

# **DEVELOPMENTS IN PATENT LAW 2003**

**(COURT DECISIONS)**

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**BRADLEY C. WRIGHT  
BANNER & WITCOFF, LTD  
1001 G STREET, N.W.  
WASHINGTON, D.C. 20001  
(202)-824-3160  
[bwright@bannerwitcoff.com](mailto:bwright@bannerwitcoff.com)  
[www.bannerwitcoff.com](http://www.bannerwitcoff.com)**



**BANNER & WITCOFF, LTD.  
INTELLECTUAL PROPERTY LAW**

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## **A. PATENTABILITY, VALIDITY, AND PROCUREMENT**

### **1. WRITTEN DESCRIPTION**

Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003). A claim that recited a step of lifting eggs from a moving conveyor belt was adequately supported by the written description, which showed that the inventor was in possession of that limitation as of the filing date. In a concurring opinion, Judge Rader criticized the use of the written description requirement to police anything other than priority issues.

### **2. ON-SALE BAR**

Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc., 322 F.3d 1335 (Fed. Cir. 2003). The Federal Circuit vacated and remanded a ruling that the patented invention was on sale more than one year before the filing date, because the district court applied the wrong standard for determining whether there was a commercial offer for sale. Applying its 2001 decision in Group One, which looked to the Uniform Commercial Code (UCC) to determine whether an offer was legally binding, the Federal Circuit stated that the court should look at industry custom and practice to determine whether Lacks's solicitations rose to the level of a commercially binding offer for sale. In her dissenting opinion, Judge Newman criticized the deviation from a uniform standard for determining whether an offer constitutes an invalidating offer for sale, stating that, "remand for the purpose of ascertaining that industry practice is at variance with Pfaff and its implementing precedent."

Minton v. National Ass'n of Securities Dealers, Inc., 336 F.3d 1373 (Fed. Cir. 2003). A patent for a computerized securities trading method was held to be invalid because more than one year before the filing date, Minton leased a computer program that carried out the patented process. The court distinguished its earlier decision in In re Kollar, 286 F.3d 1326 (Fed. Cir. 2002), on the basis that Kollar involved a mere transfer of technical information for a process that required further development.

### **3. ENABLEMENT**

Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335 (Fed. Cir. 2003). The Federal Circuit held that "pioneer" patents are not entitled to a lower standard of enablement than other patents. The Court upheld the district court's determination that the claimed invention was invalid because the patent did not enable a person of ordinary skill in the art to make the invention as claimed.

#### 4. ANTICIPATION

Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373 (Fed. Cir. 2003). A patent for an antihistamine metabolite was anticipated by a prior patent for the underlying antihistamine. (A metabolite is a compound formed in the patient's body upon ingestion of a pharmaceutical). Schering's prior '223 patent covers the compound used in its CLARITIN antihistamine. Its later '716 patent covers a metabolite of that compound that differs slightly from the compound shown in the original '223 patent. According to the Federal Circuit, even though the metabolite was not specifically shown in the earlier '223 patent, it was inherently disclosed in the patent because ingestion of the drug described in the '223 patent would necessarily result in the creation of the metabolite claimed in the later '716 patent. Three judges dissented from the denial of a petition for rehearing.

#### 5. OBVIOUSNESS

In re Peterson, 315 F.3d 1325 (Fed. Cir. 2003). The Federal Circuit upheld the PTO's determination that Peterson's claimed invention, which recited a range of 1% to 3% rhenium and about 14% chromium, was obvious over a prior art reference that showed a range of 0% to 7% rhenium and 3% to 18% chromium. According to the Federal Circuit, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." The inventor did not show any unexpected increase in strength in the claimed range of 1% to 3%.

#### 6. ADMISSIONS AS PRIOR ART

Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346 (Fed. Cir. 2003). The fact that a patent was listed on an Information Disclosure Statement did not constitute an admission that the earlier patent was prior art. The Federal Circuit distinguished the CCPA's decision in In re Nomiya, 509 F.2d 566 (CCPA 1975) as being limited to admissions concerning "prior art" invented by others (i.e., not the inventor). In this case, one of the inventors on the patent at issue was an inventor on the earlier patent, which did not in fact constitute prior art. The Federal Circuit stated that, "While Nomiya and Fout stand for the proposition that a reference can become prior art by admission, that doctrine is inapplicable when the subject matter at issue is the inventor's own work."

#### 7. INDEFINITENESS

Honeywell Int'l, Inc. v. International Trade Comm'n, 341 F.3d 1332 (Fed. Cir. 2003). A claim was held invalid for indefiniteness where the recited limitation of a "melting point elevation" reaching a certain point could not be measured without knowing which of four different known sample preparation methods was to be used, and the patent did not identify what method should be used. Depending on which method was used, a different number would be obtained.

## 8. DOUBLE PATENTING

Geneva Pharm., Inc. v. Glaxosmithkline PLC, 2003 WL 22748633 (Fed. Cir. Nov. 21, 2003). Several Glaxo patents covering an antibiotic drug were held invalid for double patenting, even though the PTO had allegedly issued a restriction requirement in an earlier application. (35 U.S.C. § 121 precludes use of one patent against another if they resulted from a restriction requirement in the PTO). The Federal Circuit held that an ambiguous examiner interview summary stating that "method of use claims will go in a divisional application" did not constitute a clear restriction requirement. According to the court, "restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of §121's protections."

## B. INTERPRETATION OF PATENTS

### 1. CLAIM CONSTRUCTION

Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364 (Fed. Cir. 2003). A claim that recites a first step of growing cells at a temperature of 18° C to 32° C was improperly interpreted to preclude an additional step (prior to the first step) of growing cells at 37° C (i.e., foreclosing any growth outside of the claimed range). During prosecution, the patent examiner had stated that the 18° C to 32° C range was essential to the invention. In response, the applicants amended the claim to recite that range and argued that the claimed range avoided undesirable effects of growth at 37° C. According to the Federal Circuit, this did not preclude the applicant from asserting the claims against an accused method that first applied growth at 37° C and then followed the claimed steps.

Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346 (Fed. Cir. 2003). A district court erred by interpreting the claimed term "bus interface unit" as being limited to as a unit capable of functioning in a command/response system. Despite the fact that the specification highlighted the command/response system in various objects of the invention, the Federal Circuit adopted the ordinary meaning of the term, continuing its trend toward giving a "heavy presumption" to the ordinary meaning of claim language. The court also stated that components that were not necessary to perform a recited function of a means-plus-function clause cannot qualify as "corresponding" structure under 35 U.S.C. ¶ 112, sixth paragraph.

Kumar v. Ovonic Battery Co., 2003 WL 22922369 (Fed. Cir. Dec. 11, 2003). Although dictionaries can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term, the Federal Circuit relied instead on a definition of the word "amorphous" that was found in a prior art patent that was discussed during prosecution of the patent at issue. The defendant had argued that the ordinary dictionary definition of "amorphous" should be used. The Federal Circuit noted that the prior art patent was considered part of the intrinsic record and contained a definition that was "to be preferred" over the general dictionary definition. The patent specification did not specifically define the term.

Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094 (Fed. Cir. 2003). Where an applicant made an allegedly broadening amendment to the claims after a final rejection, but did not provide any explanation for the amendment, the Federal Circuit concluded that it could not have been a broadening amendment. The Federal Circuit pointed to PTO Rule 1.116, which does not permit entry of amendments "touching the merits of the application" after a final rejection unless the applicant makes a showing of good and sufficient reasons why they are necessary and were not earlier presented. According to the Federal Circuit, "the examiner could not accept a second (supplemental) after-final amendment broadening the scope of the rejected claims without formal comment from the applicant. Under the applicable Patent Office Rules, amendments to patent claims after final rejection cannot alter the substantive scope of the claims without explanation about the necessity of the amendment and without reasons for the delay in proposing the change." The court interpreted the phrase "chromosomally integrated" to require introduction of exogenous -Gal A sequences into a host cell, and hence the patent was not infringed.

Altiris, Inc. v. Symantec Corp., 318 F.3d 1363 (Fed. Cir. 2003). A method claim is not limited to the specific ordering of steps as recited in the claim. The Federal Circuit vacated the district court's conclusion that the specification implicitly required such an ordering. On a second issue, the Federal Circuit ruled that despite the fact that the recited term "boot selection flag" did not have a common meaning in the art, a proper meaning could be determined by looking at the individual meanings of "boot," "selection," and "flag." ("Simply because a phrase as a whole lacks a common meaning does not compel a court to abandon its quest for a common meaning and disregard the established meanings of the individual words.") The Federal Circuit looked at dictionary definitions for these words and concluded that "boot selection flag" referred to one or more bits of data or information indication which boot cycle has been selected. As to another phrase, however, ("automation code"), the Federal Circuit concluded that dictionary definitions of the words did not give any clarity to the claim term, so resort to the specification was necessary to determine its meaning.

Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (Fed. Cir. 2003). A claimed method for treating pernicious anemia by administering folic acid and vitamin B12 "to a human in need thereof" was properly limited to uses for patients who knew they were in need of treatment of pernicious anemia. The defendant marketed a product that fell within the language of the claim except that it was marketed for maintenance of proper blood homocysteine levels, not for treatment of anemia. The Federal Circuit rejected the patent owner's argument that all persons were "humans in need" of such treatment.

Alloc, Inc. v. International Trade Comm'n, 342 F.3d 1361 (Fed. Cir. 2003). Claims that did not explicitly recite a "play" (space) between panels were nevertheless interpreted to require such "play," because the specification and prosecution history emphasized such "play." Judge Schall wrote a lengthy dissent emphasizing the lack of anything in the claims implying "play."

## 2. DOCTRINE OF EQUIVALENTS (SCOPE OF CLAIMS)

Lockheed Martin Corp. v. Space Systems/Loral, Inc., 324 F.3d 1308 (Fed. Cir. 2003). On remand from the Supreme Court in light of Festo, the Federal Circuit again concluded that Space Systems/Loral did not infringe the patent, but this time it applied the "all elements" rule. In its original decision, the Federal Circuit held that the patent was not infringed under the doctrine of equivalents because of prosecution history estoppel. After the Supreme Court vacated and remanded in light of its ruling in Festo, the Federal Circuit found a different reason to find the patent not infringed, invoking the "all elements" rule. According to the Federal Circuit, the district court erred by identifying the claimed limitation as "rotating said wheel," rather than "rotating said wheel in accordance with a predetermined rate schedule which varies sinusoidally over the orbit at the orbital frequency of the satellite." Given that this more specific limitation was missing from the accused device, no infringement could be found.

Abbott Labs. v. Novopharm Ltd., 323 F.3d 1324 (Fed. Cir. 2003). The "all elements rule" was invoked to preclude infringement under the doctrine of equivalents. The claim recited "a micronized mixture of particles of fenofibrate and a solid surfactant." The defendant used a non-solid surfactant, and the court thus held that asserting equivalents infringement would "vitate that limitation altogether." [Note: this case illustrates how a "limitation" can be as narrow as a single word].

## 3. PROSECUTION HISTORY ESTOPPEL

Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352 (Fed. Cir. 2003). (On remand from the Supreme Court in light of Festo). Pioneer was estopped from asserting that its patent was infringed under the doctrine of equivalents. The Federal Circuit held that Pioneer could not rely on a declaration by the patent attorney to explain that the narrowing amendment was "inadvertent." The Court stated that "only the public record of the patent prosecution, the prosecution history, can be a basis for such a reason [for the amendment]." The Court also rejected the argument that because the amendment was voluntary, it did not give rise to estoppel. Finally, the court ruled that Pioneer could not overcome the presumption that it had surrendered the alleged equivalent, because the equivalent was well known at the time of the amendment.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359 (Fed. Cir. 2003). In this long-awaited decision on remand from the Supreme Court, the en banc Federal Circuit clarified the nature of prosecution history estoppel. The Supreme Court had previously ruled that amending a patent claim during prosecution did not necessarily create a complete bar for purposes of infringement under the doctrine of equivalents, although making a narrowing amendment without any explanation would give rise to a rebuttable presumption that the equivalent in question had been surrendered. The Supreme Court had identified three circumstances in which the presumption could be rebutted: (1) where the accused equivalent was not foreseeable at the time of the amendment; (2) where the amendment bore no more than a "tangential" relation to the accused equivalent; or (3) where "some other reason" prevented the patent owner from covering the accused equivalent in the



claims. The Federal Circuit further developed the Supreme Court's ruling, stating that:

- (1) whether the presumption of surrender had been rebutted was a purely legal issue, despite potential fact issues regarding the level of skill in the art;
- (2) the specific factors to be considered in evaluating the rebuttal would be developed on a case-by-case basis;
- (3) unforeseeability is an objective inquiry relating to what a person of ordinary skill in the art would have foreseen at the time the amendment was made;
- (4) later-developed technology is generally not foreseeable for purposes of rebuttal;
- (5) earlier-developed technology is likely to have been foreseeable; and
- (6) a district court may hear expert testimony and consider extrinsic evidence regarding whether an alleged equivalent would have been foreseeable, but "tangential relation" and "some other reason" reasons should be determined based solely on the prosecution history. Additionally, the "tangential relation" reason could not be relied upon if the alleged equivalent was present in the prior art that the amendment was intended to overcome. The court remanded in this case to determine whether one of ordinary skill would have thought that a single two-way sealing ring was an objectively unforeseeable equivalent of two one-way sealing rings.

Ranbaxy Pharm., Inc. v. Apotex, Inc., 2003 WL 22799768 (Fed. Cir. Nov. 26, 2003). Rewriting a dependent claim in independent form in response to an examiner's objection constitutes a narrowing amendment for purposes of prosecution history estoppel, and there is a rebuttable presumption that the alleged equivalent was surrendered. The Federal Circuit concluded based on the evidence before it that the alleged equivalent (acetic acid) was likely foreseeable at the time of the amendment, and the patent owner surrendered coverage for the equivalent. (The appeal was from the denial of a preliminary injunction, so presumably additional evidence could be introduced during further proceedings in the district court).

Talbert Fuel Sys. Patents Co. v. Unocal Corp., 347 F.3d 1355 (Fed. Cir. 2003). In one of the first decisions issued after its revised Festo decision was released, the Federal Circuit held that amending a claim to recite "a boiling point range of 121F to 345F" in the face of a prior art rejection that showed a boiling point of 390F constituted a narrowing amendment that surrendered coverage over an alleged equivalent that fell within the surrendered range of 345F to 390F. The court refused to remand to permit Talbert to introduce new evidence in an attempt to overcome the rebuttal, concluding that the Festo rebuttal criteria could not be met.

Deering Precision Instruments, LLC v. Vector Distribution Sys., Inc., 347 F.3d 1314 (Fed. Cir. 2003). Although Deering narrowed its claims by canceling broader claims and substituting narrower claims, the Federal Circuit remanded to determine whether Deering could rebut the Festo

presumption that the alleged equivalents had been surrendered. The court did not explain what evidence might be relied upon to rebut the presumption.

## **C. ENFORCEMENT OF PATENTS**

### **1. OWNERSHIP**

Regents of the Univ. of New Mexico v. Knight, 321 F.3d 1111 (Fed. Cir. 2003). University faculty members were contractually obligated to assign to the university their rights in patents and patent applications, based on the university's patent policy and by conduct indicating that the professors intended to be bound by the patent policy. Two faculty members assigned several patent applications to the University of New Mexico arising from their work at the university. However, they refused to assign several continuation-in-part applications to the university. The university brought suit seeking a declaration of ownership based on breach of the university's Intellectual Property Policy and a Co-Inventor Agreement. The Federal Circuit concluded that one of the faculty members had entered into a written contract that incorporated the university's patent policy, and that the other faculty member was bound under the policy because, under New Mexico law, a written personnel policy may form an implied employment contract.

### **2. INFRINGEMENT ISSUES**

Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003). Merck had conducted research using patented peptides to identify new drugs. Integra sued Merck, claiming its use constituted patent infringement. Merck defended that its use of the patented peptides was exempt from infringement under 35 U.S.C. § 271(e)(1), which was intended to permit generic drug companies to begin testing drugs to enter the market after patent expiration. Relying in part on legislative history, the Federal Circuit held that Merck's activities did not fall within the § 271 exemption. Because Merck's research was not directly related to submitting information to the FDA concerning a particular drug, but was instead directed to identifying new drugs, the exemption did not apply. Judge Newman dissented, arguing for a common law research exemption from infringement.

Bayer AG v. Housey Pharm., Inc., 340 F.3d 1367 (Fed. Cir. 2003). Information generated overseas using a patented process and then "imported" into the United States does not constitute a "product" for purposes of infringement under 35 U.S.C. § 271(g). Housey claimed that Bayer used Bayer's patented method to identify a pharmacologically active agent and then "imported" that information into the United States. The Federal Circuit concluded that section 271(g) was limited to manufactured physical goods, thus excluding intangible information.

### **3. IMPLIED LICENSE**

Anton/Bauer, Inc. v. PAG, Ltd., 329 F.3d 1343 (Fed. Cir. 2003). A patent owner who sold female connectors intended to be mated with male connectors necessarily granted an implied license to its customers to practice the claimed invention, which required both male and female connectors. Anton/Bauer's patent claims recited both a "flat male plate" and a "flat female plate." Anton/Bauer makes and sells both female plates and battery packs containing male plates. Instead of selling the combination, however, it sells female plates to video camera manufacturers, and sells the male plates separately. The defendant sold battery packs containing only a male plate that can be used with Anton/Bauer's female plates. The Federal Circuit held that Anton/Bauer could not proceed under an induced infringement or contributory infringement theory, because its customers had an implied license to use the patented combination, and without any direct infringement there could be no contributory or induced infringement by PAG.

### **4. DAMAGES**

Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003). A jury award of \$15 million in reasonable royalty damages was vacated and remanded. The Federal Circuit found that the damages analysis was flawed because (1) reliance on a previous license entered into by Merck with another company was improper because it did not involve an analogous level of risk; and (2) the amount of damages was nearly the entire value of a company that Integra had purchased, which included many other patents.

### **5. UNENFORCEABILITY DUE TO PROSECUTION LACHES**

Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, No. CV-N-99-397-PMP (D. Nev.). 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. One major defense raised by the bar code manufacturers is that Lemelson's patents are unenforceable because of "prosecution laches" -- in other words, undue and unexplained delays at the patent office. If successful, the court could throw out most of the patents. A bench trial was concluded in January 2003, and a ruling is expected before the end of the year.

The "prosecution laches" defense was first explicitly recognized by the Federal Circuit last year in Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, 277 F.3d 1361 (Fed. Cir. 2002). The equitable doctrine of laches can bar enforcement of a patent that issued after an unreasonable and unexplained delay in prosecution, even though the patent applicant complied with the patent statute and rules. The Federal Circuit concluded that enactment of sections 120 and 121 of the patent statute, which permitted continuation and divisional applications to receive the benefit of an earlier-filed patent application, did not foreclose application of prosecution laches.

## 6. WILLFUL INFRINGEMENT

State Contracting & Eng'g Corp. v. Condotte Am. Inc., 346 F.3d 1057 (Fed. Cir. 2003). Even though the defendant did not produce an opinion of counsel as to non-infringement or validity, it reasonably relied on a belief that it had the right to practice the invention based on the agreement it had with the State of Florida, which was a licensee of the invention. The court stated that obtaining the opinion of counsel is not necessarily the only way to avoid a finding of willful infringement.

Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 344 F.3d 1336 (Fed. Cir. 2003). The Federal Circuit sua sponte decided to hear this case en banc in order to clarify the circumstances under which an adverse inference should be drawn against an accused infringer who obtains legal advice but refuses to reveal that advice during litigation. The court identified four issues for further briefing:

- (1) Whether it is appropriate to draw an adverse inference with respect to willful infringement where the defendant invokes attorney-client privilege or work product privilege;
- (2) Whether it is appropriate to draw an adverse inference when the defendant has not obtained legal advice;
- (3) If the law regarding adverse inferences is changed, what are the consequences to this case; and
- (4) Should the existence of a substantial defense to infringement be enough to defeat a charge of willful infringement, even if no legal advice was obtained?

## 7. INEQUITABLE CONDUCT

Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358 (Fed. Cir. 2003). The fact that a different patent examiner rejected similar claims in a different but related patent application can be material to patentability and thus factor into an inequitable conduct determination. In this case, the applicant's patent attorney failed to disclose a different examiner's rejection of claims in a copending patent application. The Federal Circuit concluded that this was material information: "We hold that a contrary decision of another examiner reviewing a substantially similar claim meets the Akron Polymer 'reasonable examiner' threshold materiality test." However, the Court remanded for a determination of intent to deceive, which was lacking in the record. The Court declined to resolve which standard for materiality should be applied. (Under the old rules, the "reasonable examiner" test was applied; the new rules adopt a "prima facie case of unpatentability" or "refutes or is inconsistent with a position that the applicant takes" standard).

Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003). Inventors who used past tense to describe in a patent application an experiment that had never been performed potentially committed inequitable conduct. The patent application described an example procedure for repeatedly refining a bacterial culture. The example used past tense phrases such as "Active

fractions with no detectable nucleases were pooled and run . . . The results show a single 88 kd band . . . Example VI was found to be free of any contaminating Taq endonuclease and exonuclease activities." The past tense was used more than 75 times in explaining the protocol. The inventor later admitted that he had never performed the example as described. After concluding that this constituted a misrepresentation, the Federal Circuit upheld the district court's finding that it was material and that it was intentional, since the inventors provided no explanation as to why the past tense was used. However, the Federal Circuit vacated and remanded because some of the other district court findings were not upheld.

Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226 (Fed. Cir. 2003). A patent on the cancer drug taxol was held to be unenforceable because the applicants failed to disclose to the patent office an article that was published by the inventors. Although the article was not prior art, it cast doubts on the enablement of the claims because it stated that certain chemicals relied upon in the patent application were unstable. Although the patent examiner had independently uncovered the article, he did not place his initials on the form indicating that he had considered the article. The applicants' French patent agent knew about the article but failed to provide it to the patent office or to the U.S. patent attorney.

## **8. UNJUST ENRICHMENT & PATENT PREEMPTION**

The Univ. of Colorado Foundation, Inc. v. American Cyanamid Co., 342 F.3d 1298 (Fed. Cir. 2003). A claim for unjust enrichment based on filing a patent application for an invention that was attributable to another person was not preempted under the patent laws. The defendant incorporated confidential materials from the plaintiff into a patent application and obtained a patent without listing the plaintiff as an inventor. The plaintiff was awarded millions of dollars in damages under an unjust enrichment theory. The Federal Circuit concluded that the claim was not preempted under the patent law, because it did not create new patent rights or extend the scope of federal patent rights to cover otherwise unpatentable ideas. Unlike the boat hulls involved in the Supreme Court's Bonito Boats decision, the invention here was patentable.

## **9. PROCEDURE**

Pandrol USA, LP v. Airboss Railway Prods., Inc., 320 F.3d 1354 (Fed. Cir. 2003). A party did not waive an invalidity defense by failing to raise it in response to a motion for summary judgment of infringement. Although the Federal Circuit upheld the grant of summary judgment of infringement, it vacated the district court's ruling that Airboss had waived the affirmative defense of invalidity by failing to raise it in response to Pandrol's motion for summary judgment.

## **10. PATENTS IN STANDARD-SETTING ORGANIZATIONS**

Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081 (Fed. Cir. 2003). The Federal Circuit overturned a jury verdict that Rambus committed fraud under Virginia law by failing to disclose to a standards-setting organization that it held patents relating to memory devices. Rambus participated

in JEDEC, a standard-setting body in the electronics industry. JEDEC had a written patent policy encouraging the adoption of standards free of patented items, and requiring members to disclose patents and patent applications "related to" the standardization work of its various committees. The Federal Circuit interpreted the patent policy to require disclosure only if a license under the patent claims was required to practice the standard. Judge Prost dissented, concluding that the patent policy contained a broader disclosure requirement.

## **11. STANDING TO SUE FOR INFRINGEMENT**

Paradise Creations, Inc. v. UV Sales, Inc., 315 F.3d 1304 (Fed. Cir. 2003). A corporation lacked standing to sue for patent infringement because, at the time it obtained an exclusive patent license and filed the lawsuit, it was administratively dissolved under Florida law for failing to file its annual report. The Federal Circuit upheld dismissal of the lawsuit even though Paradise had been reinstated as a corporation after the lawsuit was filed. According to the Federal Circuit, standing must be present at the inception of the lawsuit.

## **12. STATE IMMUNITY FROM PATENT INFRINGEMENT**

Regents of the Univ. of New Mexico v. Knight, 321 F.3d 1111 (Fed. Cir. 2003). After the University of New Mexico brought suit against two faculty members to force them to assign certain patents developed while at the university, the faculty members filed counterclaims for compensation under various theories. The district court dismissed the counterclaims as being barred under the 11th Amendment sovereign immunity clause. The Federal Circuit vacated the decision, concluding that by filing suit in federal court the university waived its sovereign immunity with respect to all compulsory counterclaims (i.e., those arising from the same transaction or occurrence), and remanded to the district court for a determination as to which counterclaims should be reinstated.

## **13. HATCH-WAXMAN ACT**

Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003). It is not an act of infringement to submit an ANDA for approval to market a drug for a use that is not covered by an existing patent. Warner-Lambert obtained FDA approval to market its patented drug for use in treatment of seizures in adults with epilepsy. Warner-Lambert also had a second patent covering use of the same drug for use in treating neurodegenerative diseases. Apotex filed an Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of the drug for the treatment of epilepsy after Warner-Lambert's first patent expired. Warner-Lambert sued, alleging that Apotex would induce infringement of its second patent directed to treating neurodegenerative diseases with the drug. The Federal Circuit held that Warner-Lambert could not assert infringement by alleging that the generic manufacturer would induce infringement of one of its other patents that did not cover the use for which the generic drug was being approved.

Allergan, Inc. v. Alcon Labs, Inc., 324 F.3d 1322 (Fed. Cir. 2003). The owner of a patent for a non-FDA approved method of using a drug cannot sue a generic drug manufacturer for infringement based on the generic manufacturer's filing of an Abbreviated New Drug Application (ANDA) that seeks approval for a use different from that claimed in the patent. Allergan's two patents cover a method of using an unpatented drug for (1) protecting the optic nerve and (2) neural protection. Neither of these uses of the unpatented drug has been approved by the FDA. Alcon submitted an ANDA to the FDA seeking approval for a generic use of the unpatented drug to reduce interocular pressure, a use not claimed in Allergan's patents. Allergan sued, claiming that Alcon's proposed use would induce infringement of its patents because doctors would prescribe the drug for Allergan's patented uses. The Federal Circuit held that this case was controlled by its earlier decision in Warner-Lambert (see above), and that Allergan could not base a claim on uses not approved under the asserted patent.

Apotex, Inc. v. Thompson, 347 F.3d 1335 (Fed. Cir. 2003). The FDA is not required to substantively review patents before listing them in its "Orange Book." SmithKline had listed one of its patents in the Orange Book with respect to one of its FDA-approved drugs. After a generic competitor filed a request with the FDA to produce a generic version of the drug, SmithKline listed additional patents in the Orange Book with respect to the drug and sued the generic competitor for patent infringement. The competitor sued the FDA to force removal the additional patents, claiming that they did not cover the drug that was originally approved by the FDA. The Federal Circuit held that the FDA's regulation, under which it did not substantively examine Orange Book listings, was reasonable in light of the fact that the Hatch-Waxman Act did not require the FDA to examine the listings.

## **D. FTC ACTIONS INVOLVING PATENTS**

### **1. RAMBUS**

The FTC has filed an antitrust case against Rambus, charging that the company deceived an industry standard-setting organization by failing to disclose that it held key patents involving memory technology. The Federal Circuit in a related case held that Rambus did not commit fraud under Virginia law by failing to disclose the patents. Rambus v. Infineon Technologies, Inc., 318 F.3d 1081 (Fed. Cir. 2003).

### **2. UNOCAL**

The FTC filed a complaint against Unocal in March 2003, alleging that its actions in not disclosing its patents to the California Air Resources Board during its rule-making for reformulated gasoline were anticompetitive. Unocal's patents broadly cover cleaner-burning gas mandated by California.

# **BONUS: HOW TO "FESTO-PROOF" YOUR PATENT APPLICATION**

The Supreme Court in Festo Corp. v. Shoketsu Kinzoku Kabushiki Co., 535 U.S. 722, 122 S. Ct. 1831 (2002) held that prosecution history estoppel applies to any claim amendment made to satisfy any requirement of the patent statute, not just those made to avoid the prior art. However, the Supreme Court rejected the Federal Circuit's "bright line" rule, holding that the estoppel should not completely bar assertion of equivalents infringement except under certain circumstances. In short, the Supreme Court held that the patentee should bear the burden of showing that a particular amendment does not surrender the particular equivalent in question, 122 S. Ct. at 1842, and that "The patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." 122 S. Ct. at 1842. The Court continued:

There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

122 S. Ct. at 1842.

One Federal Circuit decision since then has clarified that the Federal Circuit will restrict applicants to relying only on evidence in the public file history in order to rebut the presumption of estoppel. See, Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352 (Fed. Cir. 2003) ("only the public record of the patent prosecution, the prosecution history, can be a basis for such a reason.") In that case, the Federal Circuit also reaffirmed the principle that voluntary amendments, as well as amendments arising from a patent examiner's rejection, could create estoppel.



## WHAT'S A PATENT PRACTITIONER TO DO?

1. Do a thorough prior art search. Filing a patent application with claims when you have no idea what is the closest prior art is like shooting in the dark. Although it adds time and cost to the patent application, finding prior art before the examiner does may avoid the need to make major claim amendments down the road. If your client doesn't want to pay for a prior art search, do a quick keyword search on the free PTO web site, and ask the inventor to provide you with copies of the closest prior art. A side benefit of doing a prior art search is it may enable you to file a petition to make special, speeding up the examination of your patent application. See MPEP 708.02.

2. Use the prior art to identify alternative embodiments. Given the Supreme Court's warning that estoppel may arise unless the equivalent was "unforeseeable," prior art in the same field as the invention will likely be used against you as evidence in litigation that a particular equivalent was foreseeable. Put the foreseeable variations found in the prior art for the most critical inventive elements into your patent application, and claim them. (Recall Johnson & Johnston case; disclosed but unclaimed embodiments are "dedicated to the public.")

3. Ask the inventor to think of all possible alternatives. One technique is to ask the inventors to "design around" the broadest claim you have drafted, allowing you to tweak it or add new claims to cover the "design arounds." Again, this will increase the cost of the patent application, both in attorney time and inventor time. Explain to the inventors that if you don't perform this exercise, the patent may be worthless because an infringer could get around the patent by using a "foreseeable" alternative. You don't want the inventor to admit on the witness stand that he knew of a foreseeable alternative but never mentioned it to his patent attorney because the attorney never asked him about such alternatives.

4. Make sure all embodiments and variations are claimed. See Johnson & Johnston Associates Inc. v. R.E. Serv. Co., 285 F.3d 1046 (Fed. Cir. 2002) (disclosed but unclaimed embodiments are "dedicated to the public.")

5. Leave out "objects of the invention" and similar discussions. These are not required, yet practitioners frequently list many different "objects" or "goals" of the invention. The accused infringer will demonstrate that its device lacks some or all of the "goals" listed in the patent in an attempt to show that it is substantially different. The Federal Circuit has used language like this in the specification to interpret the claims narrowly.

6. Don't criticize the prior art in the application. Criticism of a particular feature in a patent application may prevent a patentee from reclaiming that subject matter through the doctrine of equivalents. Schwing GMBH v. Putzmeister Aktiengesellschaft, 305 F.3d 1318, 1329 (Fed. Cir. 2002).

7. Define and then use broad terminology for the claims. Rather than relying on assumptions (including common usage and dictionary definitions) for terminology used in the claims, define terms in the specification broadly and then use the broad terminology in the claims. For example, rather than reciting that a method operates on a "file," you can instead define an "object" as "a file, directory, collection of bits or data, or any other grouping of information," and then use "object" in the claim rather than "file." This avoids an infringer's argument that "file" has a narrow definition lacking an equivalent in the accused device. It also avoids the need to show equivalence in the first place.

8. Consider, but don't exclusively rely on, means-plus-function claims. Means-plus-function claims provide built-in equivalence that can be proved as literal infringement, rather than relying on the doctrine of equivalents. Make sure you also include other independent claims that do not rely on means-plus-function clauses.

9. Have a second patent attorney review the claims. No matter how experienced you are, a second patent attorney with a fresh set of eyes may spot an unnecessary or unclear limitation that you had not considered. Fixing problems and ambiguities before the application is filed may avoid the need to amend the claims during prosecution. Again, it will add minimally to the cost of drafting the application, but you can explain to your client that doing so will result in a stronger patent.

10. Try to "redefine" a claim limitation rather than "narrowing" it. Given that prosecution history estoppel only applies to narrowing claim amendments, try to characterize amendments made during prosecution as "redefining" limitations made for clarity only, rather than narrowing limitations made to avoid the prior art. See e.g., Interactive Pictures Corp. v. Infinite Pictures Inc., 274 F.3d 1371 (Fed. Cir. 2001) (amending the claim term "output signals" to "output transform calculation signals" did not narrow the claim, since it merely rendered explicit what was already implicit in the claim); Bose Cop. v. JBL, Inc., 274 F.3d 1354 (Fed. Cir. 2001) (fixing an antecedent basis problem in a claim did not constitute a narrowing amendment for purposes of prosecution history estoppel); Turbocare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111 (Fed. Cir. 2001) (newly added claim only "redefined" the small clearance position without narrowing the claim; prosecution history estoppel did not apply).

11. Appeal more often. This sounds obvious, but overturning an examiner's rejection rather than acquiescing to a slightly narrowing claim may make a huge difference in patent scope when the "slightly narrowing" amendments are scrutinized under the microscope of litigation. The pendency of appeals at the Board of Appeals has been significantly reduced in the last year or so, speeding up the appeals process. Recent statistics also suggest that 30% of appeals are resolved in the appeal conference that takes place before the file is transmitted to the Board of Appeals.

12. Interview the patent examiner before filing an amendment. If you can convince the examiner that one out of a set of arguments or amendments is persuasive during an interview, without reducing all of those reasons or amendments to writing, this leaves you with the flexibility of only relying on those amendments or arguments in the response that are likely to be persuasive with the examiner.

13. Swear behind a reference rather than arguing that the reference is distinguishable. Removing prior art by showing that it is not "prior" avoids estoppel altogether (no amendments, no arguments).

14. Explain amendments as merely clarifying the scope of the invention, rather than as being required to avoid the prior art. Leaving out an explanation will give rise to a presumption of surrender.

