutted the Festo presumption of surrendered coverage as to the equivalent. The claim was amended during prosecution to add numerous limitations, including the use of a "cup" connected to a vacuum source. The purpose for narrowing the claim was to avoid a prior art reference to Everson, and thus emphasized the difference of a large compressor at the end of the liner. There was no indication in the prosecution history of any relationship between the narrowing amendment and the multiple cup process, which was the alleged equivalent.

C. ENFORCEMENT OF PATENTS

1. INFRINGEMENT OF DESIGN PATENTS

Bernhardt, LLC v. Collezione Europa USA, Inc., 386 F.3d 1371 (Fed. Cir. 2004). Proof of infringement requires evidence of both substantial similarity of designs under the "ordinary observer" test and evidence that the defendant's design appropriated the "points of novelty" of the patented design that distinguishes it from the prior art. In order to establish the points of novelty, a plaintiff need only introduce (1) the design patent; (2) its prosecution history; (3) relevant prior art references cited during the prosecution; and (4) contentions regarding proposed points of novelty, such as by proposed findings of fact. Additional evidence, such as expert testimony, is not required. In this case, the district court erred by requiring the plaintiff to introduce testimony, expert or otherwise, to explain its proposed points of novelty.

2. DAMAGES

Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303 (Fed. Cir. 2004). A patent owner may not rely on lost sales of a patent licensee if the patent owner himself has sold nothing under the patent. A patent owner may recover lost profits even if he is not selling the patented device, but it must be selling some item that results in lost profits in order to recover lost profits.

3. WAIVER OF ATTORNEY-CLIENT PRIVILEGE

Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337 (Fed. Cir. 2004). The Federal Circuit abolished the inference that a legal opinion was unfavorable if an infringer failed to produce the legal opinion in response to a charge of willful infringement. In a major change in policy, the Federal Circuit en banc overruled decades of precedent that had assisted patent owners in painting a negative picture of infringers. The district court had relied on the failure of the infringer to turn over opinion of counsel regarding infringement in finding that the infringement was willful. The Federal Circuit reversed, holding that, "the adverse inference that an opinion was or would have been unfavorable, flowing from the infringer's failure to obtain or produce an exculpatory opinion of counsel, is no longer warranted."

The court first stated that the mere fact that an infringer invokes the attorney-client privilege or work product

privilege could not give rise to an adverse inference of willful infringement. The court also held that the fact that an accused infringer had not obtained an opinion at all could also not give rise to an adverse inference of willful infringement. The court stated that “there are no hard and fast per se rules with respect to willfulness of infringement” and that various factors must be considered. The Federal Circuit also declined to rule on whether the jury should be informed as to whether an opinion of counsel had been obtained. Finally, the court held that the existence of a substantial defense to infringement would not by itself be sufficient to defeat liability for willful infringement. Judge Dyk dissented in part, arguing that the due care requirement was not consistent with Supreme Court precedent holding that punitive damages could only be awarded in cases where the defendant’s conduct was reprehensible.

4. PATENT TERM RESTORATION DUE TO FDA DELAYS

The Arnold Partnership v. Dudas, 362 F.3d 1338 (Fed. Cir. 2004). A patented drug combination having two active ingredients was not eligible for patent term restoration due to FDA regulatory delays where each active ingredient had been separately marketed prior to the FDA regulatory review of the combination. The Federal Circuit interpreted the statute to require examination of drug patent eligibility on a component-by-component basis, rather than as a whole.

5. INTERNATIONAL TRADE COMMISSION

Kinik Co. v. International Trade Comm’n, 362 F.3d 1359 (Fed. Cir. 2004). The defenses to patent infringement under 35 U.S.C. § 271(g), which exempt from infringement process products that were “materially changed” by a subsequent process, or that have become a “trivial and nonessential component of another product,” do not apply in the ITC. The Federal Circuit relied on the legislative history of the 1988 amendments to the patent statute in reaching its decision.

6. UNENFORCEABILITY DUE TO PROSECUTION LACHES

Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, 301 F. Supp.2d 1147 (D. Nev. 2004). In this closely-watched lawsuit, bar code manufacturers representing more than 90% of the bar code reader industry sued the Lemelson Foundation to stop the Foundation from suing hundreds of companies over patents that claim priority back to the 1950s. On January 23, 2004, the district court ruled against Lemelson, concluding that all of his patents were unenforceable for “prosecution laches.” The court noted that Lemelson’s 18 to 39-year delay in filing the asserted claims after they were first disclosed in 1954 and 1956 was unexplained and unreasonable, and stated that it was not necessary to show that the inventor had “intentionally stalled.” The case is on appeal to the Federal Circuit.

7. WILLFUL INFRINGEMENT

Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004). The mere act of filing an Abbreviated New Drug Application (ANDA) cannot constitute an act of willful infringement. The court distinguished an earlier ANDA case where a “wholly unjustified” paragraph IV certification in an ANDA filing, when combined with litigation misconduct, gave rise to an exceptional case finding.

8. IMPLIED LICENSE

Jacobs v Nintendo of Am., Inc., 370 F.3d 1097 (Fed. Cir. 2004). A patent owner who entered into a license agreement with a supplier to make parts under the patent granted an implied license to customers of the supplier. Jacobs’ patent covered a video game controller that could be tilted to achieve motion in a video game. Jacobs sued Analog Devices for contributory infringement and inducement for making a tilt-sensitive accelerometer that could be used in the claimed combination. Analog Devices signed a license with Jacobs that gave Analog Devices the right to make the accused accelerometers. When Jacobs sued Nintendo for making an infringing combination containing the Analog Devices accelerometer, the district court held that Jacobs had impliedly licensed Nintendo as a customer of Analog

Devices. The Federal Circuit applied ordinary principles of contract law and affirmed.

9. VIOLATION OF 35 U.S.C. § 271(f)

Pellegrini v. Analog Devices, Inc., 375 F.3d 1113 (Fed. Cir. 2004). Merely providing instructions for selling devices overseas, where the devices are never physically present in the United States, cannot give rise to liability under 35 U.S.C. § 271 (f), which concerns components “supplied or caused to be supplied in or from the United States.”

10. PATENT MISUSE

In The Matter of Certain Recordable Compact Discs and Rewritable Compact Discs, Investigation No. 337-TA-474, 2004 WL 1435791 (U.S.I.T.C. 2004). In this ITC proceeding, the ITC ruled that Philips engaged in patent misuse by requiring mandatory package licensing of several patents that were essential to manufacture CD-Rs and CD-RWs with licenses to other patents that were not essential to that activity. The ITC concluded that Philips had misused its patents by including them as “essential” patents even though they were not essential. The case is on appeal at the Federal Circuit.

Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004). Monsanto did not commit patent misuse by requiring that its licensees execute licenses with farmers, which restricted the farmers’ ability to use seeds containing a modified gene for a single season. McFarling was a farmer who had signed such a license but violated its terms by saving and replanting seeds in later seasons. The Federal Circuit held that the license restriction was “reasonably within the patent grant.” The patent covered not only first-generation seeds but also seeds made by the plants resulting from the farmers’ efforts. Hence, there could be no patent misuse.

11. ANTITRUST

Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341 (Fed. Cir. 2004). Although the patent owner was stripped of antitrust immunity based on a fraudulently obtained patent, the Federal Circuit threw out an antitrust verdict. The Federal Circuit first ruled that a Walker Process antitrust claim could be brought by a declaratory judgment plaintiff even though the patent owner had not overtly attempted to enforce its patent. Under Tenth Circuit law, however, Unitherm failed to prove a Sherman Act claim because Unitherm’s expert defined the relevant market to be identical to the scope of the patent. According to the Federal Circuit, nothing in the record addressed whether potential customers of the patented process faced with a price increase would shift to other processes offering different combinations of benefits.

12. PRE-FILING INVESTIGATION

Q-Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295 (Fed. Cir. 2004). A patent owner was not liable for sanctions and attorneys’ fees despite the fact that he did not prepare a claim chart prior to bringing a lawsuit for patent infringement. The evidence showed that an attorney interpreted the asserted patent claims and compared the accused product with those claims before filing suit. The Federal Circuit also held that although the patent owner had not conducted a chemical analysis of the defendant’s product, it reasonably relied on advertising literature produced by the defendant.

13. REASONABLE APPREHENSION OF SUIT

Gen-Probe Inc v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004). A patent licensee may not continue paying royalties “under protest” and bring a declaratory judgment action for invalidity and noninfringement. The Federal Circuit distinguished Lear v. Adkins, 395 U.S. 653 (1969), which held that licensees are not estopped from contesting the validity of a patent. Unless a licensee stops paying royalties, thus giving rise to a material breach of the license, there can

be no reasonable apprehension of a lawsuit.

14. TEMPORARY PRESENCE IN THE UNITED STATES

National Steel Car, Ltd. V. Canadian Pacific Ry., Ltd., 357 F.3d 1319 (Fed. Cir. 2004). A railway car used to haul lumber into and out of the United States meets the infringement exception under 35 U.S.C. § 272, which excuses infringement for any vehicle that enters the United States on a temporary basis. Although the district court had found that the accused railway cars were in the United States for about 57% of their useful life, the Federal Circuit defined “temporary” as a vehicle entering the United States for a limited period of time for the sole purpose of engaging in international commerce.

15. ARBITRATION

Microchip Technology, Inc. v. U.S. Philips Corp., 367 F.3d 1350 (Fed. Cir. 2004). Philips and General Instrument had previously signed a patent license agreement. Microchip sued Philips for a declaratory judgment of non-infringement under patents owned by Philips, claiming that Microchip was a successor to General Instrument under the license, but Philips denied that Microchip was licensed. Philips moved to compel arbitration under the Philips/General Instrument license, and Microchip opposed, seeking to have the court determine its rights. The Federal Circuit held that the license issue was a “threshold” question for the court to decide, and therefore the court had jurisdiction to decide the issue. The Federal Circuit concluded that the arbitration agreement had not expired, and ruled that the district court must determine whether Microchip was a party to the license agreement.

16. ELEVENTH AMENDMENT IMMUNITY FROM SUIT

Xechem Int’l, Inc. v. Univ. of Texas M.D. Anderson Cancer Center, 382 F.3d 1324 (Fed. Cir. 2004). A state university did not waive its immunity for purposes of a lawsuit brought by Xechem to correct inventorship under 35 U.S.C. § 256 by entering into commercial relationships and contracts with Xechem, and by having its employee apply for the patent.