



SUPREME COURT FINDS THAT LICENSEES CAN FILE DECLARATORY JUDGMENTS	1
DELIBERATE DECISIONS DO NOT CONSTITUTE "ERROR" CORRECTABLE BY REISSUE	3
FEDERAL CIRCUIT CLARIFIES PROSECUTION HISTORY ESTOPPEL	6
UN-CLAIMED EMBODIMENT USED TO NARROWLY DEFINE CLAIM TERM "AUTHENTICATION"	7
R&D AGREEMENT DID NOT VEST FULL OWNERSHIP	7
LICENSEE NOT GRANTED SUFFICIENT RIGHTS TO SUE DESPITE RIGHT TO SUE CLAUSE	9
FEDERAL CIRCUIT CLARIFIES GOVERNMENT CONTRACTOR DEFENSE TO PATENT INFRINGEMENT ACTIONS	10
FEDERAL CIRCUIT CLARIFIES CLAIM INTERPRETATION TO PRESERVE VALIDITY OF CLAIMS	11
MERE DISCLOSURE OF GENUS DOES NOT ENABLE SPECIES FOR PURPOSES OF ANTICIPATION	12
"CARD" IN LIGHT OF SPECIFICATION TO NARROW SCOPE	14
FEDERAL CIRCUIT CLARIFIES ON SALE BAR	16
BPAI CASE OF NOTE	17
DISTRICT COURT CASE OF NOTE	18
FEATURE COMMENTARY	19

SUPREME COURT FINDS THAT LICENSEES IN GOOD STANDING CAN FILE DECLARATORY JUDGMENTS AGAINST LICENSORS WITHOUT FIRST BREACHING THE LICENSE

On January 9, 2007, the United States Supreme Court issued its decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. ___; 81 USPQ2d 1225 (2007), which reversed a line of decisions by the Federal Circuit most recently set forth in *Gen-Probe Inc. v. Vysis Inc.*, 359 F.3d 1376; 70 USPQ2d 1087 (Fed. Cir. 2004). Under *Gen-Probe*, unless the licensee breached the license as was done in *Lear, Inc. v. Adkins*, 395 U.S. 653; 162 USPQ 1 (1969), the licensee was not in sufficient imminent threat of suit to satisfy the case or controversy requirement of Article III of the Constitution. Therefore, under *Gen-Probe*, the licensee could not file a request for declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), to contest the validity or enforceability of the licensed patent. In reversing this line of decisions, the Court held that a sufficient case or controversy exists to allow a licensee in good standing to file a declaratory judgment to determine whether, under the license, continued royalty payments are required if payments are not required if the licensed patent is invalid, unenforceable, or not infringed.

BACKGROUND

MedImmune, Inc. ("MedImmune"), the petitioner, manufactures the drug Synagis. Synagis is used to prevent respiratory tract disease in infants and children. Synagis currently represents more than 80% of MedImmune's total sales revenue. In 1997, MedImmune entered into a license agreement with Genentech, Inc. ("Genentech") and City of Hope, the respondents. The license agreement covered

an existing patent, U.S. Patent No. 4,816,567 ("Cabilly I"), as well as a patent application then pending before the U.S. Patent and Trademark Office. Among other provisions, the license agreement required MedImmune to pay royalties under the Cabilly I patent (as well as the patent application, should it mature into a patent) until the patent(s) expired or were held invalid by a court.

The United States Patent and Trademark Office issued a patent for the licensed application, U.S. Patent No. 6,331,415 ("Cabilly II"), in December 2001. Upon receiving the Cabilly II patent, Genentech sent MedImmune a letter stating its belief that the Cabilly II patent covered Synagis. Since Cabilly I was not alleged to cover Synagis, no license royalties were owed prior to issuance of Cabilly II. MedImmune, however, alleged it did not believe the Cabilly II patent was either valid or enforceable. Nevertheless, MedImmune made a strategic decision to pay the royalties under the 1997 license agreement rather than risk an injunction, payment of the attorney's fees and/or treble damages should MedImmune lose a subsequent infringement action. MedImmune paid the royalties "under protest" and "with reservation of all of [its] rights", but otherwise complied fully with the requirements of the 1997 license agreement.

Subsequently, and while continuing to pay royalties under the license agreement, MedImmune filed a declaratory judgment in the District Court for the Central District of

California. The basis of the declaratory judgment was that no royalties were owed under the license because the license only required payment for an enforceable and valid patent, and the Cabilly II patent was invalid and unenforceable. As such, MedImmune filed suit to determine whether the Cabilly II patent was valid such that continued royalty payments should be made under the terms of the license agreement.

The District Court dismissed the suit for lack of subject matter jurisdiction. Citing the Federal Circuit's decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the District Court held that the Declaratory Judgment Act, 28 U.S.C. § 2201(a) only allows parties to file for declaratory judgments consistent with the limits of Article III of the Constitution, which requires an actual case or controversy. As interpreted by the District Court, the *per se* rule under *Gen-Probe* is that licensees in good standing cannot establish an actual controversy regarding patent validity or enforceability as there is no imminent threat of litigation. As MedImmune was paying the required royalties, there was no *imminent* threat. Therefore, the District Court, following *Gen-Probe*, held that MedImmune had not established an actual controversy and dismissed the suit for lack of subject matter jurisdiction.

The Federal Circuit affirmed the District Court's dismissal of the case based upon its prior *Gen-Probe* decision.

QUESTION PRESENTED TO SUPREME COURT

Following the Federal Circuit's decision, MedImmune filed a writ of certiorari on the following question:

Does Article III's grant of jurisdiction of "all Cases . . . arising under . . . the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?

The Supreme Court granted certiorari to determine whether the actual controversy requirement of the Declaratory Judgment Act and the case or controversy requirement of Article III of the Constitution required a licensee to breach the contract before suing to declare the patent invalid, unenforceable, or not infringed.

HOLDING OF THE SUPREME COURT

In an 8-to-1 decision, the Supreme Court found that neither the Declaratory Judgment Act nor Article III of the Constitution is restricted to situations where there is an imminent threat of suit. In the context of a patent license, the threat of serious business injury should the royalty payment be stopped (i.e., an injunction, attorneys fees, potential treble damages) presented a sufficient controversy that the licensee should not be required to breach the license merely to bring an existing validity or noninfringement dispute into court. As such, the Supreme Court overruled the Federal Circuit's prior holdings, as set forth more recently in *Gen-Probe*, and allowed the District Court to exercise its discretion as to whether MedImmune can continue its suit against Genentech and to reach a decision on the merits of the case.

In reaching this conclusion, the Supreme Court extended a prior line of cases allowing parties to file declaratory judgments against the government without first exposing themselves to criminal liability. The deciding factor in those cases was the degree of risk the plaintiffs would have borne had they been required to engage in a possibly illegal act before going to court. See *Terrace v. Thompson*, 263 U.S. 197 (1923)(lease with alien), and *Steffel v. Thompson*, 415 U.S. 452 (1974)(distribution of handbills). The Supreme Court found similar factors at play in the patent context, where a loss at trial could result in attorney's fees, treble damages, and an injunction. The combination of these factors could easily drive a losing defendant out of business such that the resulting serious business injury was sufficiently coercive to satisfy the case or controversy requirement of Article III.

Moreover, the Court drew heavily on its prior decision in *Altvater v. Freeman*, 319 U.S. 359, 364; 57 USPQ 285 (1943), for the proposition that a justiciable controversy exists even where payments are being made. As stated in *Altvater*, "[t]he fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" 319 U.S. at 364, quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937). As such, Justice Scalia, writing for the Court, found that existing precedent did not force licensees to "bet the farm" as the only way to create a case or controversy sufficient to support filing a declaratory judgment suit.

The Court turned aside Genentech's counter-arguments that a license was merely an insurance policy and that granting subject matter jurisdiction was contrary to the common law rule that "a party to a contract cannot at

one and the same time challenge its validity and continue to reap its benefits." *MedImmune* at 1233. The Court held that the license was not an "insurance policy" protecting Genentech from an invalidity suit because the license did not explicitly forbid such suits. Nor was *MedImmune* barred from suit by the common law rule since *MedImmune's* argument was not that the contract was invalid, but was instead that the contract, if interpreted properly, did not require payment of royalties *if the patent was invalid*. As such, *MedImmune's* challenge was in the context of a valid contract, and the justifiable controversy was over the enforcement of a contractual requirement requiring payment only where the patent is infringed, valid, and enforceable.

In its decision, the Court noted that the existence of a case or controversy does not require that the District Court exercise jurisdiction. Specifically, the Court noted that the Declaratory Judgment Act provides that a court "may declare the rights..." Moreover, the Court also noted that common law defenses and other contract law principles relied upon by Genentech do not preclude jurisdiction, but instead relate to any decision on the merits that the District Court may make to resolve the case. As such, the Court explicitly limited the effect of its ruling to allowing the District Court to

exercise its discretion (which was not allowed under the Federal Circuit's *Gen-Probe* decision), and left for the District Court to determine on remand the "equitable, prudential and policy arguments for such a discretionary dismissal" and "any merits-based arguments for denial of declaratory relief."

SIGNIFICANCE TO PATENT OWNERS

As also noted in greater detail below in the Feature Commentary entitled *Licensing Strategies After MedImmune: The Potential Impacts of the Supreme Court Allowing Licensees in Good Standing to file Declaratory Judgments Against Licensors*, the Supreme Court's decision appears to overturn what had been an assumed rule based upon Federal Circuit precedent that the licensee in good standing had not recourse to contest the validity or scope of the licensed patent while under the license. However, the Supreme Court's finding will likely cause licensors to devise alternate mechanisms to avoid costly litigation with licensees. Moreover, cases such as *MedImmune* have caused speculation as to whether the Supreme Court is becoming increasingly hostile to patents as a whole, or whether the Supreme Court is merely recognizing the importance intellectual property plays in the modern economy.

FEDERAL CIRCUIT HOLDS THAT DELIBERATE DECISIONS MADE DURING PROSECUTION DO NOT CONSTITUTE "ERROR" CORRECTABLE BY REISSUE UNDER 35 U.S.C. §251

In *In re Serenkin*, 81 USPQ2d 2011 (Fed. Cir. 2007), the Federal Circuit upheld the final decision of the USPTO Board of Patent Appeals and Interferences ("Board") sustaining the Examiner's rejection of all claims in Reissue Application No. 10/134,550 ("the '550 reissue application") for failure of Serenkin to establish a correctable error under 35 U.S.C. §251.

On January 29, 1997, Serenkin filed U.S. Provisional Application No. 60/036,649 ("the '649 provisional application") in the USPTO entitled "Apparatus and Method for Uniformly Discharging Bulk Solid Material from Overhead Drag type Conveyors" including several pages of text and eight pages of figures. On January 28, 1998, Serenkin filed an application in the United States Receiving Office (USRO) under the Patent Cooperation Treaty claiming priority to '649 Provisional Application. The PCT application indicated that eight pages of figures were included with the application, and the specification specifically referenced the figures;

however, no figures were included with the application. Upon notice of missing drawings received from the USRO, Serenkin submitted the eight sheets of figures on February 17, 1998. On February 26, 1998, the USRO indicated that the originally filed application did not include the figures and provided Serenkin with the choice of either (1) prosecuting the originally filed application without the subsequently submitted figures and receive the January 28, 1998 filing date and concomitant priority back to the '649 provisional application, or (2) prosecuting the originally filed application with the subsequently filed figures and received the filing date of February 17, 1998 with no priority back to the '649 provisional application. If Serenkin chose (2), no priority could be given as the drawings in the PCT application were filed more than one year after the filing of the '649 provisional application. On March 24, 1998, the USRO again required that Serenkin make the decision to proceed

with no figures and retain the filing date of January 28, 1998 or to incorporate the drawings into the application and receive the filing date of February 17, 1998.

On March 31, 1998, Serenkin accepted the February 17, 1998 filing date and intended to proceed to prosecute the application including the figures. And again, on August 19, 1998, Serenkin requested that the drawings be included in the application and the application be republished "showing a filing date of 17 February 1998 with no priority claim and the eight sheets of drawings filed on 17 February 1998." On August 21, 1998, Serenkin requested to commence the United States national phase of the PCT application, and the application was assigned Application No. 09/125,736. The request to commence the national stage included a preliminary amendment deleting from the original application "This application claims the benefit of U.S. Provisional Patent Application No. 60/036,649, filed January 29, 1997" and replacing such deletion with "This is the national phase of International Application No. PCT/US98/01446 filed February 17, 1998." On August 29, 2000, the '736 application issued as U.S. Patent 6,109,425 (the '425 patent").

On April 30, 2002, Serenkin sought reissue of the '425 patent in an attempt to obtain the benefit of the previously forgone January 29, 1997, filing date of the '649 provisional application. The reissue application was finally rejected on November 4, 2002 as "the error which is relied upon to support the reissue application is not an error upon which a reissue can be based" under §251. Serenkin also sought a retroactive award of an earlier international filing date in the PCT application but was denied.

The Board sustained the Examiner's final rejection of the reissue application on the basis that Serenkin had failed to perfect priority from the '649 provisional application because of a deliberate choice, which the Board construed as an error of judgment not correctable by reissue under §251, and not because of inadvertence, accident, or mistake, which are correctable by reissue under §251.

On appeal, Serenkin argued that the Board erred in determining that reissue was not an available remedy for the error of simply making the incorrect procedural choice during prosecution of the PCT application. Serenkin argued that the error would have been correctable by accepting the January 28, 1998, international filing date for the application with no figures, adding the figures to the national stage '736 application, and arguing that the drawings would not introduce new matter. Such avenue would very well likely have succeeded unless the drawings disclosed a

patentable feature relied on during the prosecution which was not adequately disclosed in the '649 provisional application; however, such avenue was not pursued. Serenkin also argued that the Board improperly relied on recapture cases to conclude that Serenkin's error of judgment was not correctable under §251. The Federal Circuit reviewed Serenkin's appeal de novo as a matter of law.

The Director of the USPTO responded that the Board correctly concluded that reissue was improper as Serenkin made a deliberate choice to forgo the earlier filing date in exchange for the benefit of including the drawings in the PCT application and that such deliberate choice is not the type of error correctable by reissue under §251. Also, the Director asserted that the international filing date of February 17, 1998 was proper and to change the priority date of the '425 patent would be to violate the treaty agreement.

The issue for appeal is whether Serenkin's "choosing of a later filing date during prosecution of the PCT application in exchange for the inclusion of the missing drawings constitutes an "error" that is correctable under §251." The Federal Circuit emphasized the deliberateness and consciousness of Serenkin's actions and concluded that such actions do not constitute correctable "error" under §251.

The Federal Circuit reviewed and distinguished case law to conclude that "the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under §251." In *In re Mead*, 581 F.2d 251 (CCPA 1978), the inventor's attorney deliberately chose to not file a continuing application during the pendency of the parent application so as to cover subject matter that was disclosed, but not claimed, in the original application, thereby breaking the chain of copendency. The Court in *Mead* concluded that in making the "conscious choice" of breaking the chain of copendency with the plan to claim the previously unclaimed subject matter in a subsequent application, the attorney knew, or should have known, that there could exist intervening references to render the unclaimed subject matter unpatentable. Further, the Court in *Mead* stated that the "intentional omission" of the unclaimed subject matter from the original application combined with the plan to claim such subject matter in a subsequently filed application did not constitute "error" under §251 as to allow correction would defeat the purpose of the copendency requirement of §120.

Similarly, in *In re Orita*, 550 F.2d 1277 (CCPA 1977), Orita argued that the failure to timely file a divisional application, after acquiescing to an Examiner's

restriction requirement, was a correctable error under §251. However, the Court concluded that the original patent was not partially inoperative due to the error of failing to file the divisional application, and that to hold that such failure was an error would be to render the copendency requirement meaningless.

Here, with regard to Serenkin, the Court disagrees with the Board's characterization of this case as Serenkin's failure to perfect priority. Similar to *Mead* and *Orita*, Serenkin's actions are more accurately described as an applicant intentionally and knowingly surrendering a right to a claim of priority, as evidenced by Serenkin's communications with the USRO, in exchange for the benefit of including the drawings in the PCT application. And now, in light of time and necessity, Serenkin is unhappy with the conscious decision to forgo the right to a claim of priority dating back to the January 29, 1997 filing date of the provisional application.

The Court distinguished Serenkin's situation from the case law Serenkin cited since there was evidence that there was a deliberate decision to forgo any right to a claim of priority in exchange for the benefit of inclusion of the drawings. In *Brenner v. State of Israel*, 400 F.2d 789 (D.C. Cir. 1968), the Court held that reissue under §251 was appropriate to correct the clerical error of failing to file a certified copy of the foreign application from which priority was claimed. In *Fontijn v. Okamoto*, 518 F.2d 610 (CCPA 1975), the Court concluded that reissue under §251 was appropriate to perfect priority when the patentee failed to notify the USPTO of earlier-filed copending applications during prosecution of the original application. And in *Sampson v. Comm'r*, 195 USPQ 136 (D.D.C. 1976), the Court held that reissue under §251 was appropriate where the patentee omitted the filing dates from prior applications but otherwise substantially complied with the statutory requirements. The Court here states that the distinction between Serenkin's situation and the above cases is the difference between "a genuine error, or mistake, and a deliberate, but subsequently found to be disadvantageous, choice."

The Court was not persuaded that the Board's reliance on recapture cases was in error as the argument fails to focus on the dispositive issue of this case, namely, whether Serenkin committed a remediable error under §251. Further, the Court stated that the recapture cases are illustrative of the types of errors that are correctable under §251.

And finally, the Court rejected Serenkin's argument that error under §251 may include "actions taken in full consciousness" as stated in *In re Wadlinger*, 469 F.2d 1200, 1207 (CCPA 1974). The Court here dismissed as dictum the statements in *Wadlinger* that errors correctable under §251 can include "mistakes" which the *Wadlinger* Court defined as including "to choose wrongly." However, Serenkin's reading of *Wadlinger* was too broad since the applicant in *Wadlinger* only sought reissue to include claims narrower in scope than those cancelled during prosecution of the original application. The *Wadlinger* Court stated that deliberate cancellation of a claim in an original application to secure a patent will prevent, in most cases, the applicant from obtaining the cancelled claim through reissue, but as the claims at issue were different and specifically narrower than the cancelled claims, reissue was appropriate. As such, *Wadlinger* claimed less than he had a right to claim, which is an explicitly statutory reason for reissue. Again, the Court here emphasizes Serenkin's deliberate decision to give up an earlier filing date in exchange for the benefit of inclusion of the figures, and the Court characterizes such conscious decision as different from *Wadlinger's* claiming less than he had a right to claim. As such, Serenkin's error is not correctable by reissue under §251.

The Federal Circuit held that remediable error correctable by reissue under §251 does not include a decision made intentionally and knowingly during the prosecution of an application. Here, Serenkin was informed of the possible effects of the decision to forgo the acceptance of the earlier filing date but evidently thought that the inclusion of the drawing was sufficiently important to give up such right to a claim of priority. Such a deliberate, conscious decision during prosecution is not an error correctable by reissue.

SIGNIFICANCE TO PATENT APPLICANTS

In re Serenkin highlights the latest in a long string of caselaw which limits an applicant's ability to correct strategic errors or missteps taken during prosecution. As such, common decisions, such as those relating to whether to file a divisional application after a restriction requirement, may not be repairable using instruments such as reissue. While possibly not repairable using reissue, the possibility always exists of other mechanisms, such as reexamination, which allows corrections affecting validity of the patent and does not require the showing that the error is accidental.

FEDERAL CIRCUIT FINDS THAT PROSECUTION HISTORY ESTOPPEL IS LIMITED TO CLAIM ELEMENT HAVING FUNCTION

In *Aquatex Industries v. Techniche Solutions*, 81 USPQ2d 1865 (Fed. Cir. 2007), Aquatex is the assignee of U.S. Patent No. 6,371,977 (“the ‘977 patent”). The ‘977 patent claims a method for cooling a person through evaporation by use of a multi-layered, liquid-retaining composite material in evaporative cooling garments. Claim 1 of the ‘977 patent claims a method performed using a device “comprising a fiberfill batting material, and hydrophilic polymeric fibers that absorb at least 2.5 times the fiber’s weight in water.” The defendant Techniche performs a method similar to the method recited in claim 1 of the ‘977 patent, using a commercially available product called Vizorb® as its filler layer. Vizorb® is an airlaid non-woven fabric predominantly made of cellulose fluffed pulp, incorporating both natural and synthetic fibers.

In 2004, Aquatex sued Techniche for contributory infringement, asserting that Techniche made a product which its customers used to perform the method recited in claim 1 of its ‘977 patent. Techniche conceded that most of the claim limitations were satisfied, but asserted that Vizorb®, which Techniche used in its product, did not satisfy the “fiberfill batting material” limitation of claim 1. Specifically, Techniche argued that only a batting material using exclusively synthetic fibers satisfied the “fiberfill” limitation of claim 1, and that Techniche’s Vizorb® material used both natural and synthetic fibers.

The District Court construed the term “fiberfill” to require only synthetic batting material, and therefore held that Techniche did not literally infringe claim 1. The District Court also found that the claim of infringement under the doctrine of equivalents was barred by prosecution history estoppel. During prosecution, Aquatex had amended its claims to distinguish the Zafiroglu prior art patent, U.S. Patent No. 4,897,297, by narrowing its claims to claim a method that cooled by evaporation, whereas Zafiroglu cooled through use of a compress and involved only slight evaporation over time. Based on the prosecution history, the District Court concluded that Aquatex was estopped from arguing that Techniche’s accused product was equivalent.

On appeal, the Federal Circuit affirmed the District Court’s finding of no literal infringement. However, the Federal Circuit remanded the case to determine

whether Techniche’s Vizorb® material infringed the “fiberfill” limitation of claim 1 under the doctrine of equivalents. The Federal Circuit noted that the subject matter surrendered by Aquatex during prosecution, which related to evaporation, bore no relation to the composition of the fiberfill batting material.

On remand, the District Court re-considered whether the defendant Techniche’s product infringed claim 1 under the doctrine of equivalents. In its defense, Techniche argued that: (1) Aquatex was barred by amendment estoppel from asserting the doctrine of equivalents, (2) its product did not include the equivalent of fiberfill batting, and (3) Aquatex failed to provide particularized testimony and linking argument as to the insubstantiality of the differences between the claimed invention and the accused device, or with respect to the “function, way, result” test. The District Court again held that Aquatex’s narrowing amendments made during prosecution surrendered the subject matter within which Techniche’s products falls, holding that Techniche did not infringe claim 1 under the doctrine of equivalents.

On appeal, the Federal Circuit held that, although the District Court misapplied the doctrine of equivalents in concluding that the defendant Techniche’s product did not infringe claim 1, the plaintiff failed to provide particularized testimony and linking argument in support of infringement under the doctrine of equivalents. Specifically, the District Court misapplied the doctrine of equivalents because the narrowing amendment related to evaporation, while the limitation at issue related to the composition of filling material. The amendment was directed to a completely different claim limitation - the requirement that the overall method of cooling of the garment be by evaporation. Thus, Aquatex surrendered no claim to the characteristics of the fiberfill during prosecution and was not barred from asserting equivalents as to the “fiberfill batting material” limitation.

While agreeing that the District Court had misapplied doctrine of prosecution history estoppel, the Federal Circuit found that there was harmless error since, in order to prove infringement under the doctrine of equivalents, Aquatex was required to provide particularized testimony and linking argument on a limitation-by-limitation basis as to the insubstantiality

of the differences between the claimed invention and the accused device or process, or with respect to the function, way, result test. *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558 (Fed. Cir. 1996). Here, Aquatex failed to provide particularized testimony from an expert or person skilled in the art that specifically addressed equivalents on a limitation-by-limitation basis, instead relying solely on legal

argument and generalized testimony. Aquatex therefore failed to demonstrate a genuine issue of material fact that would prevent the grant of summary judgment, and so the Federal Circuit affirmed the decision of the District Court granting summary judgment of noninfringement to the defendant Techniche.

FEDERAL CIRCUIT USES UN-CLAIMED EMBODIMENT TO NARROWLY DEFINE CLAIM TERM “AUTHENTICATION”

In *MyMail Ltd. v. America Online Inc.*, 81 USPQ2d 1832 (Fed. Cir. February 20, 2007), MyMail, Ltd. brought a patent infringement action in the US District Court for the Eastern District of Texas, charging eight internet service providers with infringing U.S. Patent No. 6,571,290. U.S. Patent No. 6,571,290 is drawn to allowing a user who is away from home to dial an 800 number to find out a local phone number for his internet access. Specifically, a customer at a remote location uses contact and login information to access the internet through an internet service provider (ISP) or through a third-party modem bank affiliated with that ISP (referred to generally as an NSP). The NSP performs authentication of the user and allows an internet connection to another entity called an “internet service provider access service” or ASP. The ASP provides the user with login information for a new ISP that is more suitable to the customer's remote location, typically because it is closer to that location. The user then terminates the connection to the internet established through the first ISP and reconnects to the internet by using the new ISP.

Under the defendant's system, the user calls a third-party phone bank and provides the ID and password to the phone bank. The phone bank (after a check to see if the login id is applicable) sends the id/password to the defendant. The defendant then sends the result back to the modem bank. The modem bank then allows or denies internet service. As such, the defendants

asserted non-infringement since their systems correspond to the ASP and perform authentication such that there was no element corresponding to the NSP performing authentication. The District Court agreed with the defendants, and granted summary judgment on the issue of authentication not being performed at a provider corresponding to the recited NSP.

On appeal, the Federal Circuit reviewed the specification in order to determine the proper scope of the claimed “authentication” as described in the intrinsic record. The specification required the modem banks/ISP to perform the authentication step, but did not describe the ASP as performing authentication. Instead, the Federal Circuit found that the specification required a user to be authenticated before being given access to internet (i.e., prior to being connected to the ASP). Moreover, if the ASP performed authentication instead of the ISP, the interpretation would obviate the need for distribution of the user and login for the new ISP, which is included in the claimed system. Lastly, while an unclaimed embodiment described the ASP performing authentication, since that embodiment is admittedly not claimed, it is not relevant to defining which entity performs authentication according to the claimed invention. As such, the Federal Circuit affirmed the District Court's holding that the defendant's system, performed the authentication at the ASP, not the modem bank/ISP and therefore the claimed method is not infringed.

FEDERAL CIRCUIT FINDS R&D AGREEMENT DID NOT VEST FULL OWNERSHIP OF PATENT SINCE PATENT DEVELOPED OUTSIDE OF R&D PERIOD

In *Israel Bio-Engineering Project v. Amgen, Inc.*, 475 F.3d 1256, 81 USPQ2d 1558 (Fed. Cir. 2007), IBEP, a New York based limited partnership, entered into a series of financing contracts with Inter-Yeda, a joint

venture of Yeda and Inter-Pharm. Yeda and Inter-Pharm are Israeli firms funding and commercializing research performed at the Weizmann Institute of Science. Separately, Yeda and Inter-Yeda agreed that Inter-Yeda

would obtain financing for their venture. There were two contracts of interest between IBEP and Inter-Yeda. The first contract was an "R&D Contract," which provided that Inter-Yeda would seek patents on all inventions resulting from the R&D Programs and that all rights to such patents and patent applications forming part of the Proprietary Information was to be assigned to IBEP. The terms and conditions of the Sub-R&D Contract were consistent with the second contract, the "Technology Option and Sale" contract, which provided specifically that all proprietary information developed during the term of the R&D agreement would become the sole property of IBEP (subject to a buyout right by Inter-Yeda that was not exercised). The contracts excluded from coverage pre-existing technologies not developed during the term of the R&D contract. The R&D contract term expired December 27, 1987, and the Technology Option and Sale contract expired September 14, 1985.

In April of 1987, after the expiration of the Technology Option and Sale contract but while R&D contract was in effect, scientists working under the R&D project discovered TBF, a protein ultimately used to treat rheumatoid arthritis. This discovery was patented in U.S. Patent 5,981,701 (the "'701 patent"), which issued November 9, 1999, naming among others Wallach and Rubinstein as inventors, and was assigned to Yeda. Of the three claims of the '701 patent, only the subject matter of claim 1, relating to the protein itself, was invented during the R&D contract term. The subject matter of claim 2 and 3 however, relating to the protein and including amino acid sequences, uses and delivery methods, was invented after the expiration of the R&D contract in 1988, and was based on the research of Rubinstein. However, IBEP claimed that Wallach had conducted similar research in 1987, prior to the end of the R&D contract, and on which Rubinstein's work followed such that ownership fully vested in IBEP under the terms of the R&D contract.

In 2002, IBEP filed an infringement action against Amgen, claiming infringement of claim 1 of the '701 patent. Yeda intervened, motioning for summary judgment against IBEP. Yeda asserted that because the inventors of the '701 patent were not Inter-Yeda employees at the time of the R&D agreement, they could not assign that invention to Inter-Yeda under Israeli law; thus, Inter-Yeda could not assign the patent to IBEP and therefore IBEP had no rights in the patent. The District Court granted the motion; IBEP appealed. The Federal Circuit reversed and remanded, finding that there were genuine issues of material fact concerning whether the inventors were employees at the time of the invention under Israeli law. Yeda again motioned

for summary judgment, claiming IBEP lacked standing. Claims 2 and 3, according to Yeda, resulted from research conducted in 1988, after the expiration of the R&D contract. Therefore, Yeda claimed, IBEP had only a partial interest in the patent, not full ownership and couldn't sue. The District Court agreed; IBEP again appealed.

On appeal, the Federal Circuit agreed with the District Court's conclusions that IBEP had no standing on infringement due to the fact that Rubinstein was a co-inventor of subject matter of claims 2 and 3, which was not discovered until after the expiration of the R&D program. Citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998), *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237 (Fed. Cir. 1993) and *Jones v. Hardy*, 727 F.2d 1524 (Fed. Cir. 1984), the Federal Circuit restated the rule that each claim of patent is its own invention, and joint inventors claim pro rata ownership in the full patent despite making unequal contributions. A consequence of this rule is that, since IBEP did not have full ownership, it had no standing to sue. Specifically, without the joinder of Yeda (by assignment from Rubinstein), IBEP had no standing to sue Amgen. Rubinstein/Yeda, co-owner of the patent through claims 2 and 3, did not join in the action. IBEP, through claim 1, was at most only a co-owner of the '701 patent. The Court again cited *Ethicon's* holding that all patent co-owners must join as plaintiffs in an infringement suit.

In response, IBEP disputed that Yeda was a co-owner since the R&D contract should apply to any invention *resulting* from the R&D performed under the R&D contract. IBEP claimed that any construction that gave it anything less than exclusive ownership rights was contrary to their contractual intent. However, the Federal Circuit used the strict language of the R&D contract, noting its clearly finite duration and associated coverage for the assignment. The Court read this duration in conjunction with the "resulting from" provision to conclude that, as a whole, the rights pertained to inventions only discovered as a result of research during the exact contract term; not after. The Federal Circuit found similar language in the Technology Sale contract, which supported the construction that the assignment only applied to R&D conducted during the contractual duration. In addition, to the extent that Rubinstein's work built upon Wallach's, which occurred during the R&D program, IBEP never claimed that the subject matter of claims 2 and 3 was discovered during the contract term and did not bring breach of contract claims for failure to assign all rights in these claims. Therefore, the Federal Circuit affirmed the District Court since the subject matter of claims 2 and 3 was

outside of the scope of the R&D agreement, making Yeda a co-owner of the '701 patent who did not consent to the suit. Without the consent of Yeda, the Federal

Circuit affirmed that IBEP had no standing to sue Amgen on infringement.

FEDERAL CIRCUIT FINDS THAT LICENSEE NOT GRANTED SUFFICIENT RIGHTS TO SUE DESPITE RIGHT TO SUE CLAUSE

In *Propat Intern. Corp. v. Rpost, Inc.*, 473 F.3d 1187, 81 U.S.P.Q.2d 1350 (Fed. Cir. 2007), the inventors of U.S. Patent No. 6,182,219 had assigned the patent to Authenticational Technologies LTD (hereinafter "Authentix"). In May 2002, Authentix entered into an agreement with Propat, allowing Propat to license the patent to third parties, to enforce the license agreement, and to sue infringers. In return, Propat was given a percentage of licensing royalties and a percentage of any judgment or settlement. However, the license also placed certain restrictions on the licensee's right to sue without consultation, and was not allowed to assign its patent rights without consent. Moreover, Propat was required to use its best efforts to develop licenses for the technology, the royalties for which Authenticational received a share.

Propat International Corporation sued RPost, Inc in the United States District Court for the Central District of California, charging RPost with patent infringement. The District Court held that Propat was not the owner of the patent and thus did not have standing to sue. The District Court also held that because Propat had no proprietary interest in the patent, Propat lacked standing to sue infringers even with the patent owner, Authentix, joined as a party-plaintiff. After the District Court dismissed the case, RPost moved for attorney's fees and costs, which were denied. Both parties appealed.

On appeal, the Federal Circuit applied the rule that, to sue in its own name, a party must have ownership or all substantial rights in the patent. In contrast, a bare licensee with no ownership interest in the patent has no right to participate in an infringement action at the outset such that the bare licensee cannot add the patent owner to the suit to correct the lack of standing. The rule is based upon 35 U.S.C. §281, which provides that "patentee shall have remedy by civil action for infringement of his patent." In 35 U.S.C. § 100, the word "patentee" includes both the original patent owner, as well as "the successors in title to the patentee." In combination, only the patentee can originally bring suit under 35 U.S.C. §281.

In defining "successors in title to the patentee," even where the patentee does not transfer formal legal title, the patentee may effect a transfer of ownership for standing purposes (and the right to sue for infringement) if it conveys "all substantial rights" in the patent to the transferee. In that event, the transferee is treated as the patentee and has standing to sue in its own name. The patentee is not required to join in such a suit; the transferee may sue alone. As such, for Propat to have standing to sue alone and to have initially brought the suit without Authentix, Propat would have to have to be the owner, assignee, or have "all substantial rights" in the patent.

In view of the rule, the Federal Circuit reviewed the agreement between Propat and Authentix to determine if the agreement transferred all substantial rights to Propat. According to the Federal Circuit, the Agreement gave Propat the right to license the patent to third parties, to enforce the license agreement, and to sue infringers, all of which are factors in favor of showing that all substantial rights had been conferred. However, there were several factors in the Agreement which showed that Authentix retained enough control over the patent that all substantial rights had not truly been conferred.

Specifically, in the Agreement, Propat was given a percentage of licensing royalties and a percentage of any judgment or settlement. The agreement did not explicitly give Propat a license to practice the patent, and Propat was not an exclusive licensee. The Federal Circuit specifically noted that the Agreement allowed Authentix to retain an equity interest in the proceeds of licensing and litigation activities, a right to notice of licensing and litigation decisions and the right to veto such decisions, and the unrestricted power to bar Propat from transferring its interest in the patent to a third party. Finally, Propat was required under the Agreement to "use reasonable efforts consistent with prudent business practices" in its licensing and enforcement efforts, and Authentix received a substantial percentage of these efforts, which is a provision that is more consistent with the status of an agent than a co-owner. On balance, the Federal Circuit found that the rights allocated to Propat under the

Agreement made Propat a mere agent, and are not sufficiently substantial to make Propat in effect the assignee of the patent due to the rights retained by Authentix.

The Federal Circuit then reviewed the right to sue clause of the Agreement, and noted that the mere granting of a right to sue "unaccompanied by the transfer of other incidents of ownership, does not constitute an assignment of the patent rights that entitles the transferee to sue in its own name. See *Indep. Wireless Tele. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 474-75 (1926); *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 35-36 (1923); *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1485 (Fed. Cir. 1998); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1034 (Fed. Cir. 1995)." Therefore, the Federal Circuit affirmed the District Court in dismissing the suit for lack of standing on the grounds found the 2002 Agreement between Propat and Authentix did not

transfer all substantial rights in the patent, but instead made Propat a bare licensee.

The Federal Circuit further noted that, as a bare licensee, Propat did not have a sufficient ownership interest to be involved in the suit even where Authentix was joined in the suit. Specifically, while an exclusive licensee has a sufficient interest in the patent to have standing (even if the patent owner is a necessary party to the litigation), Propat was not an exclusive licensee under the terms of the Agreement. By contrast to the ownership interest of the exclusive licensee, a bare licensee lacks standing to sue third parties for infringement of the patent, this lack of standing is not curable by joining the patentee as a party since the bare licensee cannot be involved as a plaintiff in the suit. The Federal Circuit thus agreed with the District Court that Propat's rights created by the May 2002 agreement did not accord it rights in the patent sufficient to give it standing to sue, even with Authentix named as a co-plaintiff.

FEDERAL CIRCUIT CLARIFIES RULE ON SCOPE OF GOVERNMENT CONTRACTOR DEFENSE TO PATENT INFRINGEMENT ACTIONS

In *Sevenson Environmental Svcs, Inc. v. Shaw Environmental Inc.*, 81 USPQ2d 1906 (Fed. Cir. February 21, 2007), Shaw Environmental contracted with the U.S. Army Corps of Engineers to clean up a lead-contaminated parcel of land. The contract included the following authorization and consent clause:

The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent . . . used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance.

Sevenson Environmental owns U.S. patents nos. 5,527,982; 5,732,367; 5,916,123; 5,994,608; and 6,139,485, which relate to hazardous waste remediation, including some that claim methods for treating hazardous waste by applying phosphoric acid. Sevenson Environmental sued Shaw Environmental alleging that Shaw Environmental infringed these patents during performance of the contract. Shaw Environmental moved for summary judgment based upon the authorization and consent clause of the contract and

28 U.S.C. §1498 requiring the suit to be dismissed as the suit must be maintained only against the United States Government. The District Court granted the summary judgment dismissing the suit.

On appeal, the Federal Circuit noted that 28 U.S.C. §1498 precludes suits against Government contractors to the extent that the contractor's use of a patented method is use for the United States. In order to show that the use is for the United States, there needs to be evidence that "(1) the use is 'for the Government'; and (2) the use is 'with the authorization and consent of the Government.'"

Sevenson Environmental argued that the primary purpose of the contract was not to use the patented method such that Shaw Environmental's use did not satisfy the first prong of this test. The Federal Circuit rejected this argument since the first prong does not restrict the use to a primary purpose of the contract so long as the use falls within the contract. So long as the Government exercises control over the use of the contractor's performance of the contract and this control results in infringement, the first prong is satisfied. In reviewing the facts of the case, the Federal Circuit held that, since the Shaw Environmental's use was in its capacity as a Government contractor and the result was for the direct benefit of the Government in

achieving environmental remediation, Shaw Environmental's use of the patented method satisfied the first prong.

In contesting the second prong of the test, Severson Environmental argued that the contract's authorization and consent clause was to be construed narrowly. While the Federal Circuit acknowledged that the clause was to be construed narrowly, the Federal Circuit held that the clause's language was broad enough to encompass the activities of Shaw Environmental. Specifically, the Federal Circuit noted that the authorization and consent

clause encompassed the specifications and work plans for the contract such that Shaw Environmental's compliance with these plans was within the authorization and consent of the Government. As such, any infringement, such as that alleged by Severson Environmental, that resulted from this compliance was within the explicit authorization and consent clause of the contract such that Shaw Environmental's contract performance also satisfies the second prong of the test.

As such, the Federal Circuit affirmed the District Court's grant of summary judgment dismissing the case.

FEDERAL CIRCUIT INTERPRETS CLAIM TERMS BASED UPON SPECIFICATION EXAMPLES AND CLARIFIES CLAIM INTERPRETATION TO PRESERVE VALIDITY OF CLAIMS

In *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 81 USPQ2d 1661 (Fed. Cir. January 24, 2007), the Court of Appeals for the Federal Circuit affirmed-in-part, and reversed-in-part claims construction, and vacated a summary judgment ruling by the U.S. District Court for the District of Massachusetts. MBO appealed the holding of summary judgment of non-infringement for Becton, of MBO's patent relating to a hypodermic safety syringe, U.S. Patent No. RE 36, 885 ('RE '885 patent').

The RE '885 patent covers a safety syringe with an attached guard device. When the needle is extracted from a patient, a guard body mechanism attached to the syringe engages as the needle is retracted into the guard, and a flange portion covers and prevents the needle tip within the guard from exposure, preventing accidental puncture. Prosecution history indicates a series of patents, based on continuations and continuations-in-part, ultimately resulting in issuance of U.S. Patent No. 5,755,699 (the '699 patent).

MBO sought a broadening reissue of the '699 patent based on 35 U.S.C. § 251. The United States Patent and Trademark Office allowed the reissue application without objection. The reissue application issued as RE '885 in 2000. MBO's basis for the reissue request was that it was entitled to claim "any relative movement between the needle and the body", not just a "system wherein the needle must be bodily moved toward the safety device." MBO sued Becton for infringement of various claims of RE '885, including claims 32 and 33 which were added in the reissue process. The District Court conducted Markman hearings, construing

"immediately", "relative movement", "slidably receiving", "adjacent", "proximity", and "mounted on said body." Conceding that under the District Court's construction, there would be no infringement of the disputed claims, MBO appealed the District Court's ruling on summary judgment for Becton.

TERM "IMMEDIATELY" MEANS "SIMULTANEOUSLY" IN THE CONTEXT OF THE SPECIFICATION

The Federal Circuit, mirroring the District Court's analysis, focused on the specification and claim preamble where "immediately" appeared. The Federal Circuit noted that the uses in the specification, which were consistent with the entire prosecution history, indicated that MBO clearly distinguished its invention from the prior art by stressing that the needle would be made instantly safe upon withdrawal from the patient (by activation of the blocking flange at the front of the guard body). The Federal Circuit agreed with the District Court's construction that "immediately" meant "simultaneously with the needle's withdrawal from the patient", and its appearance in the claim preamble carried the meaning over into the claim itself.

However, the District Court had also given this meaning to claims 32 and 33, in which "immediately" did NOT appear. Despite the tenor of the specification and prosecution history stressing "immediately", the Federal Circuit could not allow construction to include this same requirement in claims 32 and 33 since no actual textual reference to "immediately" could be found in those claims. In addition, no other actual textual references

within claims 32 and 33 indicated a "simultaneity" requirement.

CLAIM INTERPRETATION TO PRESERVE VALIDITY
OF CLAIM NOT ALLOWABLE WHERE ONLY ONE
INTERPRETATION POSSIBLE

In interpreting the phrases "relative movement" and "slidably receiving," the Federal Circuit noted the primary motivation for MBO's reissue request was a broadening of claims in the RE '885 patent to permit replacing "retraction" with "relative movement." That is, the embodiments MBO envisioned did not limit the invention to a stationary guard body, while only the needle was moving. Rather MBO sought the equivalent act of pushing the guard forward while holding the needle still. The District Court did not permit this expansion of claim scope since the District Court believed that the expanded definition would render the claims invalid under the recapture rule. Therefore, the District Court limited the claims to only cover "retraction."

On appeal, the Federal Circuit found the District Court's interpretation to be too narrow an application of the recapture rule. The recapture rule, based in 35 U.S.C. 251, would prohibit such broadening of claim scope if the earlier withdrawals or claim amendments were deliberate. Without ruling whether there was actual recapture, the Federal Circuit found in the prosecution history that MBO's explicitly stated purpose clearly sought to broaden the scope of its coverage to include relative movement and not just retraction. The Federal Circuit held that the rule of interpreting a claim to preserve its validity only applies where there are competing interpretations. As there was no doubt of

FEDERAL CIRCUIT FINDS THAT MERE DISCLOSURE OF GENUS IN PRIOR ART DOES NOT ENABLE SPECIES FOR PURPOSES OF ANTICIPATION UNLESS SPECIES CAN BE ENVISIONED

In *Impax Laboratories, Inc. v. Aventis Pharmaceuticals Inc.*, 81 USPQ2d 1001 (Fed. Cir. 2006), Impax sued Aventis for a declaratory judgment arguing that, by filing an Abbreviated New Drug Application (ANDA), Impax did not infringe, induce infringement of, or contribute to the infringement of U.S. Patent No. 5,527,814 (the '814 patent) owned by Aventis. The Federal Circuit evaluated whether Impax failed to prove (1) that the '814 patent was unenforceable due to inequitable conduct, and (2) that the '814 patent was

the applicant's desire to capture the expanded claim scope, the Federal Circuit held that the District Court's interpretation was too narrow and improperly rewrote the claims.

CLAIM TERM "ADJACENT" NOT LIMITED TO
CONTIGUOUS RELATIONSHIPS SINCE
INTERPRETATION EXCLUDES PREFERRED
EMBODIMENTS

Again, relying on embodiments shown in various figures of RE '885, the Federal Circuit found the District Court's construction too narrow relating to "adjacent", "proximity", and "mounted on said body." The District Court found that the term "adjacent" meant contiguous. However, the Federal Circuit noted that such an interpretation excluded the preferred embodiment, which did not show the term adjacent being connected to or contiguous bodies. Quoting *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004), the Federal Circuit held that "[A] claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." As such, the Federal Circuit held that "adjacent" should be more broadly construed to mean "next to" and not strictly "contiguous" or "connected".

The Court of Appeals for the Federal Circuit affirmed the District Court's construction for "immediately" in all claims except 32 and 33, reversing the construction of them and the other disputed claims terms. Summary judgment was vacated and the case remanded for further proceedings.

invalid as anticipated. In an opinion by Judge Schall, the Federal Circuit found (1) that there was no inequitable conduct in the prosecution of the '814 patent, and (2) that the District Court incorrectly analyzed the '814 patent with regard to anticipation.

Aventis owns the '814 patent, which claims priority to U.S. Patent Application Serial No. 07/945,789 filed September 16, 1992. Five claims of the '814 patent were at issue, the first of which recites a method for treating amyotrophic lateral sclerosis (ALS) by administering to a

mammal in recognized need of treatment “an effective amount of [riluzole] or a pharmaceutically acceptable salt thereof.” Claims 2 and 3 recite limitations regarding treating ALS in the bulbar muscles of the throat, tongue, and respiratory system. Claims 4 recites that the effective amount of the compound being administered should be 25 to 200 mg, and claim 5 depends upon and narrows claim 4 to administering 50 mg. ALS is more commonly known as Lou Gehrig's disease.

Under 35 U.S.C. §271(e)(2), it is an act of infringement to file an ANDA if the purpose of such submission is to obtain approval for commercial manufacture, use, or sale of a drug that is claimed in patent or the use of which is claimed in a patent before the expiration of such patent. On March 16, 2001, Impax filed an ANDA with the FDA seeking approval to market and sell generic riluzole tablets for treatment of ALS. Impax discovered the '814 patent during prosecution of the ANDA, and on June 25, 2002, Impax filed the declaratory judgment that was the basis for this Federal Circuit's opinion. On January 29, 2003, the FDA approved Impax's ANDA.

Impax alleged that the '814 patent was invalid as anticipated by U.S. Patent 5,236,940, (the '940 patent) which claimed priority from French Application No. 2,640,624 (the '624 application). Under 35 U.S.C. §102(b), a patent claim is invalid as anticipated if every limitation in a claim is found in a single prior art reference, either explicitly or inherently. As such, the prior art reference must enable one of ordinary skill in the art to make or use the claimed invention. However, the enablement requirement for anticipation purposes does not require utility as is required for enablement with regard to written disclosures under 35 U.S.C. §112.

The '940 patent, which is also owned by Aventis, claimed a formulaic compound that would include riluzole; however, the '940 patent specifically exempts the formula for riluzole stating that riluzole is not new and not part of the claimed invention. The '624 application contains a substantially similar disclosure but does not exempt riluzole. The Court analyzed each reference in turn.

With regard to the '940 patent, the District Court found that the '940 patent did not anticipate the '814 application as the formula disclosed in the '940 patent “entail[ed] such a large number of compounds... [that] one of ordinary skill in the art would not have recognized that riluzole was effective in treating ALS without additional detail or guidance” not contained therein. The District Court found that despite the '940 patent disclosing riluzole, suggesting that riluzole could be used to treat ALS, providing dosage information that

the '814 patent was not anticipated by the '940 patent as the '940 patent provided “no evidence that [riluzole] would be effective,” thus, the '814 patent was not sufficiently enabled.

The Federal Circuit, relying on *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005), rejected such analysis as effectiveness is not required to be shown for enablement analysis for the purposes of anticipation. The Federal Circuit framed the issue as “whether the '940 patent is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.” On such a finding, the Federal Court reversed the District Court's decision and remanded for further analysis.

The District Court analyzed the '624 application in the same manner as the '940 patent as both the plaintiff and defendant provided substantially similar arguments with respect to each. However, the Federal Circuit employed a different analysis since there were material differences between the '940 patent and the '624 application. The '624 application does not name riluzole and only includes riluzole as one of hundreds of compounds within the formulaic compound disclosed. The Federal Circuit recognized that in order to enable a member of a class of compounds - or a species of a genus, one of ordinary skill in the art should be able to at once envisage each species of the genus. Specifically, the Federal Circuit held that the general rule for enablement is as follows:

“When a reference discloses a class of compounds, *i.e.*, a genus, a person of ordinary skill in the art should be able to “at once envisage *each member of th[e] ... class*” for the individual compounds, *i.e.*, species, to be enabled. *In re Petering*, 301 F.2d 676, 681 [133 USPQ 275] (C.C.P.A. 1962). If the members cannot be envisioned, the reference does not disclose the species and the reference is not enabling.” 81 USPQ2d at 1013.

The Federal Circuit found that with such a large number of compounds included in the '624 application and no specific identification of riluzole, the '624 application could not anticipate any of the claims of the '814 patent.

NO INEQUITABLE CONDUCT WHEN ADVANCED ARGUMENTS EXCLUDE INFORMATION NOT RELEVANT TO AN EXAMINER'S REJECTION

Impax also alleged that the '814 patent was unenforceable due to inequitable conduct during

prosecution. The Court required that Impax provide clear and convincing evidence of (1) affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, and (2) an intent to deceive. The standard for materiality may be met, as the Court discussed in *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309 (Fed. Cir. 2006), under five different tests:

1. *Present USPTO Rule 56* - information is material if it establishes a prima facie case of unpatentability of a claim, or refutes or is inconsistent with arguments advanced by the applicant;
2. *Past USPTO Rule 56* - information is material if a "reasonable examiner" would have considered such information important in determining patentability;
3. *Objective "but for" standard* - where the misrepresentation was so material that the patent should not have issued;
4. *Subjective "but for" standard* - where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so; and
5. *"But it may have" standard* - where the misrepresentation may have influenced the examiner in the course of prosecution.

Upon a finding of materiality, the equities must be balanced to determine whether the patentee committed such conduct that warrants holding the patent unenforceable. "The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003). Furthermore, if inequitable conduct occurred in the prosecution of one claim, the entire patent is unenforceable.

Here, Impax alleged that Aventis failed to disclose material information during the prosecution of the '814 patent by withholding data generated by experiments involving riluzole. Impax argued that the withheld data was material as the data was inconsistent with arguments advanced by Aventis in support of patentability. Specifically, in 1993 and 1994, Aventis

tested riluzole and seven other compounds for effectiveness in treating ALS as judged by several parameters. During the prosecution of the '814 patent, Aventis argued that the test results of riluzole and only 2 of the 7 compounds indicated that riluzole demonstrated unexpected results while not providing information on the tests of the other 5 of the 7 compounds. Impax alleged that the results of the 5 not disclosed compounds were material and inconsistent as some of the 5 compounds demonstrated better qualities for at least a few parameters than the 2 disclosed compounds. Thus, as Impax argued, as several of the compounds tested exhibited beneficial qualities as predicted by the prior art, the results with respect to riluzole were not unexpected.

However, the Federal Circuit found no error in the District Court's decision as the tests were not material even though some of the compounds showed beneficial qualities. The Court found that no prima facie case of unpatentability was established as there was no indication that the test results demonstrated that the undisclosed compounds were effective in treating ALS. The Federal Circuit further found that Aventis's argument was not inconsistent as Aventis had argued that riluzole demonstrated unexpected results over compounds disclosed in the '940 patent and that the 2 disclosed compounds of the 7 tested were similar to the compounds in the '940 patent. Also, there was no evidence of that a "reasonable examiner" would find such irrelevant test data important to the determination of patentability of the application. The Court only applied the Present and the Past USPTO rules 56 and did not analyze materiality under the two "but for" or the "but it may have" standards. However, the three ignored standards remain valid.

The Federal Circuit found that the above reasoning - attempting to overcome prior art - indicated that there was no intent to deceive as the disclosed tests were relevant to distinguishing over the '940 patent while the undisclosed tests were not relevant. As such, the Federal Circuit found no clear error in the lower court's finding of no inequitable conduct.

FEDERAL CIRCUIT DEFINES CARD IN LIGHT OF SPECIFICATION TO EXCLUDE COVERAGE OF PDA

In *E-Pass Technologies, Inc. v. 3Com Corp.* 81 USPQ2d 1385 (Fed. Cir. 2007), E-Pass is the assignee of U.S. Patent No. 5,276,311 (the "'311 patent"), entitled

"Method and Device of Simplifying the Use of a Plurality of Credit Cards, or the Like." The object of the invention is to provide a method and device for

substituting a single electronic multifunction card for multiple credit cards ...to address problems associated with carrying multiple cards, "the user needs, and is required to carry about, [only] a single card." On February 28, 2000, E-Pass filed a complaint of patent infringement against 3Com Corporation and Palm, Inc. (collectively, "3Com"). In the complaint, E-pass accused 3Com of inducing consumers to practice the steps of the patented method on its Palm VII and Palm VIIx personal digital assistant ("PDA") products. Claim 1 of the '311 patent recites:

1. A method for enabling a user of an electronic multi-function card to select data from a plurality of data sources such as credit cards, check cards, customer cards, identity cards, documents, keys, access information and master keys comprising the steps of:

transferring a data set from each of the plurality of data sources to the multi-function card;

storing said transferred data set from each of the plurality of data sources in the multi-function card;

assigning a secret code to activate the multi-function card;

entering said secret code into the multi-function card to activate the same;

selecting with said activated multi-function card a select one of said data sets; and

displaying on the multi-function card in at least one predetermined display area the data of said selected data set."

The District Court originally construed "electronic multi-function card", as recited in claim 1, as a "device having the width and outer dimensions of a standard credit card with an embedded electronic circuit allowing for the conversion of the card to the form and function of at least two different single-purpose cards." Applying this claim construction, the District Court had granted 3Com's motion for summary judgment of noninfringement for both literal infringement and infringement under the doctrine of equivalents. On appeal, the Federal Circuit, in *E-Pass Techs. v. 3Com Corp.*, 343 F.3d 1364; 67 USPQ2d 1947 (Fed. Cir. 2003), vacated and remanded the case based on the District Court's erroneous claim construction of "electronic multi-function card." The Federal Circuit held that the District Court improperly added dimensional limitations to the claim construction. The Federal Circuit then construed the term "card" as a "flat rectangular piece of stiff material," a construction derived from several general-purpose dictionaries, and remanded the case to

the District Court to address issues of infringement under this modified construction.

On remand, the District Court again granted summary judgment of noninfringement as to all defendants based on the remanded claim construction of "electronic multi-function card."

On E-Pass Technologies' second appeal to the Federal Circuit, the Federal Circuit upheld the District Court's finding of noninfringement. The Federal Circuit noted that, although there was not a precise restriction on size or portability in the specification, the specification and the plain meaning of the term card indicates that recited card needed to have attributes of being able to be "carried about," and of not having protruding buttons, keyboards, antennae, indented display screens, or hinged covers. In view of this definition, the Federal Circuit agreed with the District Court that the accused devices are neither flat nor rectangular, and had buttons, joysticks and keyboards which project above the surface, screens which sit below the surface, indented spaces holding a stylus, projecting antennae, and flip covers which sit at a 150 degree angle. Likewise, the accused devices are not "pieces of stiff material," but rather are all elaborate mixes of multiple pieces and multiple materials. Accordingly, the Federal Circuit affirmed the District Court's grant of summary judgment of noninfringement as to the "electronic multi-function card" limitation.

Regarding the issue of infringement under the doctrine of equivalents, the Federal Circuit affirmed the District Court's holding that there was insufficient evidence that the recited method of claim 1 was ever practiced such that there was no need to reach the question of infringement under the doctrine of equivalents. Specifically, the District Court granted summary judgment of non-infringement since E-Pass had submitted no evidence that the patented method has ever been practiced on any Palm VII, Tungsten, Zire or Trio devices. E-pass, therefore, did not meet its burden of proving the actual practice of the patented method. E-pass's citations to business analyses of proposed contactless payment protocols failed to show that any such protocol was ever actually deployed or that, if deployed, would infringe. Finally, the product manuals for various of the accused devices do not teach all of the steps of the claimed method together, much less in the required order. As such, there was no situation like that in *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986), where a Rubix-Cube like puzzle distributor was found to have induced infringement of a patented method for solving such a puzzle by disseminating an instruction sheet teaching the method

of restoring the pre-selected pattern with each puzzle. Instead, the mere existence of the product manual

requires too speculative a leap to conclude that any customer actually performed the claimed method.

FEDERAL CIRCUIT CLARIFIES ON SALE BAR UNDER 35 U.S.C. §102(B)

In *Plumtree Software, Inc. v. Datamize, LLC*, 81 USPQ2d 1251 (Fed. Cir. 2006), Datamize owned U.S. Patent No. 6,460,040 (the "'040 patent"), which contained method claims, and U.S. Patent No. 6,658,418 (the "'418 patent"), which contained both method and apparatus claims. The '040 patent and the '418 patent are drawn to the software used to create interactive computer programs and the computer program itself. Such programs were used to design kiosks used to display skiing information (slope conditions, resort particulars, etc.) to consumers at a ski trade show. Both patents were continuations of U.S. Patent No. 6,014,137 (the "'137 patent"). Datamize had informed Plumtree that Plumtree infringed the '137 patent, in addition to potentially infringing the yet to be issued continuations. Datamize also engaged in infringement proceedings against other parties concerning the '040 patent.

In response, Plumtree brought a declaratory judgment action under the Declaratory Judgment Act, 28 U.S.C. § 2201(a) alleging that the '040 and '418 patents were invalid under 35 U.S.C. §102(b) for having been sold more than one year prior to the earliest filing date. Upon Plumtree's declaratory judgment action, Datamize sought dismissal because of lack of subject matter jurisdiction, and Plumtree motioned for summary judgment with regard to patent validity. The District Court had held that it had proper jurisdiction, and that the '040 and '418 patents were invalid for violating of the on-sale bar.

Under 35 U.S.C. 102(b), the on-sale bar applies when an invention is sold or offered for sale more than one year prior to the application filing date, the so-called "critical date." For an event to be considered an on sale bar, the invention must be sold or offered for commercial sale and must be ready for patenting. The parties agreed that the latter element was met. The issue was whether the offer to create a kiosk for a ski trade show in return for a waived entrance fee met the test for the offer/sale prior to the critical date when the completed kiosk was not provided until after the critical date.

The Federal Circuit reviewed the dates relative to the on sale bar. Specifically, the critical date was February

27, 1995 since the provisional application to which the '040 and '418 patents claim priority was filed February 27, 1996. The District Court found that there was an on sale event prior to February 27, 1995. Specifically, The inventors had completed the kiosk authoring tool in December 2004. On January 26, 1995, Datamize and the Ski Industry of America (SIA) entered into an agreement requiring Datamize to provide its "SkiPath kiosk at a trade show in Las Vegas. In return, SIA waived its entrance fee of \$10,000 such that there was mutual consideration as required in a commercial offer for sale. However, the District Court found that, while the agreement was ambiguous concerning whether the patented method had to be used in producing the kiosk, which itself was unpatented, the record supported that the method claims were invalid under the on-sale bar since the kiosk system (and the underlying agreement for it) had embodied the claims of the patent.

But the Federal Circuit found this reasoning misguided and relied instead on its holding in *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321; 60 USPQ2d 1687 (Fed. Cir. 2001). Noting that the invention was the process or method for creating the kiosk system, not the kiosk itself, the Federal Circuit found ambiguity as to whether the agreement required providing the kiosk system software or that the kiosk be made using the patented method. As such, the Federal Circuit held that, although there was consideration sufficient for an on sale bar, the record did not establish that the invention that is the subject of the offer for sale satisfied each claim limitation of the patent. Of special importance was Plumtree's failing to provide extrinsic evidence that Datamize specifically performed the patented method under the contract. At best, the evidence showed that, while one of the inventors had created the kiosk using the patented method claims, since the kiosk system was not completed until *after* the critical date, there was insufficient evidence that the inventor had used *all* of the method steps prior to the critical date. Therefore, the Federal Circuit vacated the District Court's holding of summary judgment for Plumtree and remanded the case for further proceedings.

BOARD OF PATENT APPEALS AND INTERFERENCES

CASE OF NOTE

DESIGNATION OF DRAWINGS DISCUSSED IN
BACKGROUND CREATES PRESUMPTION THAT IS
PRIOR ART UNDER 35 U.S.C. § 102

In *Ex parte Ji-young Lee*, Appeal No. 2006-2328 (February 23, 2007) (non-presidential), the application under appeal is a reissue of U.S. Patent 6,064,443, issued May 16, 2000, to Ji-Young Lee entitled "Method for Detecting and Separating Vertical and Horizontal Synchronous Signals from Computer System," based on Application 08/880,675, filed June 23, 1997. Among the issues on appeal was the final rejection of claim 58.

During prosecution, the applicant had amended Figures 1 and 2A-2C to replace the "Prior Art" label with the "Background Art." When the Examiner contested this revision, the applicant successfully petitioned to have the change made. Since the drawings were amended, the Examiner concluded that Figures 1 and 2A-2C were not "prior art" because Appellant identifies it as "Background Art."

On its own initiative and after the existing rejection of claim 58 was reversed, the Board requested that the counsel for the applicant explain at oral argument "what was meant by 'background art' in Figures 1 and 2A-2C." While the Board was unclear on counsel's answer, the Board interpreted counsel's response to be that "prior art" is only an appropriate label where the depicted device is from a publication. In response, the Board noted that non-publications can be prior art, such as prior art under 35 U.S.C. §§ 102(f)/103(a). Since counsel was unable to provide a satisfactory explanation as to whether the "Background Art" in Figures 1 and 2A-2C were prior art under other categories of 35 U.S.C. §102, the Board then requested that counsel "submit a paper within a week clarifying the nature of the subject matter of Figures 1 and 2A-2C."

After oral argument, counsel for the applicant responded by noting that the original correspondence had been destroyed, and that there was no evidence as to the source for the subject matter of the "Background Art" in Figures 1 and 2A-2C. Instead, applicant argued:

1. No section of § 102 disqualifies a patent application if the subject matter was based on what anyone else in the foreign country may or may not have known.

2. § 102(f) does not concern itself with the knowledge "of another" regarding the subject matter sought to be patented.
3. "Whether Figs. 1-2C constitute 'Prior Art' hinges only on an inquiry of whether or not the subject matter of Figs. 1-2C was published in this or a foreign country, or was known or used by others in this country."

Based upon the above, the Board found that, when applicants describe a device or method in the background of the invention, the United States Patent and Trademark Office is entitled to *presume* that the device or method is not within the invention. The presumption exists since there are multiple categories of prior art under 35 U.S.C. §102, such as 35 U.S.C. §102(f), which merely relate to prior development by another. Moreover, applicants are in a better position to provide such information. As set forth by the Board:

The issue is whether applicants can be required to admit or deny that the subject matter is "prior art." It is a common problem in the USPTO that applicants describe or label subject matter as "background art," or "related art," or as "conventional," but do not "admit" that it is "prior art." That is the situation in this case. The Examiner presumed that the figures labeled "Background Art" were not "Prior Art" because Appellant did not use that exact terminology. Although terms like "background art" (or "related art" or "conventional" or some other term) suggest an admission that the subject matter is "prior art" to the applicant, the admission is not clear. If subject matter designated "background art" (or some other term) is "prior art" or is evidence of knowledge of the level of skill in the art, it is manifestly highly relevant to the issue of patentability. In our opinion, it is in the public interest for the USPTO to *require* applicants to admit or deny that the subject matter is "prior art."

Therefore, the Board held that, subject to rebuttal by the applicant, any device or method described in the background of the invention is presumed to be eligible for use in a prior art combination under 35 U.S.C. §103. Based upon this presumption and since no rebuttal was included in the record, the Board directed that a new obviousness rejection be made for claim 58 using the presumed prior art of FIGs. 1 and 2A-2C.

DISTRICT COURT FINDS JOINT VENTURER NOT "A SUBSIDIARY" AS DEFINED IN LICENSE AGREEMENT

In *Nano Proprietary, Inc. v. Canon, Inc.*, Case No. A-05-CA-258-SS (W.D. Tx. November 14, 2006), Nano owns patents on electron field emission display (FED) devices, which are used in flat screen televisions. In 1998, Nano approached Canon, proposing to enter a joint development and licensing agreement for Canon and its subsidiaries to use Nano's technology to develop flat screen displays. Canon initially rejected Nano's offer. Instead, Canon and Toshiba began to negotiate a joint venture to make flat screen displays using a subset of FED technology called 'SED'. Nano contends that SED devices are covered by the FED patents.

While conducting secret negotiations with Toshiba, Canon returned to Nano and obtained a non-exclusive, non-transferable right to use Nano's FED patents. This Patent License Agreement prohibited sublicensing, but permitted Canon to share the technology with subsidiaries. The license agreement specifically defined a subsidiary as any company or entity which Canon "(a) owns or controls directly or indirectly more than fifty percent (50%) ... of the outstanding stock conferring the right to vote at general meetings; or (b) has the right to elect the majority of the board of directors or its equivalent; or (c) has the right directly or indirectly to appoint or remove management." Nano was unaware at the time of the Patent License Agreement that Canon and Toshiba were close to finalizing their joint venture.

On June 13, 1999, Nano learned of the planned joint venture, and notified Toshiba that it would need a license to use Nano's FED patents.

In 2004, Canon-Toshiba formed a joint venture to produce the SED, with Canon holding one more share of voting stock than Toshiba. Nano sued Canon in the Western District of Texas, alleging 1) fraudulent inducement, 2) fraudulent non-disclosure, and 3) breach of the covenant of good faith and fair dealing; 4) seeking a declaratory judgment that SED is not a subsidiary, and thus not covered by the licensing agreement, and 5) alleging breach of contract. Defendant Canon moved for summary judgment on claims three, four, and five, arguing that these claims must fail because SED is a subsidiary under the Canon-Nano license agreement, and its activities are therefore within the scope of the Patent License Agreement.

In forming SED, Inc., Canon and Toshiba agreed that each would select and nominate an equal number of directors. Also, both Canon and Toshiba agreed that both must consent to major business decisions made by

SED Inc. Both parties also agreed that Canon will, at all times, own exactly one more share of SED's common voting stock than Toshiba. As such, Canon theoretically had more than 50% of the "voting stock such that SED Inc. was a subsidiary.

The District Court found that SED was not a subsidiary of Canon. Specifically, although Canon owns more than 50% of the "voting stock," Canon agreed not to vote against Toshiba's interest in their Joint Venture Agreement. Under New York Law, Canon's stock is therefore no longer "stock conferring the right to vote at general meetings" even if this change is not reflected in SED's Charter of Incorporation. The Joint Venture Agreement also prevents Canon from electing a majority of the board and from controlling management. Thus the court found that SED, Inc. is not a subsidiary as defined by the Nano-Canon Patent License Agreement.

The District Court also recognized the broader equitable principle that corporate form will not be regarded when to do so would work fraud or injustice. In this instance, the Court found that Canon's characterization of SED as a subsidiary "... simply can't pass the smell test. Canon has bargained away its voting rights in SED. Dead fish don't swim, dead dogs don't hunt, and Canon's dead voting rights don't give it a "majority of the shares entitled to vote" in SED."

Because SED met none of the license's definitions of a subsidiary, Canon's motion for summary judgment was denied. A trial date is set for March 2007.

LICENSING STRATEGIES AFTER *MEDIMMUNE*: THE POTENTIAL IMPACTS OF THE SUPREME COURT ALLOWING LICENSEES IN GOOD STANDING TO FILE DECLARATORY JUDGMENTS AGAINST LICENSORS

BY GREGORY L. CLINTON¹ AND JAMES G.

MCEWEN²

INTRODUCTION

On January 9, 2007, the United States Supreme Court issued its decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. ___ (2007) that reversed a line of decisions by the Federal Circuit most recently set forth in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). Under *Gen-Probe*, unless the licensee breached the license as was done in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the licensee was not in sufficient imminent threat of suit to satisfy the case or controversy requirement of Article III of the Constitution. Therefore, under *Gen-Probe*, the licensee could not file a declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), to contest the validity or enforceability of the licensed patent. In reversing this line of decisions, the Court held that a sufficient case or controversy exists to allow a licensee in good standing to file a declaratory judgment to determine whether, under the license, continued royalty payments are required where payments are not required if the licensed patent is invalid, unenforceable, or not infringed.

BACKGROUND

MedImmune, Inc. ("MedImmune"), the petitioner, manufactures the drug Synagis. Synagis is used to prevent respiratory tract disease in infants and children. Synagis currently represents 80% of MedImmune's total sales revenue. In 1997, MedImmune entered into a license agreement with Genentech, Inc. ("Genentech") and City of Hope, the respondents. The license agreement covered an existing patent, U.S. Patent No. 4,816,567 ("Cabilly I"), as well as a patent application then pending before the U.S. Patent and Trademark Office. Among other provisions, the license agreement

required MedImmune to pay royalties under the Cabilly I patent (as well as the patent application, should it mature into a patent) until the patent(s) expired or were held invalid by a court.

The United States Patent and Trademark Office issued a patent for the licensed application, U.S. Patent No. 6,331,415 ("Cabilly II"), in December 2001. Upon receiving the Cabilly II patent, Genentech sent MedImmune a letter stating its belief that the Cabilly II patent covered Synagis.³ MedImmune, however, alleges it did not believe the Cabilly II patent was either valid or enforceable. Nevertheless, MedImmune made a strategic decision to pay the royalties under the 1997 license agreement instead of risking a potential injunction and payment of the attorney's fees and/or treble damages should MedImmune lose a subsequent infringement action. MedImmune paid the royalties "under protest" and "with reservation of all of [its] rights", but otherwise complied fully with the requirements of the 1997 license agreement.

Subsequently, and while continuing to pay royalties under the license agreement, MedImmune filed a declaratory judgment in the District Court for the Central District of California. The basis of the declaratory judgment was that no royalties were owed under the license because the patent was invalid and unenforceable, and since royalties were only owed if the patents were valid and enforceable under the terms of the license. As such, MedImmune filed suit to determine, under the terms of the license agreement, whether the patent was valid such that continued royalty payments should be made.

The District Court dismissed the suit for lack of subject matter jurisdiction. Citing the Federal Circuit's decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the District Court held that the Declaratory Judgment Act, 28 U.S.C. § 2201(a) only allows parties to file declaratory judgments consistent with the limits of Article III of the Constitution, which requires an actual case or controversy to exist. As interpreted by the

¹ Associate, Stein, McEwen & Bui, LLP.

² Partner, Stein, McEwen & Bui, LLP. The opinions expressed in this article do not represent the official positions of the authors' employers or former employers.

³ Cabilly I was not alleged to cover Synagis such that no license royalties were owed prior to issuance of Cabilly II.

District Court, the per se rule under *Gen-Probe* is that licensees in good standing could not establish an actual controversy regarding patent validity or enforceability since there was no imminent threat of litigation. As MedImmune was paying the required royalties, there was no *imminent* threat. Therefore, the District Court, following *Gen-Probe*, held that MedImmune had not established an actual controversy and dismissed the suit for lack of subject matter jurisdiction.

The Federal Circuit affirmed the District Court's dismissal of the case for lack of subject matter jurisdiction based upon its prior *Gen-Probe* decision.

QUESTION PRESENTED TO SUPREME COURT

Following the Federal Circuit's decision, MedImmune filed a writ of certiorari on the following question:

Does Article III's grant of jurisdiction of "all Cases . . . arising under . . . the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?

The Supreme Court granted certiorari to determine whether the actual controversy requirement of the Declaratory Judgment Act and the case or controversy requirement of Article III of the Constitution required a licensee to breach the contract before suing to declare the patent invalid, unenforceable, or not infringed.

HOLDING OF THE SUPREME COURT

In an 8-to-1 decision, the Supreme Court found that neither the Declaratory Judgment Act nor Article III of the Constitution is restricted to situations where there is an imminent threat of suit. In the context of a patent license, the threat of serious business injury should the royalty payment be stopped (i.e., an injunction, potential treble damages) presented a sufficient controversy that the licensee should not be required to breach the license merely to bring an existing validity or noninfringement dispute into court. As such, the Supreme Court overruled the Federal Circuit's prior holdings, as set forth more recently in *Gen-Probe*, and allowed the District Court to exercise its discretion as to whether MedImmune can continue its suit against Genentech and to reach a decision on the merits of the case.

In reaching this conclusion, the Supreme Court extended a prior line of cases allowing people to file declaratory judgments against the government without first exposing themselves to criminal liability. The deciding factor in those cases was the degree of risk the plaintiffs would have borne had they been required to engage in a possibly illegal act before going to court. The Supreme Court found similar factors at play in the patent context, where a loss at trial could result in attorney's fees, treble damages, and an injunction. The combination of these factors could easily drive a losing defendant out of business such that the resulting serious business injury was sufficiently coercive to satisfy the case or controversy requirement of Article III.

Moreover, the Court drew heavily on its prior decision in *Atwater v. Freeman*, 319 U.S. 359, 364 (1943), for the proposition that a justiciable controversy exists even where payments are being made. As stated in *Atwater*, "[t]he fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" 319 U.S. at 364, *quoting Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937). As such, Justice Scalia, writing for the Court, found that existing precedent did not force licensees to "bet the farm" as the only way to create a case or controversy sufficient to support filing a declaratory judgment suit.

The Court turned aside Genentech's counter-arguments that a license was merely an insurance policy and that granting subject matter jurisdiction was contrary to the common law rule that "a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits." The Court held that the license was not an "insurance policy" protecting Genentech from an invalidity suit because the license did not explicitly forbid such suits. Nor was MedImmune barred from suit by the common law rule since MedImmune's argument was not that the contract was invalid, but was instead that the contract, if interpreted properly, did not require payment of royalties. As such, MedImmune's challenge was in the context of a valid contract, and the justifiable controversy was over the enforcement of a contractual requirement requiring payment only where the patent is infringed, valid, and enforceable.

In its decision, the Court noted that the existence of a case or controversy does not require that the District Court exercise jurisdiction. Specifically, the Court noted that the Declaratory Judgment Act provides that a court "may declare the rights..." Moreover, the Court also noted that common law defenses and other contract law principles relied upon by Genentech do not preclude jurisdiction, but instead relate to any decision

on the merits that the District Court may make to resolve the case. As such, the Court explicitly limited the effect of its ruling to allowing the District Court to exercise its discretion, which was not allowed under the Federal Circuit's *Gen-Probe* decision, and left for the District Court on remand the "equitable, prudential and policy arguments for such a discretionary dismissal" and "any merits-based arguments for denial of declaratory relief."

IMPACT ON LICENSORS

While the Court noted that the ruling is limited, *MedImmune* may have a wide-ranging impact on patent licensing. The Court in *MedImmune* made special note that the license itself did not prevent the challenge, and seemed to acknowledge that the licensor could place some restrictions on challenges. In contrast to *MedImmune*, the Court in *Lear v. Adkins*, 395 U.S. 653 (1969) held that clauses that prevent a repudiating licensee, who has stopped making royalty payments, from contesting the validity of a patent were unenforceable as contrary to public policy. However, the Court in *MedImmune* explicitly expressed "no opinion" on whether licenses can restrict such challenges by non-repudiating licensees who continue making royalty payments. As such, licensors hoping to avoid later challenges need to balance the lack of any prohibition on challenges, as was the case in *MedImmune*, with the Court's prior decision in *Lear*.

While the Court has not provided a great deal of guidance on the subject, *MedImmune* appears to indicate that licensors can be creative in avoiding or limiting a situation where a paying licensee can challenge the licensed patent without running afoul of *Lear*. By way of example, potential clauses might grant the licensor a right to terminate a license should the licensed patent be challenged. Alternately, relying on the distinction made by the Court in *MedImmune*, licensors might include a clause which contractually prohibits challenges while royalties are being paid (i.e., while the licensee is in good standing), but allows for challenges when royalties are not being paid. Further, licensees may want to ensure that the licensee pays the licensor's reasonable court costs and attorneys fees for an unsuccessful challenge of the licensed patent. Moreover, licensors might be more inclined to avoid the situation entirely by demanding fully paid up licenses instead of ongoing royalties dependent on an amount of continued use of the patent. Whatever the form, licensors will need to consider changing their licensing practices such that licenses are not merely an insurance policy during a patent challenge.

IMPACT ON LICENSEES

From the perspective of the existing licensees, declaratory judgment suits may begin to rise as licensees in existing licenses take advantage of the new opportunity the Supreme Court has given them to challenge licensed patents without having to breach the license. From a strategic point of view, potential licensees who are likely to challenge a patent may want to copy the *MedImmune* model and obtain licenses prior to challenging the patent's validity or whether a product infringes in order to ensure that, should the patent ultimately be upheld and the product be infringing, the licensee is not exposed to willfulness damages or an injunction. Thus, for both existing and potential licensees, the licensee's ability to challenge the licensed patents while paying royalties would seemingly reduce the patent litigation risk as compared to where there is no license right.

This strategy is not without its risks, however. Specifically, such challenges will be limited to the license terms and conditions. Moreover, the District Court has the discretion not to take the challenge under the Declaratory Judgment Act. For this reason and as Justice Kennedy hinted in the oral arguments for the case, the new issue in patent licensing arising from *MedImmune* will most likely be the enforceability of clauses prohibiting or limiting declaratory judgments, and whether the licensee is a repudiating licensee as in *Lear* or a non-repudiating licensee for which the status of licensee estoppel is unclear. Additionally, licensees should be aware that the common law defenses as well as equitable defenses are available. Thus, the rule that "a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits" may still be available since the Court in *MedImmune* specifically did not comment on the effect of its ruling on these defenses.

CONCLUSION

In *MedImmune*, the Supreme Court continues to assert its authority in patent law by allowing patent licensees to file declaratory judgments of patent invalidity and unenforceability against the licensors, even though the licensee is still paying royalties under a license. *MedImmune* may also indicate the Supreme Court's direction in future patent cases. The *MedImmune* case continues the new tradition of patent skepticism at the Supreme Court that began with *eBay v. MercExchange* last year. If the Court hoped to use *MedImmune* as a way to cut down on the number of invalid patents as opposed to broadening the scope of the Declaratory Judgment Act, the decision provides a hint at the

Court's possible decision in another patent case before the Court this term, *KSR v. Teleflex*. The issue in that case is the particular test for obviousness. If, as appears from the *MedImmune* decision, the Court is trying to rein in the number of invalid patents, the Court may well overturn the Federal Circuit's "teaching-suggestion-motivation" test and substitute a more

lenient test of obviousness, or may clarify that this test is only one of the acceptable tests used for obviousness. Either way, currently with *MedImmune* and with *KSR* to follow, the Supreme Court is reshaping the field of U.S. patent law.

STEIN, MCEWEN
& BUI LLP

About us ...

ADDRESS:

1400 EYE STREET, N.W.
SUITE 300
WASHINGTON, DC
20005

PHONE:

202.216.9505

FAX:

202.216.9510

E-MAIL:

EMAIL@SMBIPLAW.COM

Stein, McEwen & Bui, LLP is a full service intellectual property law firm with an emphasis on intellectual property creation and maximization. With a diverse clientele, including large multinational corporations, as well as small to midsize domestic and international companies, the attorneys of Stein, McEwen & Bui, LLP have worked with and counseled clients on the use of intellectual property as a tool for maximizing the protection of their research and development efforts.



WWW.SMBIPLAW.COM