

## ADDITIONAL DEVELOPMENTS— PATENT LAW

### *PROVERIS SCIENTIFIC CORP. V. INNOVASYSTEMS, INC.*

*536 F.3d 1256 (Fed. Cir. 2008)*

The United States Court of Appeals for the Federal Circuit held that the manufacture, marketing, or sale of a device used in the development of Food and Drug Administration (FDA) regulatory submissions, but not itself subject to FDA pre-market approval, is not immune from patent infringement under the “safe harbor” provision of the Hatch-Waxman Act. The court also affirmed the district court’s findings of patent infringement and validity as a matter of law.

Proveris Scientific Corp. (Proveris) held U.S. Patent No. 6,785,400 (the ’400 patent), which claimed an apparatus for measuring the properties of aerosol sprays widely used in drug delivery devices, such as inhalers or nasal spray pumps. Innovasystems, Inc. (Innova) manufactured a device that analyzed aerosol sprays by optical methods, and Proveris sued Innova for infringement of the ’400 patent. In its defense, Innova argued that because third parties used its device to obtain data for FDA submissions, Innova was therefore protected from infringement claims under the 35 U.S.C. § 271(e)(1) Hatch-Waxman safe harbor provision. Innova also claimed that the Proveris patent was invalid. The district court disagreed, ruling as a matter of law that (1) the ’400 patent was valid, (2) Innova infringed, and (3) the safe harbor did not immunize Innova’s activities from patent infringement suits.

Innova appealed to the Federal Circuit. The section 271(e)(1) safe harbor provides that:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The court explained that Congress intended section 271(e)(1) to correct the “de facto extension” of a patent term that necessarily occurs when a patentee’s competitors cannot even begin the often lengthy

regulatory approval process until the patent term expires. Section 156(f) of the Hatch-Waxman Act corrects the “de facto reduction” of a patent term when the regulatory process delays the patentee’s product coming to market.

The Federal Circuit therefore reasoned that a “perfect ‘product’ fit” between these two provisions was necessary for a party to claim the safe harbor for use of the product. Because Innova’s device was not a product which required FDA pre-market approval under section 156(f), it did not constitute a “patented invention” under section 271(e)(1) and could not benefit from immunity.

Innova also failed to persuade the Federal Circuit to overturn the district court’s judgment of infringement and validity as a matter of law. Innova argued that Proveris had not met its burden of proof with respect to infringement, but the court pointed out that the plaintiff and Innova’s own witness had made statements during trial which Innova had not disputed, and held that Innova had therefore conceded infringement. The court also rejected Innova’s argument that the testimony of its expert with regard to validity of the patent had been improperly excluded, noting that the expert had not submitted a written report.

***IN RE TS TECH USA CORP.****551 F.3d 1315 (Fed. Cir. 2008)*

The District Court for the Eastern District of Texas has been one of the most popular courts for patent owners to file patent infringement suits, but the Federal Circuit's ruling in *TS Tech* may lead to a decrease in the number of patent cases that the Eastern District of Texas hears. The Federal Circuit held that the Eastern District of Texas erred when it denied defendant's motion to transfer venue to a more convenient district court. The Federal Circuit reached its decision by applying recent Fifth Circuit precedent from *In re: Volkswagen*.

The patent owner, Lear Corporation, filed suit against its competitor, TS Tech, in the Eastern District of Texas, alleging infringement of a patent relating to pivotally attached vehicle headrest assemblies. Lear asserted that TS Tech induced Honda Motor Co. to infringe the patent by selling headrest assemblies throughout the United States, including in the Eastern District of Texas. Lear was a Delaware corporation with its principal place of business in Southfield, Michigan. TS Tech's offices were incorporated and had principle places of business in Ohio and Ontario, Canada.

TS Tech filed a motion to transfer venue to Southern District of Ohio pursuant to 28 U.S.C § 1404(a), which gives the district-court judge discretion to transfer the civil action to another district for the convenience of parties and witnesses and in the interest of justice. Judge T. John Ward of the Eastern District of Texas denied the motion, and TS Tech subsequently filed a petition with the Federal Circuit for a writ of mandamus.

The Federal Circuit held that the district court clearly abused its discretion because it incorrectly applied the "public" and "private" factors for determining *forum non conveniens* when deciding a § 1404(a) venue transfer question. The Federal Circuit held that the district court incorrectly evaluated the recently established Fifth Circuit factorial test in several ways. First, the district court erred by giving too much weight to plaintiff's choice of venue. The Federal Circuit stated that the plaintiff's choice of venue was not a distinct factor in the analysis because the plaintiff's choice was already taken into account via the high burden of proof on the moving party. Second, the district court ignored the cost of attendance for witnesses. The Federal Circuit stated that all of the witnesses were in Ohio, Michigan, and Canada, and that traveling 900 miles to Texas weighed in favor of transferring. Third, the district court minimized the weight of the ease of access to sources of proof. The

Federal Circuit stated that the vast majority of physical evidence was located closer to the Ohio venue, and that factor therefore weighed in favor of transferring. Finally, the district court incorrectly held that the public interest factor disfavored transfer. The Federal Circuit reasoned that the citizens of the Eastern District of Texas had no more of a meaningful connection with the case than any other venue since the alleged infringement was national.

Accordingly, the Federal Circuit held that the Eastern District of Texas abused its discretion by denying the motion to transfer to the substantially more convenient forum of Ohio. However, whether this decision gives patent infringement defendants a better opportunity to get out of certain venues remains to be seen. It will most likely depend on whether the other circuits adopt the Fifth Circuit's factorial test, and whether other courts will follow the *TS Tech* calculus in situations where the convenience of venue issue presents a closer case.

***KYOCERA WIRELESS CORP. V. INTERNATIONAL  
TRADE COMMISSION***

*545 F.3d 1340 (Fed. Cir. 2008)*

The United States Court of Appeals for the Federal Circuit vacated a ban against Qualcomm and third-parties from importing all products containing cell phone chips infringing upon Broadcom's patents, on the basis that the United States International Trade Commission (ITC) lacked authority under the circumstances to issue a limited exclusion order that affected third parties.

The action began when Broadcom filed a complaint in the ITC against Qualcomm alleging unfair acts in violation of section 337 of the Tariff Act of 1930, alleging that Qualcomm's chipsets infringe several of Broadcom's patents. Although the ITC determined that Qualcomm's chips did not infringe two of Broadcom's patents, an issue subject to a separate appeal, the ITC found that after the chips were programmed with battery-saving software by third-party manufacturers, Qualcomm's chips infringed Broadcom's '983 patent. Furthermore, the ITC determined that Qualcomm was liable for inducing the third-party manufacturers, who were not respondents in Broadcom's complaint, to incorporate the battery-saving software and Qualcomm's chips into their mobile devices. Accordingly, the ITC issued a limited exclusion order prohibiting the importation of handheld wireless communications devices containing Qualcomm's chipsets that are programmed to enable the power-saving features covered by the '983 patent.

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Inducement requires the patentee to show "first that there has been a direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." The inducer must have more than just a general intent to cause the acts that produce direct infringement. It must have an affirmative intent to cause the direct infringement.

On appeal, the Federal Circuit found the ITC's finding of intent insufficient because the ITC applied the general intent standard, rather than a specific intent standard, when it determined that Qualcomm intended to induce infringement by providing its customers with the system determination code. In reaching this conclusion, the Federal Circuit concluded that Qualcomm's actions only showed that Qualcomm generally intended to cause acts that produced infringement. Accordingly,

the Federal Circuit remanded the case to the ITC to determine if Qualcomm's actions satisfied the specific intent requirement.

The Federal Circuit also determined that the ITC's limited exclusion order was inappropriate because it excluded imports of articles made by downstream manufacturers who were not named as respondents in Broadcom's initial complaint. Limited exclusion orders can only exclude articles manufactured by respondents. General exclusion orders can exclude articles manufactured by non-respondents, but the Federal Circuit found that Broadcom never attempted to prove the heightened requirements necessary to obtain a general exclusion order. A general exclusion order requires a showing of: (1) circumvention of an existing limited exclusion order, or (2) a pattern of unfair acts in import trade and a difficulty in identifying the source of infringing products. Accordingly, the Federal Circuit vacated the limited exclusion order because it affected non-respondents.

## PATENT MALPRACTICE AND FEDERAL JURISDICTION

In a pair of 2007 cases, the Federal Circuit expanded its federal subject matter jurisdiction to cover state malpractice claims that hinge on issues of patent law. In *Air Measurement Technologies, Inc. v. Akin Gump Strauss Hauer & Feld, L.L.P. (AMT)*, and *Immunocept, LLC v. Fulbright & Jaworski, LLP (Immunocept)*, the Federal Circuit reasoned that, because these malpractice claims would require the court to decide substantial issues of patent law, “arising under” jurisdiction was warranted under 28 U.S.C. § 1338. Two subsequent cases, however, have refused to find federal subject matter jurisdiction in malpractice cases. In *Eddings*, the Northern District of Texas distinguished the cases and found that a malpractice claim did not raise a substantial question of patent law. In *Singh*, the Fifth Circuit refused to follow the decisions in a trademark malpractice claim.

***AIR MEASUREMENT TECHNOLOGIES, INC. V. AKIN GUMP  
STRAUSS HAUER & FELD, L.L.P.***  
*504 F.3d 1262 (Fed. Cir. 2007)*

In *AMT*, the Federal Circuit evaluated a state malpractice claim involving the patent prosecution and subsequent litigation of a safety device for supplemental breathing apparatuses used by firefighters. In 1989, Air Measurement Technologies, Inc. (AMT) retained the law firm Akin Gump Strauss Hauer & Feld, L.L.P. (Akin Gump) to prosecute patents for the safety device technology, and concurrently marketed the prototype of the invention. In 1991, Akin Gump filed the first application for a patent on the technology, and subsequently prosecuted continuation applications on four additional patents. Beginning in 2000, AMT asserted the patents in six infringement suits in the Western District of Texas. AMT settled all six suits and collected a total of approximately \$10 million.

In 2003, AMT filed a malpractice claim against Akin Gump and several other law firms in Texas state court. The claim alleged that, due to Akin Gump’s negligence in prosecuting and litigating the AMT patents, AMT was forced to settle the six infringement suits for lower amounts than it would otherwise have because the patents were vulnerable to defenses of invalidity and unenforceability. Akin Gump removed the case to federal court, where AMT filed a motion to remand back to state court for lack of subject matter jurisdiction. The Western District of Texas

denied the motion in an interlocutory decision. Subsequently, Akin Gump and AMT reversed their positions, with Akin Gump moving to remand the case to state court and AMT opposing. The district court denied the motion on the ground that federal jurisdiction was appropriate under section 1338. Akin Gump appealed the decision to the Federal Circuit.

In an opinion authored by Chief Judge Paul Michel, the Federal Circuit affirmed the district court decision, holding that federal jurisdiction was appropriate because the malpractice claim required a determination of patent infringement. First, the court looked at AMT's complaint to determine whether it raised legal issues warranting federal jurisdiction. The court found that the complaint, which enumerated seven allegations of erroneous patent prosecution and litigation, warranted federal jurisdiction. In doing so, the court employed the Supreme Court's application of section 1338 in *Christianson v. Colt Industrial Operating Corp.*, which stated that federal jurisdiction applies to cases "in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims."

Second, the court observed that, to prevail in their state malpractice claim, AMT was required to show that it would have won the six prior infringement suits but for Akin Gump's negligence. Therefore, the district court would be required to try a "case within a case" to determine the validity of the malpractice allegations. The Federal Circuit reasoned that, because the patent infringement cases presented substantial questions of patent law and the resolution of these cases weighed substantially in the determination of the malpractice case, federal jurisdiction was appropriate under section 1338 and the *Christianson* decision.

Third, the court discounted Akin Gump's argument that the Supreme Court's decision in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing* required remanding the malpractice case to state court to preserve the balance between state and federal jurisdiction. The court observed that *Grable* held that federal jurisdiction was limited to cases that involve "determining whether a 'state law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.'" The court applied the *Grable* analysis, and found that: (1) the patent infringement cases were actual disputes involving federal issues, (2) the fact that patents are issued by a federal agency indicated a strong interest in favor of federal jurisdiction, and (3) the expertise of the federal courts in



adjudicating patent disputes suggested a compelling interest in keeping the case in federal court. Thus, the court affirmed the district court's denial of the motion to remand, and the malpractice claim remained in federal court.

***IMMUNOCEPT, LLC v. FULBRIGHT & JAWORSKI, LLP***

*504 F.3d 1281 (Fed. Cir. 2007)*

The *Immunocept* decision, published the same day and heard by the same judges as *AMT*, employed much of the same reasoning used in *AMT*. In *Immunocept*, the Federal Circuit held that, while Immunocept's state malpractice claim was barred by the statute of limitations, federal jurisdiction was appropriate because the claim was based on allegations of negligent patent prosecution. The three original inventors of Immunocept's claimed subject matter, a blood-filtration device, hired Fulbright to secure patent protection for their invention in 1996. The inventors subsequently assigned their patent rights to Immunocept, which then hired a separate attorney, Thomas Felger, to pursue additional patents based on the filtration device. Felger reviewed the original patent and file history, and, in 1999, discussed his analysis with Immunocept. In 2002, Immunocept entered negotiations with Therakos, Inc., a subsidiary of Johnson & Johnson, to bring the device to market. However, during these negotiations, Johnson & Johnson's patent attorneys determined that the closed construction of one of the patent's independent claims compromised the protection offered by the patent, and made the patent vulnerable to competing products. As a result, Therakos ended negotiations with Immunocept in April 2002.

Immunocept subsequently filed a state malpractice claim in the Western District of Texas in May 2005. Fulbright moved for summary judgment in March 2006, asserting that the claim was barred by the statute of limitations and that, as a matter of law, the damage remedy was too speculative. The district court granted this motion, and Immunocept appealed. The Federal Circuit agreed to hear the case, and instructed the parties to brief the question of federal jurisdiction under section 1338. Both Immunocept and Fulbright agreed that, under section 1338, federal jurisdiction is proper for state malpractice claims based on alleged errors in patent prosecution.

The court held that federal jurisdiction extended to Immunocept's claim, but that Immunocept's claim was barred by the statute of limitations. In the opinion, Chief Judge Michel addressed the *Christianson* and *Grable* tests for federal jurisdiction under section 1338, and found that the allegations of negligent patent prosecution satisfied these tests. The

court observed that the analysis of the scope of a patent claim involved a substantial question of patent law, and that this analysis was necessary to determine if Fulbright was negligent in drafting the claim. The court noted that, because patent infringement cases warrant federal jurisdiction under section 1338, and an evaluation of claim scope is the initial step in deciding a patent infringement claim, cases based on errors in defining a patent claim's scope must also fall under federal jurisdiction. As in *AMT*, the court noted the policies supporting the recognition of federal jurisdiction in state law claims that are based on patent law. Specifically, the court noted that the expertise of federal judges in adjudicating patent cases benefits the litigants, and that steering patent cases to the Federal Circuit is consistent with Congressional intent to standardize the application of patent law.

***EDDINGS V. GLAST, PHILLIPS & MURRAY***

*3:07-CV-1512-L, 2008 WL 2522544 (N.D. Tex., Jun. 25, 2008)*

In *Eddings v. Glast, Phillips & Murray*, the United States District Court for the Northern District of Texas held that federal jurisdiction was not appropriate for state malpractice claims. The plaintiffs sued Glast in Texas state court for negligent representation in a prior suit. Among other claims, the plaintiffs alleged that Glast had failed to timely produce evidence pertaining to development and production costs, which would have reduced the damages in the prior suit. Glast removed the case to federal court in September 2007 and the plaintiffs moved to remand to state court shortly thereafter.

The district court granted the plaintiffs' motion and remanded the case to Texas state court. The court noted that the burden of establishing federal subject matter jurisdiction rests on the party seeking to invoke it. The court held that Glast, who removed to federal court, failed to meet that burden, in part, because it completely failed to address the plaintiffs' first theory of liability—the failure to timely produce evidence pertaining to development and production costs.

The court distinguished *AMT* and *Immunocept* by stating that the plaintiffs in this case “are not required to prove that they would have succeeded on their patent infringement claims” and that the malpractice claims relate to procedural errors. In addition, the court highlighted a portion of the Federal Circuit's holding in *AMT* that stated, “[i]f there is a theory upon which [plaintiffs] can prevail on their malpractice claim that does not involve a substantial patent law question, then patent law is not essential to the malpractice claim, and § 1338 jurisdiction is lacking.” The

court held that because “Plaintiff’s claims do not each involve a substantial question of patent law . . . the court does not have jurisdiction. . . .”

***SINGH V. DUANE MORRIS LLP***

*538 F.3d 334 (5th Cir. 2008)*

In *Singh v. Duane Morris LLP*, the Fifth Circuit declined to adopt *AMT*’s reasoning in a trademark malpractice dispute. While the court noted that *AMT*, a patent malpractice case, was distinguishable from the *Singh* trademark malpractice case, the court admonished the Federal Circuit’s *AMT* opinion for not considering the detrimental effects of its holding on federalism.

Singh, the owner of a test preparation company, sued Test Masters Educational Services, Inc. (Test Masters) over the use of the mark “Testmasters.” Duane Morris represented Singh in the lawsuit. In finding for Singh, the jury determined that Singh’s mark was descriptive and that he had established secondary meaning. However, despite the finding of infringement, Test Masters was not held liable because it was an innocent prior user. Both Singh and Test Masters appealed, and the Fifth Circuit reversed, holding that Singh had produced insufficient evidence to establish secondary meaning.

Singh subsequently sued Duane Morris for malpractice in Texas state court. Singh alleged that Duane Morris erred in not presenting available evidence that would have sufficiently solidified his mark’s secondary meaning. Duane Morris removed the case to federal court and Singh moved to remand the case back to state court. The district court denied this motion, holding that federal jurisdiction was warranted under sections 1331, 1338, and 1651 (the All Writs Act). The court granted partial summary judgment to Duane Morris and dismissed Singh’s malpractice claims on grounds of collateral estoppel and failure to supplement the evidence of secondary meaning with a Federal Rule of Civil Procedure 60(b) motion after the trademark infringement trial. Singh subsequently appealed the decision.

The Fifth Circuit vacated the district court’s judgment and dismissed the appeal for lack of subject matter jurisdiction. The court held that federal jurisdiction was not appropriate under sections 1331, 1338, or 1651 because the federal issue—the secondary meaning of a mark—was not substantial. The court reasoned that the absence of any federal remedy for trademark malpractice expressed a lack of federal substantial interest in regulating attorney malpractice in trademark cases. Additionally, the

court observed that the case hinged on a question of fact—whether Singh could produce sufficient evidence of secondary meaning—rather than a federal issue of law. The court warned that the *AMT* precedent “would sweep innumerable state-law malpractice claims into federal court,” disturbing “the balance between federal and state judicial responsibilities.” The court refused to endorse such a “substantial usurpation of state authority” for trademark law, but acknowledged that perhaps, in patent cases, the federal interest was sufficiently substantial to require federal jurisdiction.

## THE FUTURE OF BIOSIMILAR PATENT LITIGATION

As patents for commercial biologic drugs expire, new legislation is needed to establish regulations for their therapeutic equivalents to come to market. The Hatch-Waxman Act of 1984, which established the approval guidelines for generic “small-molecule” drugs, did not similarly amend the Public Health Service Act to establish the approval process for follow-on biologic products, also termed “biosimilars.” There are currently four proposed pieces of legislation seeking to establish a pathway for biosimilar approval. Each of these bills contains provisions on patent litigation that would make biosimilar proceedings different than “small-molecule” generic litigation under the rules of Hatch-Waxman.

Under Hatch-Waxman, a generic company must first serve the brand manufacturer with notice 45 days before challenging non-expired patents. The brand company can decide to initiate infringement proceedings during this 45-day window. If the brand company does initiate litigation, the generic company will not be allowed to market its product until a court invalidates the patent in question or 30 months have passed since serving the notice.

This 30-month stay period is noticeably missing from all four proposed pieces of legislation on biosimilar approval. Further differences between most of the proposed pieces of legislation and Hatch-Waxman include the exchange of patent information between the brand and applicant companies and limitations on actions for declaratory judgment.

Three of the proposed biosimilar statutes would provide a system for the exchange of patent information. The Access to Life-Saving Medicine Act, introduced by Rep. Waxman, would require the brand manufacturer to provide a list of all patents relevant to the brand product at the request of a biosimilar applicant. The Pathway for Biosimilars Act, introduced by Rep. Eshoo, would mandate the exchange of patent information after the FDA submission of a biosimilar application. The Biologics Price Competition and Innovation Act of 2007, introduced by Sen. Kennedy, would also mandate exchange of patent information. Furthermore, the Kennedy bill would require good faith patent negotiations between the two parties before the brand company can file an infringement action. In all of these bills the biosimilar applicant would provide the brand manufacturer notice explaining the factual and legal basis as to why the biosimilar would not infringe the brand patents.

The proposed laws would also add limitations to declaratory judgment actions in different ways. In the Waxman bill, the brand manufacturer

could not, prior to the marketing of the biosimilar drug, bring a declaratory judgment action for any patent that was not identified in the initial notice. The Eshoo bill states that the biosimilar applicant may not bring a declaratory judgment action for any patent until at least 120 days after giving notice to the brand company. Under the Kennedy bill, neither the biosimilar applicant nor the brand manufacturer can bring a declaratory judgment action prior to the notice; the brand manufacturer, however, can bring a declaratory judgment action if the biosimilar applicant fails to perform certain actions.

Any new biosimilar law will likely incorporate some of the elements from these four proposed bills. As a result, there will likely be substantially different patent-litigation procedures for biosimilars than there are for small molecule drugs under Hatch-Waxman.

## NEW PTO RULES OF ETHICS

*Fed. Reg. Vol. 73, No. 158 (Aug. 14 2008)*

The Patent and Trademark Office (PTO) recently promulgated new rules governing disciplinary investigations, disciplinary proceedings, and reinstatement to the Patent Bar. The new rules took effect on September 15, 2008.

Congress granted express authority to the PTO under 35 U.S.C. § 2(b)(2)(D) to establish regulations to govern the conduct of patent agents and attorneys who represent parties before the PTO.

The PTO published its proposed rule changes in the Federal Register on December 12, 2003. After receiving and reviewing over one hundred and sixty comments, the PTO decided to revise a number of the previously presented rules and it published a Supplemental Notice of Proposed Rule Making on February 28, 2007.

The new rules are located at 37 C.F.R. § 11 and replace a number of rules previously located at 37 C.F.R. § 10. Of particular importance to patent agents is section 11.5(b)(1), which makes clear that PTO registration alone does not authorize one to prepare opinions of validity or infringement for litigation. Also noteworthy is section 11.18(c), which provides a non-exhaustive list of sanctions the PTO Director may impose on parties that violate the duty of candor when submitting documents. For example, sanctions exist for presenting a paper for improper purpose, making frivolous legal contentions, and making factual assertions that lack evidentiary support. Practitioners should also note the new rules contained in §§ 11.19-11.61, which lay out in detail various aspects of disciplinary investigations and proceedings, including jurisdiction, sanctions, settlement, evidence, burdens of proof, and reinstatement.

The PTO announced that the purpose of adopting the new rules included affording practitioners due process, protecting the public, preserving the integrity of the Office, and maintaining high professional standards. The rules apply only prospectively.

## DECLARATORY JUDGMENT DEVELOPMENTS

### SONY ELECTRONICS, INC. V. GUARDIAN MEDIA TECHNOLOGIES, LTD.

*497 F.3d 1271 (Fed. Cir. 2007)*

### CAT TECH LLC V. TUBEMASTER, INC.

*528 F.3d 871 (Fed. Cir. 2008)*

The United States Court of Appeals for the Federal Circuit issued two decisions addressing the standard for declaratory judgment in patent cases. These cases follow *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), which held that the Federal Circuit's reasonable apprehension of suit test was not the proper standard for determining whether there is actual controversy under the Declaratory Judgment Act. Rather than fashioning a precise test, the Supreme Court in *MedImmune* required only that the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant relief.

In *Sony*, the Federal Circuit addressed whether in light of the Supreme Court's decision in *MedImmune*, a "threat of immediate litigation" is necessary for subject matter jurisdiction in declaratory judgment cases. Guardian Media Technologies, Inc. (Guardian) held patents claiming methods and devices for blocking access to certain programs on television sets. Sony Electronics, Inc., and several other electronics manufacturers (collectively "the plaintiffs"), manufactured TV sets and DVD products equipped with parental rating control technology. Guardian initiated independent licensing discussions with each of the plaintiffs, claiming that each of the manufacturer's television sets and DVD products equipped with the parental rating control technology infringed its patents. Before reaching a licensing agreement, the plaintiffs each sued Guardian for declaratory relief, and the district court consolidated the declaratory judgment actions. However, the district court dismissed the consolidated case for lack of subject matter jurisdiction, finding no "actual controversy" under the Declaratory Judgment Act because Guardian had not threatened to sue any of the plaintiffs for patent infringement and none of Guardian's actions or correspondence amounted to an implicit threat of immediate litigation.



On appeal, the Federal Circuit reversed, holding that the “actual controversy” standard was satisfied with respect to Guardian and each of the plaintiffs because the parties had taken “adverse positions” regarding infringement and validity of the patents. In particular, the Federal Circuit determined that Guardian took the position that the plaintiff manufacturers’ products infringed their patents while the manufacturers took the position that they had the right to sell their products without a license from Guardian. Furthermore, the Federal Circuit held that Guardian’s willingness to conduct negotiations did not prevent the plaintiffs from bringing a declaratory judgment suit.

In *Cat Tech*, the Federal Circuit examined whether the “meaningful preparation” test, the second prong of the Federal Circuit’s reasonable apprehension of suit test, was still valid following *MedImmune*. Under that test, although a party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, there must be a showing of “meaningful preparation” for making or using that product.

Cat Tech LLC (Cat Tech), the owner of a patent claiming a method for loading chemical reactors, sued TubeMaster, Inc. (TubeMaster) for patent infringement. TubeMaster counterclaimed, requesting declaratory judgment of noninfringement, invalidity, and unenforceability of Cat Tech’s patent for certain configurations of its product, including configurations of its product not subject to the original infringement suit and not yet commercially implemented. The district court granted the motion, finding a live controversy that supported jurisdiction because TubeMaster was prepared to produce devices using those configurations as soon as it received an order with the appropriate dimensions. Cat Tech appealed, claiming that no controversy existed with regards to the configurations that were not commercially implemented, because none of those configurations had been disclosed to actual or potential customers and therefore there was no evidence that preparations had been made to advertise or sell a potentially infringing device.

The Federal Circuit affirmed the district court’s jurisdiction of the declaratory judgment counterclaim, reasoning that the proper rule for determining “controversy” after *MedImmune* was to examine “all the circumstances” rather than rely on the two-prong test of “reasonable apprehension” of suit and “meaningful preparation” towards infringing activity. Acknowledging that *MedImmune* had rejected the “reasonable apprehension” prong of that test, the court ruled that the “meaningful preparation” element remained useful in considering the totality of circumstances, a factor in determining whether a declaratory judgment is

appropriate. In particular, if a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither “immediate” nor “real” and the requirements for justiciability have not been met. Although TubeMaster had not manufactured any actual products, the court held that the immediacy requirement was satisfied because TubeMaster was prepared to ship such products upon receipt of customer orders. The court also found that TubeMaster did not expect to make substantial modifications to its product design, thus meeting the “reality” requirement of the test. Accordingly, the Federal Circuit concluded that the district court had not abused its discretion in allowing the declaratory counterclaim to proceed.