THE YEAR IN REVIEW
2006
PHARMACEUTICAL
BIOTECH/CHEMICAL
PATENT LAW

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I. INTRODUCTION

During 2006, many significant developments occurred in U.S. patent law. The developments were not changes in the laws due to Congressional action, but involved interpretation of current laws by the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court.

This publication focuses on the 42 most important judicial decisions of interest to patent lawyers specializing in pharmaceutical, biotech, and chemical patent law. While some of the cases presented do not involve claims to pharmaceutical, biotech, and chemical inventions, they were included due to their impact on patent law in general.

In particular, one of the most significant decisions of the year was the U.S. Supreme Court’s decision in *eBay Inc v. MercExchange*, 547 U.S. ___, 126 S. Ct. 1837 (2006). No longer can it be assumed that a patent holder has the right to exclude others from practicing his or her claimed invention. The *eBay* decision requires Courts to apply a four-factor test before granting permanent injunctive relief. Thus, the decision to grant or deny injunctive relief now rests within the discretion of the District Courts.

Another significant case was *KSR International Co. v. Teleflex, Inc. et al.*, No. 04-1350 (U.S., oral argument presented, Nov. 28, 2006). The U.S. Supreme Court in *KSR* is considering whether the Federal Circuit has been applying the correct standard in its obviousness determinations. While a decision from the Court had not issued as of December 31, 2006, this case has already caused the U.S. Court of Appeals for the Federal Circuit in 2006 to more carefully consider obviousness in several cases.

All of the cases presented here can be read in their entirety at either:

[www.fedcir.gov](http://www.fedcir.gov)

or

[www.supremecourtus.gov](http://www.supremecourtus.gov)

It was our aim to highlight key points in each of the opinions, not to brief the entire case. We hope that you enjoy reading this compilation of cases and that it provides you with insight into the developments which occurred in U.S. patent law in 2006.
II. CASES


1) *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U. S. ____ (2006)

In *LabCorp*, the U.S. Supreme Court, after hearing arguments regarding invalidity under 35 U.S.C. §101, dismissed the *writ of certiorari* as improvidently granted without providing a written opinion. The issue of invalidity under 35 U.S.C. §101 had not been argued in the lower Courts. This case involved a patent that claimed a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin. The process consisted of using any test to measure the level of an amino acid called homocysteine in a body fluid and then noticing whether its level is elevated above the norm; if so, a vitamin deficiency is likely. The Lower Courts had held that the patent claim was valid. *Certiorari* was granted in the case to determine whether the patent claim was invalid on the ground that it improperly sought to claim a monopoly over a basic scientific relationship. Justice Breyer wrote in dissent that he could “find no good practical reason for refusing to decide the case. The relevant issue has been fully briefed and argued by the parties, the Government, and 20 *amicus*” and “there is no indication that LabCorp’s failure to cite §101 reflected unfair gamesmanship.”


1) *Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc.*, No. 05-1313 (Fed. Cir. 2006).

Aventis’s patent was directed to a method of treating amyotrophic lateral sclerosis (ALS or Lou Gehrig’s disease) using a chemical compound known as riluzole. Impax filed an ANDA seeking FDA approval to make and sell generic riluzole for the treatment of ALS patients. Aventis sued for infringement. Impax countersued arguing that Aventis patent was invalid under 35 U.S.C. § 102(b) and, therefore, unenforceable. The Federal Circuit vacated the District Court’s determination that the claims of Aventis’s patent were not invalid by reason of anticipation. The Federal Circuit pointed out that, for purposes of anticipation, the teachings of the prior art must enable one skilled in the art to make and use the invention, but unlike the first paragraph of 35 U.S.C. §112, it need not demonstrate utility. For example, a reference which discloses using a particular compound to treat a specific disease state, need not necessarily demonstrate the efficacy of the compound to provide an enabling disclosure under 35 U.S.C. §102. On remand, the District Court was instructed to determine whether a prior art document was enabling. Specifically, the District Court was instructed to determine whether the prior art patent would have enabled a person of ordinary skill in the art to treat ALS with riluzole since the effectiveness of the drug in treating ALS did not have to be established.

Abbott developed a highly effective inhalation anesthetic, sevoflurane. It was unknown at the time the invention was made that sevoflurane would degrade in the presence of Lewis acids to hydrofluoric acid during shipping. Consequently, sevoflurane had to be withdrawn from the market. Contrary to conventional wisdom in the art, Abbott added water to sevoflurane and discovered that it prevented degradation. Abbott filed an application, and was issued a patent directed to “the degradation-preventing combination of water or other ‘Lewis acid inhibitors’ with sevoflurane.” The Federal Circuit held that Abbott’s patent was anticipated by a prior art patent disclosure of water-saturated sevoflurane. The Court reasoned that because the prior art compound was unable to absorb additional water, it was protected from degradation. The Federal Circuit maintained its well established position that a reference may anticipate even when the relevant properties of the disclosed compound were not appreciated at the time.

3) *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, No. 05-1157 (Fed. Cir. 2006) (Petition for en banc rehearing denied, November 22, 2006)

Here, the major issue was whether the District Court properly construed the phrase “therapeutically effective amount” in the claim. Amgen’s patents were directed to the use of recombinant deoxyribonucleic acid (“DNA”) technology to produce the hormone erythropoietin (“EPO”). According to the District Court, this phrase limited the amount of EPO to that which (1) elicits one of four *in vivo* effects delineated in the specification; and (2) increases the hematocrit. A Federal Circuit majority (Schall and Clevenger) reviewed the District Court’s claim construction de novo and held that an increase in hematocrit was not separate and distinct from the four other *in vivo* effects. According to the Court, the specification disclosed “any or all of five *in vivo* effects may be a consequence of EPO therapy.” Consequently, the Court remanded the case with instructions to consider whether a prior art publication anticipated the invention under their claim construction.

Judge Michel wrote a strong dissent criticizing the majority’s claim construction. Abbott requested hearing *en banc* but was denied with 4 judges dissenting. Of significance, Judges Michel and Rader argued that the Court should consider whether they should continue to review claim construction de novo.

4) *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991 (Fed. Cir. 2006)

The Federal Circuit reversed the District Court’s holdings of invalidity on the ground of anticipation. At issue was an invention directed to a method of synthesizing difluoromethane within a particular temperature range in the presence of a chromium catalyst. The prior art disclosed a temperature range of 100°C to 500°C which was broader than and fully encompassed the specific temperature range 330°C to 450°C claimed in the patent. The Court found that given the difference between the claimed temperature range and the range in the prior art, “no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.” In addition to this anticipation issue, the issue of inequitable conduct was also raised in *Atofina* (discussed below).

The Federal Circuit affirmed the District Court’s grant of summary judgment to Apotex of invalidity of SmithKline’s patent, USPN 6,113,944 as being anticipated by an earlier SmithKline patent for paroxetine (paxel®), USPN 4,721,723. The ‘723 patent disclosed a pharmaceutical composition containing paroxetine. The ‘944 patent contained product-by-process claims to the same pharmaceutical composition containing paroxetine. The issue was whether the prior art disclosure of a product precludes a future claim to that same product when it is made by an allegedly novel process. The Court held that regardless of how broadly or narrowly one construes a product-by-process claim, such claims are always to a product, not a process. It has long been established that an earlier product disclosure anticipates a later claim to the same product even though produced by a different process. Whether the product produced by the process claimed in the ‘944 patent was, in fact, a different product than that disclosed in the ‘723 patent, was held to have been waived for failure to brief it on appeal.

On June 22, 2006, in SmithKline, the petition for hearing en banc was denied with Judge Newman and Rader writing dissenting opinions and with Judge Garjasa joining both opinions. Judge Newman argued that it is important for the Federal Circuit to distinguish two of its previous opinions concerning product-by-process claims, viz., Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) and Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992). Judge Newman distinguished these cases by emphasizing that Scripps accommodates the situation where the product is novel and complex and cannot be described other than by the way it was made, while Atlantic Thermoplastics deals with a product whose production requires the use of a certain process, whether or not the product itself is novel. Judge Rader contended that all the words in a product-by-process claim must first be construed to determine the scope of the claim before determining whether the product set forth is anticipated by the prior art.

C. 35 U.S.C. §103 – OBVIOUSNESS

1) KSR International Co. v. Teleflex, Inc. et al., No. 04-1350 (U.S., oral argument presented, Nov. 28, 2006)

The U.S. Supreme Court heard oral arguments on November 28, 2006 regarding the obviousness standard under 35 U.S.C. § 103(a). More specifically, the Supreme Court considered whether the Federal Circuit erred in holding that an invention cannot be held obvious, and thus unpatentable under 35 U.S.C. § 103(a), absent a teaching, suggestion, or motivation in the applied prior art that would have led a person of ordinary skill in the art to combine the teachings therein in the manner claimed. A decision was not published in 2006.

2) In re Leonard R. Kahn, No. 04-1616 (Fed Cir. 2006)

The Federal Circuit affirmed the USPTO Board of Patent Appeals and Interferences’ finding of obviousness under 35 U.S.C. § 103. At issue was a reading machine for the blind. The Federal Circuit justified in detail its teaching-suggestion-motivation requirement for making a prima facie case of obviousness as protecting against the entry of hindsight into the analysis.
The Federal Circuit stated that rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be an articulated reason with some rational underpinning to support the legal conclusion of obviousness. The Court stated further that the teaching-suggestion-motivation test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims and “[f]rom this it may be determined whether the overall disclosures, teachings, and suggestions of the prior art, and the level of skill in the art—i.e., the understandings and knowledge of persons having ordinary skill in the art at the time of the invention—support the legal conclusion of obviousness.”

3)  

**Bruckelmyer v. Ground Heaters, Inc., 455 F.3d 1374 (Fed. Cir. 2006)**

Each of Bruckelmeyer’s two patents were directed to a method of thawing frozen ground using rubber hoses heated with water or antifreeze so that a layer of concrete could be poured without cracking. In Bruckelmyer, the Federal Circuit determined that a disclosure located in a Canadian patent application file wrapper was a “printed publication” under 35 U.S.C. § 102(b) and could be relied upon to invalidate an invention on the ground of obviousness. Figures 3 and 4 which illustrated the use of the disclosed heating system were present in the patent application file, but not in the published patent. They were cancelled during prosecution. The Court determined that a person of ordinary skill in the art interested in the subject matter of the patents in suit and exercising reasonable diligence would have been able to locate the application at the Canadian patent office in view of the publication of the corresponding patent.

4)  


Align held two patents directed to an orthodontic device for repositioning teeth comprising a series of retainers. The Federal Circuit reversed the District Court’s grant of summary judgment that the claims of Align’s two patents were not invalid, and held that all the claims on appeal would have been obvious under 35 U.S.C. § 103(a). The Court held that a claim can be obvious even where all of the claimed features are not found in specific prior art references, when there is a showing of a suggestion or motivation to modify the teachings of the prior art to arrive at the claimed invention. The teaching, motivation, or suggestion may be implicit from the teachings of the prior art as a whole, rather than expressly stated in the references. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” With respect to Align’s evidence of secondary considerations, the Federal Circuit found that the success of Align’s invention was not due to claimed and novel features of its orthodontic device. The Court also found that the evidence of “failure by others” was not due to the lack of claimed features in their devices. Thus, the evidence of secondary considerations was not sufficient to rebut the *prima facie* case of obviousness.
5) **Alza Corporation v. Mylan Laboratories, Inc.,** No. 06-1019 (Fed. Cir. 2006)

Alza had a patent directed to oxybutinin, a drug used to treat urinary incontinence. The Federal Circuit affirmed the District Court’s finding of invalidity based on obviousness. The Federal Circuit noted that under their teaching-suggestion-motivation test, a suggestion to combine the teachings of the prior art need not be found therein. The motivation to combine can be found in the knowledge generally available to one of ordinary skill in the art.

6) **DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.,** No. 06-1088 (Fed. Cir. 2006)

DyStar’s patent claimed a method for dying textile material using leuco indigo, a reduced water soluble form of indigo. The only difference between the claimed method and the prior art was the stabilization of the leuco indigo in liquid form as opposed to a powdered form coated with molasses. The Federal Circuit reversed the District Court’s denial of a motion for JMOL of invalidity of claims 1-4 as being obvious. Applying the **Graham** factors (i.e., the factors for determining obviousness delineated by the U.S. Supreme Court in **Graham v. John Deere Co.**, 383 U.S. 1, 17 (1966)), the Federal Circuit held that the claimed method would have been obvious to one of ordinary skill in the art. In addition, the Federal Circuit defended its teaching-suggestion-motivation test describing it as flexible which requires “common knowledge and common sense.” The Federal Circuit noted that they “have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the ‘improvement’ is technology-independent and the combination of references results in a product or process that is more desirable, for example, because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical.” The Federal Circuit emphasized that they “have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him capable of combining the prior art references.”

7) **Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals., Inc.,** Nos. 05-1396, 05-1429, 05-1430 (Fed. Cir. 2006)

In the present case, Zenith Goldline Pharmaceuticals, Inc.; Dr. Reddy’s Laboratories, Ltd.; and Teva Pharmaceuticals USA, Inc. (defendants), filed an ANDA for olanzapine. In response, the plaintiffs, Eli Lilly filed suit against all defendants for infringement of U.S. Patent No. 5,229,382 (‘382 patent). The Federal Circuit affirmed the District Court’s finding that the ‘382 patent was valid and infringed. Specifically, the Federal Circuit affirmed the District Court on the issues of anticipation, obviousness, public use, and on inequitable conduct. In its obviousness analysis, the Federal Circuit stated that when the claimed properties differ from the prior art, those differences, if unexpected and significant, may lead to nonobviousness. In this case, the District Court noted some structural similarity between olanzapine and the prior art, but found olanzapine had unexpected beneficial properties. The Court also noted that Lilly
overcame any prima facie case of obviousness by proving extensive secondary considerations. The Federal Circuit affirmed the District Court’s determination that the evidence clearly established four of the five proffered secondary considerations. That is, Lilly had established (1) a long-felt and unmet need; (2) failure of others; (3) industry acclaim; and (4) unexpected results. The record showed a long-felt need for a safer, less toxic, and more effective clozapine-like drug; a decade (or more) of failure to find a replacement for clozapine; a reasonable amount of commercial success for olanzapine; and a number of awards for olanzapine as indicators of industry acclaim.


1) Go Medical Industries PTY, LTD v. Inmed Corporation, Nos. 05-1241, 05-1267, 05-1588 (Fed. Cir. 2006)

The invention at issue is directed to urinary catheters comprising a sheath with a stop member that does not extend beyond the natural pressure barrier in the urethra (i.e., about 1.5 cm). Most bacteria in the urethra are concentrated in the first 1.5-2.0 cm. Thus, the invention reduces the risk of urinary tract infections encountered with the use of prior art catheters. The Federal Circuit affirmed the District Court’s finding that the asserted claims were invalid as anticipated because Go was not entitled to claim the priority date of an earlier application since it failed to meet the best mode requirement of 35 U.S.C. § 112, ¶ 1. The inventor, Dr. O’Neil had admitted during his deposition that at the time he filed the parent patent application, he had already made sample catheters where the distance from the stop member to the distal end of the sheath was 1.5 cm. He further characterized it as the preferred embodiment at that stage. The continuation-in-part application on which the appealed patent was based described this distance as crucial to preventing bacteria from being pushed into the bladder by the catheter or by the sheath itself. The Federal Circuit held that the District Court correctly concluded that Dr. O’Neil possessed a best mode—i.e., a sheath length of 1.5 cm which was not disclosed in the priority document. The Federal Circuit also concluded that the District Court misapplied the Lear v. Adkins doctrine in reducing the damages for MMG’s breach of contract.

2) Monsanto Co. v. Scruggs, 459 F.3d 1328 (Fed. Cir. 2006)

Monsanto filed suit for infringement of its patent directed, inter alia, to a synthetic gene consisting of a cauliflower mosaic virus (“CaMV”) promoter, a protein sequence of interest, and a stop signal which creates herbicide (Roundup) resistance in a plant. Scruggs argued patent invalidity to the District Court as a defense to infringement and asserted that the patents-in-suit failed to provide an adequate written description of the invention because the specification did not disclose the specific DNA sequence of the CaMV promoter. The Federal Circuit affirmed the District Court’s finding that disclosure of a specific DNA sequence was unnecessary because the DNA sequence of several CaMV promoters were already known to those skilled in the art. Given the knowledge in the art, the Federal Circuit held the written description requirement was satisfied. The District Court had also issued a preliminary injunction, prohibiting Scruggs from further selling and using seeds containing Monsanto’s patented biotechnology. Scruggs answered with federal and state antitrust claims and patent misuse affirmative defenses. Specifically, Scruggs asserted that Monsanto violated the Sherman Act, 15 U.S.C. §§ 1-2, by
tying the purchase of seed to the purchase of Roundup through grower license agreements, grower incentive agreements, and seed partner license agreements, as well as by tying the Roundup and Bollgard traits in cotton seeds. The Federal Circuit affirmed the District Court’s decision of infringement and the lack of antitrust or patent misuse.

3)  

_Pfizer, Inc. v. Ranbaxy Laboratories, Ltd., No. 06-1179 (Fed. Cir. 2006)_

Pfizer Inc. alleged that the product described in Ranbaxy’s ANDA infringed U.S. Patent Nos. 4,681,893 and 5,273,995 under 35 U.S.C. § 271(e)(2). Pfizer’s patents in suit are directed to the prescription drug Lipitor®, which is used to reduce low-density lipoprotein (LDL) cholesterol levels.

The Federal Circuit agreed with the District Court’s claim construction of claim 1 of the ‘893 patent that it was limited to the enantiomeric trans-forms of the compounds set forth in Figure 1, and affirmed the finding of infringement. Because Ranbaxy’s arguments with respect to patent term extension were based on their proffered claim construction, the Federal Circuit also affirmed the ruling that the extension was not invalid.

However, with respect to the ‘995 patent, the Federal Circuit reversed on the question of invalidity under 35 USC § 112, ¶ 4. Pfizer had only asserted dependent claim 6 of the ‘995 patent against Ranbaxy, which read: “The hemicalcium salt of the compound of claim 2.” Claim 2 was dependent on claim 1, which recited the following compounds: (1) atorvastatin acid; (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts thereof. Claim 2, however, only recited atorvastatin acid. Claim 2 did not include the pharmaceutically acceptable salts of atorvastatin acid. The District Court explicitly recognized that “there may be a technical problem in the drafting of claim 6.” However, the Court declined to find that this drafting problem rendered the claim invalid because it would have been understood by those skilled in the art. Moreover, the District Court was unable to find any Federal Circuit precedent applying 35 USC § 112, ¶ 4 to invalidate a patent. In its reversal, the Federal Circuit stated that the claim failed to satisfy a statutory requirement, and reversed, holding the claim invalid.

4)  

_Energizer v. ITC, 435 F.3d 1366 (Fed. Cir. 2006)_

The Energizer patent is directed to an electrolytic alkaline battery cell that is substantially mercury free. The Federal Circuit reversed the ITC’s holding of invalidity of the claims for failure to comply with 35 U.S.C. §112, ¶ 2. According to the ITC, the claims were indefinite under 35 U.S.C. §112, ¶ 2, on the ground that the phrase “said zinc anode” lacked antecedent basis in the claim, and that the claims were unclear or ambiguous. However, the Federal Circuit held that antecedent basis can be present by implication since the scope of the claim could be ascertained by those skilled in the art.

**E. INFRINGEMENT**

1)  

_Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc., No. 06-1074 (Fed. Cir. 2006)_

Ventana owned patents related to automated methods and apparatuses for staining microscope slides. The claims in dispute were to methods of dispensing reagents onto a slide.
The sole issue on appeal was the proper construction of the claim term “dispensing.” The District Court construed the “dispensing” claim limitation to require “direct dispensing.” However, the Federal Circuit agreed with Ventana that there was nothing in the record to suggest that a person of ordinary skill in the art would interpret the disclosure and claims of the ‘861 patent to mean that the term “dispensing” is limited to “direct dispensing.” The Federal Circuit vacated the District Court’s judgment of noninfringement and remanded for further proceedings. Judge Lourie dissented noting that in a related grandparent application, in order to overcome an examiner’s rejection, Ventana argued that the prior art lacked the “present invention’s novel capability to dispense reagent ‘directly to a sample’” and that the “apparatus of the present invention” uses a reagent carousel and reagent container supports, “which minimize the time required to apply a given reagent, and the time between the application of multiple reagents, by dispensing reagent ‘directly to a sample.’”

2) **DSU Medical Corporation, et al. v. JMS Co., LTD, et al., Nos. 04-1620, 05-1058, 05-1052 (Fed. Cir. 2006)**

DSU’s patents claimed a guarded, winged-needle assembly which reduced the risk of accidental needle-stick injuries. The needle would remain retracted within a needle guard until it was used. Judge Rader wrote the opinion for the Court. Uncharacteristic of opinions of the Court, Section III B was an *en banc* decision while the remaining sections were decided by a three member panel. The *en banc* issue involved active inducement of infringement. Under 35 U.S.C. §271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” The statute does not define whether the purported infringer must intend to induce the infringement or whether the purported infringer must merely intend to engage in the acts that induce the infringement regardless of whether it knows it is causing another to infringe. DSU complained that the jury instruction was incorrect because it required that the inducer possess specific intent to encourage another’s infringement, and not merely that the inducer had knowledge of the acts alleged to constitute infringement. The Court held *en banc* that inducement requires evidence of culpable conduct, directed to encouraging another’s infringement, not merely that the inducer had knowledge of the direct infringer’s activities. Accordingly, the decision of the District Court was affirmed.

3) **AERO Products International, Inc., et al. v. INTEX Recreation Corp., et al., No. 05-1283 (Fed. Cir. 2006)**

AERO Products alleged both trademark and patent infringement related to its patented inflatable support systems (i.e., air mattresses). Aero’s argument for patent and trademark damages was based solely on sales of the accused Intex mattresses. The jury awarded Aero $2.95 million dollars for the patent infringement—presumably a reasonable royalty as Aero requested—and $1 million in Intex’s profits for the trademark infringement. However, the Federal Circuit concluded under the circumstances of this case, the award of both patent infringement and trademark infringement damages in favor of Aero represented an impermissible double recovery and vacated the award of the trademark damages.
4)  

**Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209 (Fed. Cir. 2006)**

Liquid Dynamic’s patent related to methods and an apparatus for handling wastewater slurries. A jury had found that Vaughan had willfully infringed Liquid Dynamic’s patent based on evidence of copying of the claimed invention. Vaughan attempted to show that it had not willfully infringed the patent because it had in good faith relied upon a non-infringement opinion from its attorney. The issue in the case was whether important information regarding the invention was concealed from Vaughn’s attorney, who had provided the opinion of counsel. The Federal Circuit affirmed the District Court’s finding of willful infringement even though an opinion of counsel was obtained. The Court reiterated the factors which should be used when determining whether an infringer has acted in bad faith and whether damages should be increased. They include: (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer, when he knew of the other’s patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed; (3) the infringer’s behavior as a party to the litigation; (4) defendant’s size and financial condition; (5) closeness of the case; (6) duration of defendant’s misconduct; (7) remedial action by the defendant; (8) defendant’s motivation for harm; and (9) whether defendant attempted to conceal its misconduct. In view of the facts presented to the jury, the Federal Circuit upheld the jury’s finding of copying. The Federal Circuit also agreed with the District Court that the jury could discount the opinion of counsel because the jury found concealment of evidence from the attorney who prepared the opinion.

5)  


The claims at issue in *Wilson Sporting Goods* did not involve a chemical or biological invention, but rather, a baseball bat. The case is significant in that the Federal Circuit provided general advice regarding how to construe claims in the context of infringement. The Federal Circuit reiterated that it reviews de novo a District Court’s determination that there is no genuine issue as to any material fact regarding infringement. The Federal Circuit noted that in reviewing claim construction in the context of infringement, the legal function of giving meaning to claim terms always takes place in the context of a specific accused infringing device or process. The Court stated that while a District Court should certainly not prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction.

However, the Federal Circuit repeated its rule that claims may not be construed with reference to the accused device. That rule posits that a Court may not use the accused product or process as a form of extrinsic evidence to supply limitations for patent claim language. Thus, the rule forbids a Court from tailoring a claim construction to fit the dimensions of the accused product or process and to reach a preconceived judgment of infringement or noninfringement. In other words, it forbids biasing the claim construction process to exclude or include specific features of the accused product or process. The rule, however, does not forbid awareness of the accused product or process to supply the parameters and scope of the infringement analysis, including its claim construction component. Stated otherwise, the rule does not forbid any glimpse of the accused product or process during or before claim construction. In light of these
principles, the Federal Circuit noted, if the litigants cannot themselves inform the District Court of the specific issues presented by the infringement inquiry—that is, issues of the breadth of the claim construction analysis and the most useful terms to facilitate that defining process—then the District Court may refer to the accused product or process for that context during the process. The Federal Circuit remanded the case for further claim construction in accordance with the guidance given.

F. INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

1) *Abraxis Bioscience, Inc. v. Mayne Pharmaceutical Products, Inc.*, No. 06-1118 (Fed. Cir. 2006)

In November 1989, AstraZeneca (now known as Abraxis Bioscience) launched in the United States an original pharmaceutical composition used to induce and maintain general anesthesia and sedation in patients. The product was marketed and sold under the trade name DIPRIVAN® for treatment in humans. In 1990, AstraZeneca became aware that patients using DIPRIVAN® were increasingly suffering from post-operative infections. The inventors of the patents in suit recommended the use of preservatives in DIPRIVAN®. The inventors ultimately discovered that one preservative in particular, disodium edetate (EDTA), was unexpectedly effective in retarding microbial growth in the propofol formulation without disrupting the oil-in-water emulsion for at least twenty-four hours. In March 1995, the inventors applied for a patent on their improved DIPRIVAN® formulation. The issue in the case was whether the use by Mayne of DTPA (the calcium trisodium salt of diethylenetriaminepentaacetic acid (pentetate)), a compound structurally similar to edetate (EDTA) in its formulation of the drug, infringed the Abraxis patent claims. Only one term, “edetate,” was at issue in the appeal. This term was construed by the District Court as “EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized.” The Federal Circuit agreed with the District Court’s factual findings that only insubstantial differences existed between calcium trisodium DTPA and edetate. The Federal Circuit noted that the District Court correctly determined that calcium trisodium DTPA performs substantially the same function in substantially the same way to achieve the same result as the edetate (EDTA). Thus, the Federal Circuit affirmed the District Court’s finding of infringement under the doctrine of equivalents.

2) *Cook Biotech v. Acell*, 460 F.3d 1365 (Fed. Cir. 2006)

Cook Biotech’s licensed patent was directed to a urinary bladder submucosa derived tissue graft composition that can be implanted to replace or support damaged or diseased tissues. The claims at issue were drawn to a composition comprising urinary bladder submucosa, and such submucosa must have been delaminated from “the luminal portion of the tunica mucosa.” The issue was whether the accused product which contains some or all of “the luminal portion of the tunica mucosa” can infringe under the doctrine of equivalents. The appellees argued that the evidence supported the theory that compositions that include lamina propria and submucosa are equivalent to compositions that consist essentially of submucosa because the two compositions perform the same function, in the same way, to achieve the same result. The Federal Circuit concluded that applying appellees’ theory of equivalence with respect to asserted claims would violate a corollary to the all limitations rule that the concept of equivalency cannot embrace a
structure that is specifically excluded from the scope of the claims. The Federal Circuit held that a claim that specifically excludes an element cannot through a theory of equivalence be used to capture a composition that contains that expressly excluded element without violating the all limitations rule. Thus, the Federal Circuit reversed the District Court’s finding of infringement under the doctrine of equivalents.

3)  

**Conoco Inc. v. Energy & Environmental International LC, 460 F.3d 1349 (Fed. Cir. 2006)**

Conoco’s patents in suit encompass processes for making drag reducing agents (“DRA”) that are injected into oil and gas pipelines to reduce friction inherent in pumping operations. By reducing friction, a supplier is able to pump more liquid more efficiently. The active ingredients in DRAs are high molecular weight polymers. The claimed invention in the ‘151 patent is a method of reducing turbulent drag in a hydrocarbon liquid stream using polymer particles suspended in alcohols and/or glycols using a fatty acid wax partitioning agent to provide a stable, nonagglomerating suspension. EEI’s alleged infringing process used C30+ wax as the partitioning agent. C30+ wax is not a “fatty acid wax” or stearamide as defined by the patent, but rather is a straight hydrocarbon wax. Conoco argued that C30+ was an equivalent of a fatty acid wax. EEI argued that Conoco was estopped from alleging doctrine-of-equivalents infringement because the inventors argued during prosecution that “fatty acid wax” applied to stearamides and the like, therefore excluding all other equivalent compounds. The District Court stated that Conoco was not estopped because although the fatty acid wax limitation was present throughout prosecution, the limitation was not amended for reasons related to patentability, and during prosecution Conoco only surrendered application of the limitation to metal stearates, not hydrocarbon waxes. Furthermore, even if there had been a narrowing of the claims, the District Court held that Conoco could rebut any estoppel presumption because the evidence indicated that the use of C30+ wax was unforeseeable and only tangentially related to the metal stearate disclaimer. The Federal Circuit agreed with the District Court and affirmed the District Court’s finding of infringement under the doctrine of equivalents.

4)  

**Bicon v. Straumann Co., 441 F.3d 945 (Fed. Cir. 2006)**

Bicon’s licensed patent claimed an apparatus used with dental implants. The Federal Circuit affirmed the District Court’s grant of summary judgment of noninfringement both literally and under the doctrine of equivalents. The Federal Circuit held that the District Court correctly rejected Bicon’s theory that the trumpet-shaped surface of the neck of Straumann’s root member dental implant, which Bicon characterized as concave, was equivalent to a convex surface. The Federal Circuit noted that a claim that contained a detailed recitation of structure was properly accorded correspondingly limited recourse to the doctrine of equivalents. By defining the claim in a way that clearly excluded certain subject matter, the patent implicitly disclaimed the subject matter that was excluded and thereby barred the patentee from asserting infringement under the doctrine of equivalents.
G. INEQUITABLE CONDUCT


Kemin’s patents in suit pertained to purified lutein which is extracted from plants and used as a dietary supplement. The defendant, Pigmentos Vegetales del Centro S.A. de C.V. (PIVEG), argued that the patents were invalid based upon the inequitable conduct of Kemin’s president, Dr. Nelson. PIVEG asserted that Dr. Nelson knew of a highly material Poultry Science article which he intentionally did not disclose to the USPTO. The District Court found that the Poultry Science article did not render the patent invalid and that the evidence of record suggested that the method disclosed in the Poultry Science article may not have worked as intended. The Federal Circuit commented that the fact that the article was not enabled did not by itself render the article immaterial. However, the Federal Circuit agreed with the District Court’s holding that while the Poultry Science article was material, it was not “highly” material. With regards to intent, the District Court found that Dr. Nelson was only tangentially involved in prosecution of Kemin’s patent and that more than two years had passed between the time Dr. Nelson experimented with the method of the Poultry Science article and the time of the prosecution. The District Court reasoned that because those facts could reasonably be viewed as mitigating against a finding of deceptive intent, they found that PIVEG did not make a strong showing of intent to deceive the PTO. The Federal Circuit affirmed the District Court’s finding of no inequitable conduct since it agreed that the prior art was not highly material and the showing of deceptive intent was not compelling.

2) Atofina v. Great Lakes Chemical Corporation, 441 F.3d 991 (Fed. Cir. 2006)

In addition to the anticipation issue in Atofina discussed supra, the issue of inequitable conduct was also raised. Great Lakes argued and the District Court agreed that the failure of Atofina to disclose the full length translation of a Japanese patent, which it had in its possession, to the USPTO and which was highly material because it anticipated the invention, rendered Atofina’s patent invalid. The District Court found intent to deceive the USPTO based on Atofina’s misrepresentation of the Japanese patent disclosure. The Federal Circuit majority reversed, finding that a Derwent abstract of the prior art patent was disclosed to the USPTO and that “there was no real difference between the disclosed Derwent Abstract and the undisclosed full English translation of [the Japanese patent] in this context.”

3) Kao Corp. v. Unilever US, Inc., 441 F.3d 963 (Fed. Cir. 2006)

Kao involved a dispute over Kao’s patent to a cosmetic skin-care product used to remove blackheads from facial skin. Unilever produces the allegedly infringing product, Pond’s Clear Pore Strips. During prosecution, Kao submitted a declaration with evidence of effectiveness. However, the District Court found that the declaration only disclosed the most positive data available. In depositions, the inventors were unable to offer any explanation for their failure to report all the results in the declaration. Unilever argued that Kao’s failure to report the full results of its testing constituted inequitable conduct that rendered the entire patent unenforceable.
However, the District Court disagreed, finding that although the omission was “material,” it was not made with intent to deceive since it was eventually provided to the Examiner. The Federal Circuit refused to second guess the District Court’s finding of no inequitable conduct. The Federal Circuit agreed that since the data was ultimately presented to the examiner, there was no intent to deceive.

4) **Ferring B.V. v. Barr Laboratories, Inc., 437 F.3d 1181 (Fed. Cir. 2006)**

Ferring’s patent claimed an antidiuretic composition comprising a gastrointestinally absorbable antidiuretic peptide, 1-deamino-8-D-arginine vasopressin. During prosecution of the patent application, Ferring had an interview with the Examiner during which the Examiner suggested that the applicants “obtain evidence from a non-inventor” to support their interpretation of the prior art. Declarations were submitted by experts who had been employed or had received research funds from Ferring. However, the Examiner was not made aware of the connections to Ferring. The Federal Circuit affirmed the District Court’s grant of summary judgment on the ground that the patent in suit was unenforceable due to inequitable conduct. The Federal Circuit reiterated that a declarant’s past relationships with the applicant are material if (1) the declarant’s views on the underlying issue are material; and (2) the past relationship to the applicant was a significant one. The Federal Circuit stated that when an inventor is asked to provide supportive declarations to the USPTO, it may be completely natural for the inventor to recommend, and even contact, his own colleagues or people who are, or who have been, affiliated with his employer and to submit declarations from such people. “Nothing in this opinion should be read as discouraging such practice. Rather, at least where the objectivity of the declarant is an issue in the prosecution, the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations.”

5) **Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc., 438 F.3d 1123 (Fed. Cir. 2006)**

Purdue alleged that Endo’s proposed generic versions of OxyContin®, Purdue’s controlled release oxycodone product, would infringe three Purdue patents. During prosecution, Purdue made repeated statements to the USPTO that it had discovered an oxycodone formulation for controlling pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids. Because Purdue did not inform the PTO that the “discovery” was based on “insight” without “scientific proof,” the District Court held that Purdue failed to disclose material information to the USPTO. The Court also found that the record as a whole reflected a “clear pattern of intentional misrepresentation.” Although the Federal Circuit affirmed the Court’s finding that Purdue’s actions met a threshold level of materiality, they stressed that the level of materiality was not especially high since “Purdue did not expressly misrepresent to the PTO that it had obtained experimental results establishing a four-fold dosage range for oxycodone, an act that likely would have been highly material.” The Federal Circuit vacated the inequitable conduct judgment and remanded to give the District Court an opportunity to reconsider its intent finding in view of the Federal Circuit’s determination that the level of materiality was not especially high.
H. INTERFERENCE PRACTICE

1) **Regents of the University of California v. University of Iowa Research Foundation**, 455 F.3d 1371 (Fed. Cir. 2006)

   The subject matter at issue was directed to immunostimulatory nucleic acid compositions and their use to minimize allergic reactions. The Federal Circuit affirmed the USPTO Board of Patent Appeals and Interferences grant of Iowa’s motion for judgment that 35 U.S.C. § 135(b)(1) barred the University of California’s sole claim interfering with Iowa’s U.S. Patent No. 6,207,646 (the ‘646 patent). Section 135(b)(1) states that a “claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.” The Federal Circuit stated that when a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for section 135(b)(1), the party must show that there is no material difference between the new claim and claims that were filed before the critical date. The Court concluded that the University of California’s position was that any claim filed within the critical time period supports, for section 135(b)(1) purposes, any later added claims, regardless of the relationship between the pre- and post-critical date claims. The Court found that the University of California’s position was not consistent with the language of the statute.

2) **Medichem v. Rolabo**, 437 F.3d 1157 (Fed. Cir. 2006)

   This interference involved two patents directed to methods of making loratadin, the active ingredient in Claritin®. The Federal Circuit reversed the District Court’s award of priority of invention to Medichem, based on the insufficiency of the evidence that Medichem introduced at trial to corroborate the testimony of its inventors regarding reduction to practice of the invention. The issue on appeal was whether Medichem provided adequate corroboration of the inventors’ testimony regarding the alleged actual reduction to practice. The Federal Circuit held that “[w]here a laboratory notebook authored by a non-inventor is offered into evidence pursuant to authentication by an inventor, where the author of the notebook has not testified at trial or otherwise attested to its authenticity, and where the notebook has not been signed or witnessed and has not been maintained in reasonable accordance with good laboratory practices sufficient to reasonably ensure its genuineness under the circumstances, then the corroborative value of the notebook is minimal.”

3) **Brown v. Barbacid**, 436 F.3d 1376 (Fed. Cir. 2006)

   In Brown, the Federal Circuit held that the USPTO Board of Patent Appeals and Interferences erred as a matter of law, in failing to view the proffered evidence for a priority of invention determination as it would be viewed by persons experienced in the field of the invention. At issue was an invention directed to an assay for identifying compounds that inhibit farnesyl transferase, an enzyme involved in the control of cell growth. The Federal Circuit acknowledged that the evidence in this case, a laboratory notebook recording daily experimentation and an accompanying declaration explaining the recorded data, must reasonably
be considered from the viewpoint of persons experienced in the field of the invention and need not reproduce on each page a statement of the larger research purpose.

### I. REISSUE PRACTICE

1)  *Kim v. Conagra Foods*, 465 F.3d 1312 (Fed. Cir. 2006)

Yoon Ja Kim is the holder of reissued U.S. Patent No. Re. 36,355. This reissued U.S. patent claims an oxidizer used for breadmaking. In the 1990’s, there was concern that potassium bromate, the generally used oxidizer in bread, was carcinogenic. Kim, a food chemist, believed that a combination of ascorbic acid and food acid would serve as a suitable alternative to potassium bromate in the breadmaking process, and applied for a patent on that composition. After the patent issued, Kim applied for a reissued patent containing amended claims which would now include ascorbic acid and food acid in different ranges than previously claimed and would now cover an oxidizer without phosphate. Kim sued ConAgra for infringement of the reissued patent. ConAgra argued that the asserted claims of the reissued patent were invalid because they improperly recaptured material that Kim surrendered during prosecution of her original patent. The recapture rule prevents a patentee from regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims. ConAgra contended that Kim added phosphate to all of the claims in the application in order to overcome a rejection based on prior art references and thus, could not remove the claim in the reissued patent. However, like the District Court, the Federal Circuit was not persuaded by ConAgra’s arguments since the prosecution history did not indicate that Kim added the phosphate limitation in order to overcome the obviousness rejection. With respect to change to the food acid range, ConAgra argued that Kim surrendered a lower limit for her food acid range when she changed the range from 0.03-0.2 parts by weight of flour in the dough in her original application to 0.02-0.15 parts per 100 parts of flour in her continuation-in-part application. However, here too, the Federal Circuit agreed with the District Court that it could not be inferred that Kim’s choice of 0.020 instead of 0.015 was because Kim was surrendering the difference between the two out of fear 0.015 would be found to be obvious while 0.020 would not. The Federal Circuit held that in determining whether surrender of subject matter has occurred, the proper inquiry is whether an objective observer viewing the prosecution history would conclude that the purpose of the patentee’s amendment or argument was to overcome prior art and secure the patent. If the objective public observer can discern a surrender of subject matter during the prosecution of an original patent in order to overcome prior art and obtain the patent, then the recapture rule should prevent the reissuing of that patent to claim the surrendered subject matter. Here, the Federal Circuit affirmed the District Court’s finding of validity of the claims.

### J. PRELIMINARY INJUNCTIONS

1)  *Sanofi-Synthelabo v. Apotex, Inc.*, Case No. 06-1613 (Fed. Cir. 2006).

Sanofi markets Plavix®, a platelet aggregation inhibiting agent used to reduce thrombotic events such as heart attacks and strokes. The active ingredient in Plavix® is clopidogrel bisulfate, which is covered by a patent owned by Sanofi. Apotex filed an ANDA pursuant to the Hatch-Waxman Act seeking FDA approval to manufacture and sell a generic version of
clopidogrel bisulfate. Sanofi sued Apotex claiming that the filing of the ANDA infringed Sanofi’s patent. Sanofi filed a motion for a preliminary injunction which was granted by the District Court and affirmed by the Federal Circuit. The Federal Circuit explained that Sanofi, as the moving party, was entitled to a preliminary injunction since it had established four factors: “(1) a reasonable likelihood of its success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction’s impact on the public interest. Each of these factors was discussed in detail. Regarding the likelihood of success on the merits, the Court noted that Apotex conceded that its accused products infringed claim 3 of Sanofi’s patent. The Court then found that Apotex failed to establish a likelihood of proving invalidity at trial—rejecting its anticipation, obviousness, and obviousness-type double patenting invalidity defenses. Additionally, the Federal Circuit found that the remaining three factors of the test favored issuance of a preliminary injunction.

2) Abbott Labs. v. Andrx Pharmaceuticals and Teva Pharmaceuticals, 452 F.3d 1331 (Fed. Cir. 2006)

Abbott Laboratories brought suit against Teva Pharmaceuticals alleging infringement of its patents relating to extended release formulations of clarithromycin and moved for a preliminary injunction against Teva. Teva argued that substantial questions existed as to the validity of Abbott’s asserted claims under 35 U.S.C. § 103. Although the District Court granted Abbott’s motion for a preliminary injunction, the Federal Circuit vacated. The Court stated that as the moving party, Abbott had to establish a likelihood of success on the merits of the underlying litigation. However, since Teva raised a substantial question of validity with each of the asserted claims, for purposes of the preliminary injunction, Abbott as the moving party did not establish a likelihood of success on the merits. Judge Newman, in dissent, wrote “the panel majority holds that if the attacker raises no more than a ‘substantial question’ of invalidity, that suffices to establish the likelihood that the attacker will succeed on the merits. That is incorrect in law and in procedure.” Instead, she argued: “[t]o support a change in the status quo before the merits are decided, it must be shown to be likely that the patent will be held invalid under the presumptions and burdens in effect at trial.”

K. PERMANENT INJUNCTIONS


In eBay, perhaps the most important patent case of 2006, MercExchange had obtained patents claiming methods of doing business on the internet and filed a patent infringement suit against eBay. A jury found that MercExchange’s patent was valid, that eBay had infringed, and that an award of damages was appropriate. Following the jury verdict, the District Court denied MercExchange’s motion for permanent injunctive relief. The Federal Circuit reversed, applying its “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.” The Supreme Court granted certiorari to determine the appropriateness of this general rule.

The U.S. Supreme Court in eBay vacated the Federal Circuit judgment holding that a plaintiff seeking a permanent injunction must satisfy a four-factor test before a Court may grant such relief. Specifically, a plaintiff must demonstrate: (1) that it has suffered an irreparable
injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. Justice Thomas, authoring the opinion for the Court, wrote that the decision of whether to grant or deny injunctive relief rests within the equitable discretion of the District Courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.

L. ATTORNEY CLIENT PRIVILEGE / WORK PRODUCT IMMUNITY

1) *In re EchoStar Communications Corp.*, 448 F.3d 1294 (Fed. Cir. 2006)

TiVo sued EchoStar for infringement of its U.S. patent which related to the time shifting of television broadcast signals. This case is of general significance in regards to the law of attorney/client privilege and work product immunity. In response to the allegation of willful infringement, EchoStar asserted the defense of reliance on advice of counsel. Prior to the filing of the action, EchoStar relied on advice of in-house counsel. After the action was filed, EchoStar obtained additional legal advice from Merchant & Gould, but elected not to rely on it. Presumably to explore further EchoStar’s state of mind in determining that it did not infringe the patent, TiVo sought production of documents in the possession of EchoStar and Merchant & Gould. The District Court held that by relying on advice of in-house counsel EchoStar waived its attorney-client privilege and attorney work-product immunity relating to advice of any counsel regarding infringement, including Merchant & Gould. The District Court indicated that the scope of the waiver included communications made either before or after the filing of the complaint and any work product, whether or not the product was communicated to EchoStar. The District Court also held that EchoStar could redact information related only to trial preparation or information unrelated to infringement.

On appeal, the Federal Circuit directed the District Court to vacate its order that EchoStar produce certain documents from its outside counsel, Merchant & Gould. The Court held that Merchant & Gould’s work product which was not communicated to EchoStar or did not reflect a communication is not within the scope of EchoStar’s waiver because it obviously played no part in EchoStar’s belief as to infringement of the patent. The Federal Circuit stated the advice-of-counsel defense to willfulness requires the Court to decide whether counsel’s opinion was thorough enough to instill a belief in the infringer that a Court might reasonably hold the patent is invalid, not infringed, or unenforceable. If a Merchant & Gould document was not communicated to EchoStar or if a Merchant & Gould document did not reference a communication between Merchant & Gould and EchoStar, the documents relevant value is outweighed by the policies of the work-product doctrine.

M. SOVEREIGN IMMUNITY

1) *Tegic Communications v. Bd. of Regents of the University of Texas System*, 458 F.3d 1335 (Fed. Cir. 2006)

The University of Texas’s involved patent was directed to a method of inputting text into a device keyboard, wherein the device software recognizes the text and predicts the word the
user intends to type. Tegic, a corporation of the State of Washington, sells and licenses text-
input software, entitled “T9 Text Input.” The University of Texas sued 48 cellular-phone
company in Texas of which 39 were customers of Tegic. In view of the suit that the University
had filed in Texas against Tegic’s customers and licensees, Tegic brought this declaratory suit
against the University in the U.S. District Court for the Western District of Washington. Tegic
sought a declaration that the University’s patent was invalid and unenforceable, and that the T9
software did not infringe, contribute to infringement, or induce infringement of the patent. Tegic
states that the University’s action in Texas, ostensibly directed against the cellular-phone
manufacturers, was actually directed against Tegic as the manufacturer and licensor of the
software infringed the University’s patent.

The issue in Tegic was whether the state had sovereign immunity and whether that
immunity has been waived. The University stressed that Tegic brought a new action, by a new
party, in a new forum and therefore the University was immune. The Federal Circuit affirmed
the District Court’s decision to dismiss this declaratory judgment action against the Board of
Regents of the University of Texas System on the ground that the suit was barred by the
Eleventh Amendment to the United States Constitution. The Federal Circuit agreed with the
University that its filing of the Texas action did not establish waiver as to this separate action.

2) Pennington Seed, Inc. et al. v. Produce Exchange No. 299, et al., 457 F.3d 1334 (Fed. Cir. 2006)

Pennington Seed is the licensee of a patent which claims a type of non-toxic fescue grass
that does not adversely affect livestock that graze upon it. Pennington alleged in its original
complaint and first amended complaint that the University of Arkansas and four University
Officials, respectively, were actively growing, marketing, offering for sale, promoting and
selling a product containing Pennington’s patented product.

Although the Eleventh Amendment to the U.S. Constitution limits the judicial authority
of the Federal Courts and prevents citizens from bringing suit against a state in a Federal Court
without its consent, the infringement of a patent by a state may be actionable in Federal Courts
“where the State provides no remedy, or only inadequate remedies, to injured patent owners for
its infringement of their patent.”

Pennington argued that the University and the University Officials are subject to suit
under the Eleventh Amendment because “the State of Arkansas provides no adequate remedies
to patent infringement.” Although the District Court found that there was no state forum in
which to contest patent infringement claims, it did not find that other available remedies pursuant
to state law were so insufficient that they violated the U.S. Constitution. Thus, the District Court
dismissed both the original complaint and the First Amended Complaint based on Eleventh
Amendment immunity. The Federal Circuit affirmed.

3) Intel Corp v. CSIRO, 455 F.3d 1364 (Fed. Cir. 2006)

Defendant-appellant CSIRO, Australia’s national science agency, is the assignee of
United States Patent No. 5,487,069, directed to wireless local area networks. CSIRO asserts that
the patent covers certain Institute of Electrical and Electronics Engineers (“IEEE”) standards for
high speed data transfer. Following CSIRO’s attempts to license the ‘069 patent to various
American companies, declaratory-judgment actions were filed by Intel and others.
Pursuant to the Foreign Sovereign Immunities Act ("FSIA"), a foreign state is presumptively immune from the jurisdiction of United States Courts. Unless a specified exception applies, a Federal Court lacks subject-matter jurisdiction over a claim against a foreign state. 28 U.S.C. § 1605(a)(2) provides that a foreign state shall not be immune from the jurisdiction of Courts of the United States or of the States in any case in which the action is based upon a commercial activity carried on in the United States by the foreign state.

Here, the Federal Circuit affirmed the District Court’s denial of a motion to dismiss based on lack of subject-matter jurisdiction. The Federal Circuit agreed that CSIRO is not entitled to claim immunity under the Foreign Sovereign Immunities Act ("FSIA"), 28 U.S.C. §§ 1602-1611, because the “commercial activity” exception applied. CSIRO argued that patent licensing negotiations that do not result in a fully-executed, binding contract do not qualify as “commercial activity.” It conceded that if its negotiations with potential licensees had been successful, (i.e., if the proffered license agreement had been signed), it would not be entitled to claim immunity under the FSIA because the commercial activity exception would apply. However, the Federal Circuit held that CSIRO’s acts of (1) obtaining a United States patent and then (2) enforcing its patent so it could reap the profits thereof - whether by threatening litigation or by proffering licenses to putative infringers - fell within the powers that could be exercised by private citizens and thus, fell within the exception to immunity.