MID-YEAR 2003 DEVELOPMENTS IN PATENT LAW

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INTELLECTUAL PROPERTY LAW

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I. LEGISLATION

A. H.R. 2215 (21st Century Dept of Justice Appropriations Auth. Act)

On November 2, 2002, President Bush signed into law H.R. 2215, the 21st Century Department of Justice Appropriations Authorization Act, which enacted Public Law 107-273. This recent legislation includes the Patent and Trademark Office Authorization Act of 2002 ("Authorization Act") and the Intellectual Property and High Technology Technical Amendments Act of 2002 ("Technical Amendments Act"). These Acts together make three significant changes that may impact the way patent attorneys prosecute patent applications and litigate patents:

- In re Portola Packaging is legislatively overruled. Prior art cited during original patent prosecution may now be exclusively used to establish a substantial new question of patentability in reexamination proceedings.

- Third party requesters in inter partes patent reexamination proceedings may now appeal to the Federal Circuit, repealing a limitation in prior legislation.

- 35 U.S.C. § 102(e) is amended to expand in some respects, and narrow in other respects, the scope of prior art available against U.S. patent applications.

1. SUBSTANTIAL NEW QUESTION OF PATENTABILITY

The patent statute requires that a reexamination request show that a substantial "new question of patentability" has been raised. See 35 U.S.C. §§ 303(a) and 312(a). The Federal Circuit has narrowly interpreted this provision, concluding that a rejection during reexamination based on a prior art reference and statutory ground previously considered during original prosecution of the patent did not raise a substantial new question of patentability. In re Recreative Techn. Corp., 83 F.3d 1394 (Fed. Cir. 1996). The Federal Circuit also ruled that "a rejection made during reexamination does not raise a substantial new question of patentability if it is supported only by prior art previously considered by the PTO in relation to the same or broader claims." In re Portola Packaging, Inc., 110 F.3d 786 (Fed. Cir. 1997). Therefore, parties requesting reexamination were effectively unable to rely on prior art that was previously considered by the PTO. This disadvantage was particularly severe in light of the practice by some patentees of citing dozens or hundreds of prior art references during original prosecution.

Congress has legislatively overturned the Federal Circuit's narrow interpretation of the statute. Sections 303(a) and 312(a) have now been amended to provide: "The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office . . . ." The new provision applies to any PTO determination made on or after November 2, 2002. This amendment should make it easier for requesters to challenge the validity of patents based on prior art that was previously considered by the PTO.

2. THIRD PARTY RIGHT OF APPEAL IN INTER PARTES REEXAMINATION

An initial goal of inter partes reexamination, first introduced by the American Inventors Protection Act of 1999, was to provide a cost-efficient means for challenging the validity of a patent in the PTO by allowing third parties to participate in the reexamination proceedings. See 35 U.S.C. §§ 311-318. However, the statute specifically prohibited a third-party requester from appealing from a decision of the Board of Patent Appeals and Interferences. See 35 U.S.C. § 134(c). This disadvantage reflected a legislative compromise made during original enactment of the inter partes reexamination statute. Because third party requesters were estopped from challenging in later litigation any facts determined by an inter partes reexamination, the disadvantage was thought to discourage third parties from requesting inter partes reexamination of patents.

The new legislation allows third party requesters of inter partes reexamination proceedings to appeal Board decisions to the U.S. Court of Appeals for the Federal Circuit. The third party's right of appeal to the Federal Circuit applies to any inter partes reexamination proceeding commenced on or after November 2, 2002. This new provision should help entice potential litigants to challenge validity questions in the PTO rather than in courts.

3. TECHNICAL CORRECTIONS TO 35 U.S.C. § 102(e)

Prior to the 1999 American Inventors Protection Act (AIPA), 35 U.S.C. § 102(e) applied to U.S. patents derived from PCT applications only when the applicant complied with certain U.S. national stage requirements – that is, payment of a fee; filing of an English language copy of the application; and filing the inventor's oath or declaration. Until those three requirements were fulfilled, no §102(e) date attached to the application. In other words, PCT applications did not become prior art until the date that all of all of the U.S. national stage requirements had been met. This put foreign inventors at a relative disadvantage compared with applications that were filed in the United States without going through the PCT, since U.S.-filed applications became prior art under 35 U.S.C. § 102(e) immediately upon filing, even if the U.S. patent applicant did not file the application with the necessary fees or declaration.

The AIPA placed foreign inventors on more equal ground by giving published PCT applications a § 102(e) date as of their international filing date, so long as the PCT application designated the U.S. and was published in the English language. The AIPA amendment to 35 U.S.C. § 102(e) was intended to apply only to PCT applications filed on or after November 29, 2000. The AIPA simultaneously introduced the concept of published U.S. applications. Unfortunately, the AIPA contained several loopholes regarding the applicability of amended 35 U.S.C. § 102(e). The Technical Amendments Act amends 35 U.S.C. § 102(e) and 35 U.S.C. § 374 to correct these loopholes, and are actually retroactive amendments to the AIPA. In particular, 35 U.S.C. § 102(e) is amended to appear as follows (Pub. L. No. 107-273 § 13205):

> A person shall be entitled to a patent unless –
> . . . .
> (e) the invention was described in –
>
> > (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
> >
> > (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,
> >
> > except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

In addition, 35 U.S.C. § 374 was changed by the Technical Amendments Act to read as follows:

> The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall be deemed a publication under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

A first loophole -- now closed -- was that, under the AIPA, it was unclear whether a U.S. published patent application could benefit from a § 102(e) international filing date if the application was filed under 35 U.S.C. § 111 and claimed priority to an English-language published PCT application designating the U.S., where the PCT was filed prior to November 29, 2000. In other words, an applicant could arguably bypass the effective date provision of the AIPA by filing a new U.S. application and claiming priority to a PCT application filed prior to November 29, 2000, thereby obtaining the PCT filing date as the effective § 102(e) date for the U.S. application. By contrast, had that applicant instead entered the U.S. national phase based on a pre-November 29, 2000 PCT, the § 102(e) date would be the U.S. filing date. The Technical Amendments Act now treats both methods of entering the U.S. equally and requires the PCT application to have been filed on or after November 29, 2000, for the corresponding U.S. application to gain a § 102(e)

international filing date. Accordingly, this aspect of the Technical Amendments Act has effectively narrowed the scope of potential prior art by closing the loophole.

A second loophole in the AIPA was that while U.S. published applications could benefit from a § 102(e) international filing date, issued U.S. patents could not. This was a bizarre outcome clearly not intended by Congress. The Technical Amendments Act corrects this such that both a U.S. patent application and its corresponding U.S. patent now may benefit from the same § 102(e) international filing date, thereby expanding the scope of prior art available.

A third loophole was that under the AIPA, the applicability of the amended version of 35 U.S.C. § 102(e) was linked to the filing date of the application under examination or the patent under reexamination. Specifically, under the AIPA, the amended version of 35 U.S.C. § 102(e) would be applied only against those applications under examination or those patents under reexamination that were filed on or after November 29, 2000. Thus, a particular prior art reference could have a different § 102(e) date depending upon the patent or patent application against which it was being used. A peculiar result was that a U.S. patent application filed prior to November 29, 2000, that may have had allowable claimed subject matter, could suddenly become unpatentable simply by the filing of a continued prosecution application after November 29, 2000.

The Technical Amendments Act changed the law to expand the scope of prior art available. The amended 35 U.S.C. § 102(e) now applies uniformly to all existing and future applications under examination, and all existing and future patents that may be or already are under reexamination. Under the new law, no published PCT application, nor any U.S. patent or U.S. patent application derived there from, will benefit from a § 102(e) filing date unless the PCT application 1) was filed on or after November 29, 2000, 2) was published in the English language, and 3) designated the U.S.

B. PROPOSED/PENDING LEGISLATION

1. GENERIC DRUG BILLS (S. 1 and H.R. 1, including original S. 1125 and H.R. 2491)

The House and Senate have passed different versions of bills that change the way patent infringement provisions for generic drugs are handled. The differing bills must be reconciled in conference. The bills are in agreement as to the following provisions:

a. Drug applicants are given the right to bring a declaratory judgment action against a patentee who does not sue within the 45-day limit under 35 U.S.C. § 271(e)(2).

b. Drug applicants who are sued under 35 U.S.C. § 271(e)(2) are given the right to assert a counterclaim that challenges patent information listed in the "Orange Book."

c. Provides damages based on improper "Orange Book" listings.

d. Limits patentees to a single 30-month stay of FDA approval for generic drugs.

2. STRIPPING STATES OF SOVEREIGN IMMUNITY (H.R. 2234 and S. 1191)

These bills propose to force states to waive their immunity from patent infringement by preventing them from recovering damages in patent infringement suits unless they waive immunity.

3. OVERRULING ODDZON PRODUCTS CASE (H.R. 2391)

The House is considering legislation that would amend 35 U.S.C. § 102(f) and § 103(c) to legislatively overrule the Federal Circuit's decision in OddzOn Products Inc. v. Just Toys Inc., 122 F.3d 1396 (Fed. Cir. 1997). In that case, the Federal Circuit held that collaborative research projects could give rise to "prior art" under 35 U.S.C. § 102(f).

4. ENDING DIVERSION OF PTO FUNDS (H.R. 1561)

This bill was recently amended in subcommittee to eliminate diversion of PTO funds. Previous attempts to enact similar legislation have failed.

II. CASE LAW

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 Commerical 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."

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. 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%.

5. 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."

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^{o} C to 32^{o} C was improperly interpreted to preclude an additional step (prior to the first step) of growing cells at 37^{o} C (i.e., foreclosing any growth outside of the claimed range). During prosecution, the patent examiner had stated that the 18^{o} C to 32^{o} 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^{o} 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^{o} 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.

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.

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 co-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 "vitiate 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.

C. ENFORCEMENT OF PATENTS

1. OWNERSHIP OF PATENTS

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

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.

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. "EXPERIMENTAL USE" DEFENSE TO INFRINGEMENT

Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002). The "experimental use" defense to patent infringement is a very narrow and limited defense. A nonprofit university that conducts research using a patented method is not excused from infringement. The defense is limited to acts of infringement performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." Note: The Supreme Court denied certiorari in this case, along with every other patent case filed this term.

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. 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.

9. 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.

10. 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.

11. 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.

12. 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.

III. FTC ACTIONS INVOLVING PATENTS

A. 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).

B. 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.

IV. 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.

Although the Federal Circuit heard oral argument en banc in Festo after remand from the Supreme Court, it has not yet issued its decision interpreting that case. 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.

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.

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 of a set of arguments or amendments is persuasive during an interview, where all of those reasons or amendments are not reduced 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.