United States Court of Appeals for the Federal Circuit

04-1300, -1384

MEDIMMUNE, INC.,

Plaintiff-Appellant,

v.

GENENTECH, INC.,

Defendant-Appellee,

and

CITY OF HOPE,

Defendant-Appellee,

and

CELLTECH R&D, LTD.,

Defendant-Appellee.

Harvey Kurzweil, Dewey Ballantine LLP, of New York, New York, argued for plaintiff-appellant. With him on the brief were Joseph Angland, Aldo A. Badini, and Henry J. Ricardo. Of counsel on the brief was Elliot M. Olstein, Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, of Roseland, New Jersey.

Daniel M. Wall, Latham & Watkins LLP, of San Francisco, California, argued for defendant-appellee Genentech, Inc. and the City of Hope. With him on the brief were Christopher S. Yates, and James K. Lynch; and Mark A. Flagel, of Los Angeles, California and Dean G. Dunlavey, of Costa Mesa, California. Of counsel on the brief were Roy E. Hofer, Cynthia A. Homan, and Meredith Martin Addy, Brinks Hofer Gilson & Lione, of Chicago, Illinois. Also, of counsel on the brief were John W. Keker, Mark A. Lemley, and Daralyn J. Durie, Keker & Van Nest, L.L.P., of San Francisco, California.

Joseph M. Lipner, Irell & Manella LLP, of Los Angeles, California, for defendant-appellee City of Hope. With him on the brief were Morgan Chu and Jason D. Linder. Of counsel on the brief was Gordon A. Goldsmith, City of Hope, Office of the General Counsel, of Duarte, California.

Charles S. Barquist, Morrison & Foerster LLP, of Los Angeles, California, argued for defendant-appellee Celltech R&D Ltd. With him on the brief were Steven M. Haines, of Los Angeles, California and Jason A. Crotty, of San Francisco, California.

Appealed from: United States District Court for the Central District of California

Senior Judge Mariana R. Pfaelzer

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DECIDED: October 18, 2005

Before NEWMAN, MAYER, and CLEVENGER, Circuit Judges.

Opinion for the court filed by Circuit Judge NEWMAN. Dissenting in part opinion filed by Circuit Judge CLEVENGER.

NEWMAN, Circuit Judge.

MedImmune, Inc., a licensee in good standing under a patent owned by Genentech, Inc. and City of Hope (collectively "Genentech"), seeks by declaratory action to challenge the validity and enforceability of the licensed patent on various grounds flowing from the

settlement of a patent interference between Genentech and Celltech R&D, Ltd. The United States District Court for the Central District of California held that because MedImmune continues to comply fully with the license terms, leaving no possibility of infringement suit or license cancellation by Genentech, there is no "case of actual controversy" as required by the Declaratory Judgment Act, 28 U.S.C. §2201. The district court also dismissed MedImmune's antitrust and unfair competition counts. We affirm the judgment.[1]

BACKGROUND

The patented technology relates to the use of cell cultures to manufacture human antibodies. Genentech, Inc. and the City of Hope are the owners of United States Patent No. 4,816,567 (the Cabilly I patent) filed on April 8, 1983, and Patent No. 6,331,415 (the Cabilly II patent), a continuation of Cabilly I, filed on June 10, 1988. Celltech owns United States Patent No. 4,816,397 (the Boss patent), having a British priority date of March 25, 1983. In accordance with 35 U.S.C. §135 the United States Patent and Trademark Office (PTO) declared an interference between the Boss patent and the Cabilly II application. The PTO interference proceedings consumed seven and a half years. The Board of Patent Appeals and Interferences decided priority in favor of the senior party Boss, holding that Cabilly had not established an actual reduction to practice before the Boss patent's British priority date. Cabilly v. Boss, 55 USPQ2d 1238 (Bd. Pat. App. & Int. 1988).

Genentech then filed a civil action in the United States District Court for the Northern District of California, in accordance with 35 U.S.C. §146. After various proceedings, the

1 MedImmune, Inc. v. Genentech, Inc., CV 03-2567 (C.D. Cal. Jan. 14, 2004; February 18, 2004; Mar. 15, 2004; April 29, 2004).

district court concluded that disputed facts concerning conception and reduction to practice required trial and, referring to the complexity of the science, stated that "[t]here appears to be a dispute amongst highly educated and apparently well-qualified experts" as to the interpretation and probative value of the evidence. The court urged Genentech and Celltech to resolve the issue of priority with the aid of mediation. Genentech and Celltech retained a mediation service, and a retired judge served as mediator. A settlement agreement was duly reached, whereby Genentech and Celltech agreed that the Cabilly II application was entitled to priority as against the Boss patent, based in part on new evidence of the content of a draft patent application during the period leading to filing of the Genentech application. Genentech and Celltech also entered into a cross-license agreement that included a formula for sharing of royalties. The district court entered judgment on the parties' resolution of the issue of priority, and directed the PTO to vacate its prior decision, revoke the Boss patent, and issue a patent on the Cabilly II application. Genentech, Inc. v. Celltech R&D, Ltd., No. 3:98cv03929 (N.D. Cal. March 16, 2001).

Genentech and Celltech jointly presented the district court's judgment to the PTO, with a petition requesting that the PTO cancel the Boss patent and issue a patent on the Cabilly II application. The Board entered an order that Cabilly was the prior inventor, but did not precisely follow the requested procedure. The Board stated that the Boss patent was cancelled by operation of law when the district court's judgment became final and was not appealed, and that no further action by the PTO was required. The Board also observed that an Information Disclosure Statement filed by Genentech in 1991 had not been acted upon, and returned the Cabilly II application to the patent examiner for review of any "ground not involved in judicial review." Genentech then cited a large number of

additional references to the examiner, and provided various documents from the record of the §146 action. After further examination the Cabilly II patent was issued on December 18, 2001, eleven years after the inception of the interference.

MedImmune had since 1997 been licensed by Genentech under the Cabilly I patent and, by the terms of that agreement, received a license under the Cabilly II patent. In addition, MedImmune had since 1998 been licensed by Celltech under the Boss patent. After issuance of Cabilly II, Genentech advised MedImmune that a MedImmune product, brand name Synagis®, was covered by Cabilly II and subject to royalties in accordance with the license terms. MedImmune objected, and filed this declaratory judgment action in the Central District of California, requesting a declaration that the Cabilly II patent is invalid or unenforceable. MedImmune paid and continues to pay the license royalties to Genentech, relying on precedent such as Cordis Corp. v. Medtronic, Inc., 780 F.2d 991 (Fed. Cir. 1985) for the holding that the licensor cannot terminate the license if the royalties are paid to the licensor and the license agreement is not otherwise breached. The district court, applying Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004), dismissed the suit as non-justiciable under the Declaratory Judgment Act.

DISCUSSION

I

The district court held that MedImmune, as a licensee in good standing and not in reasonable apprehension of suit, cannot bring a declaratory action to challenge the patent under which it is licensed. MedImmune concedes that it is free of apprehension of suit, stating that the reason it is paying the royalties is to avoid the risk and possible consequences of a successful infringement suit by Genentech. However, MedImmune

argues that under Lear, Inc. v. Adkins, 395 U.S. 653 (1969) it has the absolute right to challenge the validity or enforceability of the patent, whether or not it breaches the license and whether or not it can be sued by the patentee. MedImmune states that the Gen-Probe decision improperly resurrected the licensee estoppel that was abolished in Lear, and should be overturned.[2]

Genentech responds that this is not a question of licensee estoppel under Lear, but a question of Article III jurisdiction under the Declaratory Judgment Act. Unlike the situation in Lear, MedImmune is paying the license royalties; and unlike the situation in Lear, Genentech has no ground on which to cancel the license or otherwise bring suit affecting the licensed subject matter. In Lear the licensee stopped paying royalties and the patentee sued for royalties; there was clearly a justiciable controversy, and that aspect was not an issue in Lear. In contrast, in Gen-Probe the licensee was complying fully with the license terms and could not be sued by the patentee. Similarly, MedImmune is complying fully with the license terms and cannot be sued by the patentee.

MedImmune argues that although it has no reasonable apprehension of suit, it meets the requirements of the Declaratory Judgment Act because if it stopped paying royalties it could be sued. MedImmune states that the Cabilly II patent is subject to challenge on several grounds, and that it should not be shielded from such challenge. MedImmune also distinguishes its situation from that in Gen-Probe on the ground that the

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2 Panels of the Federal Circuit are bound by prior decisions of this court unless overturned by the court *en banc*. See, e.g., Sacco v. Dep't of Justice, 317 F.3d 1384, 1386 (Fed. Cir. 2003).

licensee in Gen-Probe negotiated for a license and then filed suit to invalidate the licensed patent, having secured its right to operate and the royalty terms should it lose the suit; MedImmune points out that it already had a license to Cabilly II under its license to Cabilly I and that the royalty rate was already set.

The district court was not persuaded by these distinctions, and we agree that they do not create a justiciable controversy. Unlike the facts in Lear, where the licensee ceased payment and disavowed the license obligation, in Gen-Probe, as for MedImmune, breach was assiduously avoided. Thus this case does not raise the question of whether patent invalidity is available as a defense to suit against a defaulting licensee -- the licensee estoppel that was laid to rest in Lear -- for there is no defaulting licensee and no possibility of suit.

Precedent follows this pattern. For example, in Intermedics Infusaid, Inc. v. Regents of University of Minnesota, 804 F.2d 129, 131 (Fed. Cir. 1986), where suit was ongoing in state court for royalties under a license agreement, the court held that a federal declaratory judgment action challenging validity was properly stayed. In Cordis v. Medtronic, 780 F.2d at 995, the court held that to avoid breach during litigation the royalties were required to be paid to the licensor, not into escrow. In C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 875-76 (Fed. Cir. 1983) the licensee had stopped paying royalties and the licensor was suing for their recovery in state court but had not terminated the license; this court held that this material breach generated an actual controversy for purposes of the federal declaratory judgment challenge to validity. The decision in Gen-Probe is in accord with this precedent, in holding that the jurisdictional requirements of a declaratory action are not met when

royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement.

MedImmune stresses the public policy served by permitting it to attack the Genentech patent, and argues that estoppel has been eliminated in the fields of intellectual property as a matter of public policy. However, the issue here is not one of estoppel, but of availability of the declaratory judgment procedure. The purpose of that procedure is to "accommodate[] the practical situation wherein the interest of one side to the dispute may be served by delay in taking legal action," BP Chemicals Ltd. v. Union Carbide Corp., 4 F.3d 975, 977 (Fed. Cir. 1993), by permitting the other side to initiate legal action. See also, e.g., EMC Corp. v. Norand Corp., 89 F.3d 807, 814-15 (Fed. Cir. 1996); Arrowhead Industrial Water, Inc. v. Ecolochem. Inc., 846 F.2d 731, 734-35 (Fed. Cir. 1988). The court in Gen-Probe discussed the inequity when the patent owner, having contracted away its right to sue, is in continuing risk of attack on the patent whenever the licensee chooses -- for example, if the product achieves commercial success -- while the licensee can preserve its license and royalty rate if the attack fails. This imbalance distorts the equalizing principles that underlie the Declaratory Judgment Act.

MedImmune states that cases from other circuits hold that a licensee need not terminate its license in order to acquire declaratory standing. However, in each of the cited cases there was an additional factor, such as money owed on the contract, or the plaintiff or its indemnitee had been threatened with suit, or there was a change in circumstances which affected performance of the contract, meeting the constitutional and statutory requirements that there must be an actual controversy in order to invoke judicial authority.

Contrary to MedImmune's argument, the fact that the licensed subject matter is intellectual property does not create a policy-driven exception to these requirements.

In MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376 (Fed. Cir. 2005) the court adhered to Gen-Probe in circumstances, like those at bar, where MedImmune had secured a license and then sued to invalidate the licensed patent. The court explained that: "To keep watch over the subtle line between an 'abstract question' and 'a controversy contemplated by the Declaratory Judgment Act' an inquiry has been formulated [whereby] there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement . . . ." This synthesis of the totality-of-the-circumstances test for determining whether there is a justiciable controversy is pragmatically useful. See BP Chemicals, 4 F.3d at 978 ("The purpose of the two-part test is to determine whether the need for judicial attention is real and immediate, or is prospective and uncertain of occurrence.")

Licensor and licensee always have "adverse legal interests," Aetna Life Inc. Co. v. Haworth, 300 U.S. 227, 241 (1937), but that relationship alone does not create a justiciable controversy. The Declaratory Judgment Act requires a "definite and concrete controversy," id. at 240, of "sufficient immediacy and reality," Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941), to warrant judicial intervention. MedImmune avoided and continues to avoid such a situation, by avoiding breach and avoiding apprehension of suit. Thus although courts have discretion in deciding whether to accept a declaratory action when the constitutional and statutory requirements are met, there is no discretion to accept

an action when there is no controversy of immediacy or reality because there is no reasonable apprehension of suit.

MedImmune directs us to the reference to "scarecrow" patents in Cardinal Chemical Co. v. Morton International, Inc., 508 U.S. 83, 96 (1993). That case concerned the appellate obligation to review a district court's decision concerning patent validity, lest an invalid patent be revived. In Cardinal Chemical the trial court had decided the issues of infringement and validity, and the Court held that the Federal Circuit has the power to review both issues on appeal, and should do so, even when the patent is held not infringed. Cardinal Chemical was an infringement suit, not a declaratory action. As commented in Super Sack Manufacturing Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995), "nothing in Cardinal undermines our decisions on declaratory justiciability at the trial court level." The present case is unaffected by Cardinal Chemical.

The district court did not err in holding that MedImmune, since under no threat or apprehension of suit, did not have standing to bring a declaratory challenge to the Cabilly II patent.

II

MedImmune also argues that the interference settlement between Genentech and Celltech was collusive and fraudulent, and that this provides an independent basis for standing to attack the Cabilly II patent, whether or not the case or controversy requirement of the Declaratory Judgment Act is met. The district court held that the joint action of Genentech and Celltech was protected by the Noerr-Pennington doctrine.

MedImmune states that Genentech and Celltech violated federal and state antitrust laws, citing sections 1 and 2 of the Sherman Act (15 U.S.C. §§1,2), and the California

antitrust and unfair competition statutes, Cal. Bus. & Prof. Code §16720 and §17200 *et seq*. MedImmune points out that the Cabilly II patent expires significantly later than the Boss patent (because of the interference delays), and argues that extension of control of the invention was the motivation for the agreement to award priority to Cabilly II. MedImmune also states that Celltech's Boss patent would have retained priority based on its British filing date if the district court had excluded the newly presented evidence of the draft Cabilly patent application. MedImmune states that this evidence, since not before the PTO, should not have been permitted in the district court. However, new evidence may be presented in §146 proceedings, see 35 U.S.C. §146 ("without prejudice to the right of the parties to take further testimony"). See also Abbott Labs. v. Brennan, 952 F.2d 1346, 1348 (Fed. Cir. 1991).

MedImmune refers to United States v. Singer Mfg. Co., 374 U.S. 174 (1963), wherein the Court found Sherman Act violation based on interference settlements and other agreements among domestic sewing machine manufacturers for the purpose of excluding Japanese competitors from the United States market. MedImmune argues that settling interferences "at least in part, to prevent an open fight over validity" of itself violates the Sherman Act, quoting the concurring opinion in Singer, 374 U.S. at 199 (White, J., concurring). The settlement of disputes such as priority in patent interferences is not a presumptive violation of antitrust law; such violation requires a showing of market power and other antitrust predicates. A patent does not of itself confer market power or a presumption thereof for purposes of the antitrust laws. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1368 (Fed. Cir. 1998) ("It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms."); Abbott Labs., 952 F.2d

at 1354 (Fed. Cir. 1991) ("A patent does not of itself establish a presumption of market power in the antitrust sense."); American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367 (Fed. Cir. 1984) ("patent rights are not *legal monopolies* in the antitrust sense of the word"); Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 18 (1984) ("any inquiry into the validity of a tying arrangement must focus on the market or markets in which the two products are sold, for that is where the anticompetitive forcing has its impact"); In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322, 1329 (Fed. Cir. 2000) ("patent alone does not demonstrate market power"); Independent Ink, Inc. v. Illinois Tool Works, Inc. 396 F.3d 1342, 1348 (Fed. Cir. 2003) ("the Supreme Court has held that there is a presumption of market power in patent tying cases"), cert. granted, 125 S. Ct. 2937 (June 20, 2005); Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and its Practice §10.3 (3d ed. 2005) ("most patents confer absolutely no market power on their owners").

The antitrust posture that MedImmune urges for patent interferences can discourage if not prevent settlements, placing unnecessary burdens on the courts and the PTO. Priority determinations may raise complex questions of law and scientific fact, and the delays in their resolution by the PTO are notorious; settlement can, as here, expedite resolution of difficult issues. The *per se* or presumptive illegality urged by MedImmune for interference settlements is contrary to both precedent and policy, as recorded in the Antitrust Guidelines for the Licensing of Intellectual Property, 4 Trade. Reg. Rep. (CCH) ¶13,132, §2.2 (1995).

III

MedImmune also argues that Genentech and Celltech colluded in the joint submission of their settlement agreement to the district court, and again in their joint submission of the court's judgment order to the Patent and Trademark Office with the request that the Boss patent be cancelled and the Cabilly II application be granted. The district court dismissed these claims, holding that petitions for governmental action are immune under the Noerr-Pennington doctrine that permits collaboration among competitors to petition the government to take an action that may restrain competition, without incurring antitrust liability by the act of collaborating. See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961) (it is permissible for railroads to act in concert to petition the legislature to take an action that creates a restraint of trade or a monopoly); United Mine Workers of America v. Pennington, 381 U.S. 657, 671 (1965) (it is permissible for a combination of workers and their employers to petition the Secretary of Labor to take an action that adversely affects competitors). In California Motor Transport v. Trucking Unlimited, 404 U.S. 508 (1972) this immunity was extended to petitions to the courts "respecting resolution of [petitioners'] business and economic interests vis-a-vis their competitors." Id. at 511.

A joint communication to a court of the terms of settlement of a matter before the court, and a joint petition to the PTO to implement the court's judgment, are not actions that would be prohibited or tainted absent immunization by Noerr-Pennington; thus it was unnecessary for the district court to have relied on Noerr-Pennington immunity. Genentech and Celltech, the parties to the litigation in the district court, were obligated to bring their settlement to the court, and to bring the court's judgment to the PTO. Although MedImmune argues that the settlement "contains misrepresentations," the putative

misrepresentation was by "representing [to the district court] that Genentech was instead entitled to priority." MedImmune Br. at 48. The district court properly rejected this theory, observing that disputed issues from the underlying litigation cannot be recast as misrepresentations, citing Kottle v. Northwest Kidney Centers, 146 F.3d 1056, 1063 (9th Cir. 1998). MedImmune's disagreement with the result of the priority settlement does not convert it into a presumptive violation of the antitrust laws, or grant MedImmune standing to require judicial review of the evidence and the conclusion reached in the settlement.

The ensuing filing of the judgment in the PTO is set by statute, and the joint filing by the parties to the judgment does not require Noerr-Pennington protection. See 35 U.S.C. §146 (filing in the Patent and Trademark Office of a certified copy of the judgment). The joint request of the litigants that the PTO implement the judgment is not a prohibited collusion.

IV

MedImmune also argues that antitrust violation arose in Genentech's prosecution of the Cabilly II application after it was returned to *ex parte* examination. MedImmune states that the additional references that Genentech brought to the examiner's attention should have been presented earlier, that Genentech did not tell the examiner about certain patents under which Genentech was licensed, that Genentech made inconsistent arguments from those it made in an opposition to the Boss patent in the European Patent Office, that Genentech cited so many references that the most important were "buried," and that Genentech did not tell the examiner about challenges to Cabilly II that Celltech had raised during the interference proceeding. Thus MedImmune states that the prosecution was fraudulent, and that enforcement of a fraudulently obtained patent violates the antitrust laws

in terms of Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965).

The district court held that "this argument fails because in its Amended Complaint, MedImmune does not plead fraud" and that "MedImmune's Walker Process theory is not supported in the pleadings." Like all fraud-based claims, Walker Process allegations are subject to the pleading requirements of Fed. R. Civ. P. 9(b). See Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1103-04 (9th Cir. 2003) (claims that are "grounded in fraud" or that "sound in fraud" are subject to Rule 9(b)). MedImmune's counsel emphasized, on questioning by the district court, that he was not charging fraud. The district court correctly held that the pleadings, which charged Genentech with inequitable conduct, not fraud, fell short of alleging a Walker Process antitrust violation.

Genentech describes MedImmune's approach as tactical. Whatever its basis, after the grant of summary judgment MedImmune sought to amend its pleadings by filing a Second Amended Complaint, to add the charge of fraud on the grounds that were previously designated as inequitable conduct. The district court denied leave to amend, referring to the litigation history and describing the proposed amendments as "prejudicial and futile." The Ninth Circuit reviews denials of leave to amend under an abuse of discretion standard. Bowles v. Reade, 198 F.3d 752, 757 (9th Cir. 1999).[3] MedImmune has provided no reasonable basis for deeming this ruling an abuse of the district court's sound discretion. In Royal Insurance Co. of America v. Southwest Marine, 194 F.3d 1009,

3 Leave to amend is a procedural matter not unique to patent law, and we apply the law of the regional circuit to review denial of leave to amend. See Ferguson Beauregard/Logic Controls Div. of Dover Resources, Inc. v. Mega Sys. LLC, 350 F.3d 1327, 1342 (Fed. Cir. 2003).

1017 (9th Cir. 1999) the court affirmed denial of leave to amend when the motion was made after the grant of summary judgment. Although the parties have in their briefs discussed at some length the prosecution aspects challenged by MedImmune, we discern no error in the district court's determination that MedImmune was without a reasonable likelihood of supporting a claim of antitrust violation, and that the proposed redesignation of prosecution issues as constituting fraud was tardy and prejudicial.

In addition, MedImmune's charge of fraud during *ex parte* patent examination does not establish standing to bring a declaratory action to invalidate a patent not involved in a case or controversy between the parties. The standards for determining jurisdiction in a declaratory judgment action of patent invalidity do not change when the declaration raises a Walker Process claim. See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1357-58 (Fed. Cir. 2004) (as for other declaratory challenges to patent validity, reasonable apprehension of suit is a prerequisite for standing to bring an antitrust challenge to the patent prosecution). A person not under reasonable apprehension of suit cannot overcome the absence of declaratory standing simply by challenging the patent prosecution and asserting fraud. There is neither statutory nor precedential authority for collateral attack on patent examination procedures, by a person who does not meet the requirements of declaratory judgment standing.

MedImmune also states that it should have been permitted to file the Second Amended Complaint after the summary judgment, to add a charge of fraud in the tardy filing of the interference settlement agreement. The PTO accepted the filing, as authorized by 35 U.S.C. §135(c). MedImmune challenges the sufficiency of Genentech's reason for its tardiness. The district court held that "MedImmune has pled no facts sufficient to assert

that the PTO acted inappropriately in accepting the settlement documents from Genentech." No abuse of the district court's discretion has been shown, and no basis whatsoever for opening to collateral attack a discretionary decision of the PTO to accept a document in accordance with the rules of the PTO.

V

MedImmune states that if this court affirms the district court on the patent counts, the antitrust and unfair competition counts should be transferred to the Ninth Circuit. That procedure would violate the jurisdictional assignment to the Federal Circuit. In Texas American Oil Co. v. Department of Energy, 44 F.3d 1557, 1564 (Fed. Cir. 1995) (*en banc*) the court explained the assignment to the Federal Circuit of "case" jurisdiction, in recognition of the burdens of "issue" jurisdiction on litigants and on the courts.

As discussed in Christianson v. Colt Indus. Operating Corp., 486 U.S. 800 (1988), the jurisdiction of the Federal Circuit is established by the well-pleaded complaint in the district court, whereupon the Federal Circuit must exercise jurisdiction of all of the issues in the case. In United States v. Hohri, 482 U.S. 64 (1987) the Court explained that the Federal Circuit must take jurisdiction of the appeal of all issues when the complaint includes any issue exclusively assigned to the Federal Circuit, in Hohri a nontax claim under the Little Tucker Act. See also Atari, Inc. v. JS & A Group, Inc., 747 F.2d 1422, 1431 (Fed. Cir. 1984) (*en banc*) (Federal Circuit must exercise jurisdiction although only copyright issue was appealed). In Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 535 U.S. 826, 829 (2002) the Court confirmed that the jurisdiction of the Federal Circuit arises from the complaint, and that the entire appeal is directed to the regional circuit when the patent count arose only by counterclaim. Similarly, when patent claims are included in order to

manipulate the direction of the appeal, or are eliminated at the threshold of the pleading stage, the entire appeal is properly taken to the regional circuit. E.g., Chamberlain Group, Inc. v. Skylink Techs. Inc., 381 F.3d 1178, 1189-90 (Fed. Cir. 2004); Schwartzopf Dev. Corp. v. Ti-Coating, Inc., 800 F.2d 240, 245 (Fed. Cir. 1986) (referring to "the transient appearance of the [patent] counterclaim"). In all cases, the purpose is to avoid the burdens of dividing the appeal between two circuits. See Texas American Oil, 44 F.3d at 1564. It would be contrary to this careful balance and efficient design for the Federal Circuit to decide part of an appeal and then, depending on the outcome of that part, to ship the residue to another circuit.[4] The request to transfer part of this appeal to the Ninth Circuit is denied.

We have considered all of the arguments raised by MedImmune. The decision of the district court is

AFFIRMED.

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4 We take note of the dissent's argument that the case should now be sent to the Ninth Circuit for decision of the Walker Process and other patent/antitrust issues raised by the appellant, on the theory that the complaint should, after this appellate decision, be deemed to have been "constructively amended" to have been filed without the patent counts of the complaint. Neither statute nor precedent provides support for such a procedure, and indeed they weigh heavily against it. In none of the "authority" mentioned by the dissent was the complaint subject to retrospective amendment of well-pleaded issues after the legal status of the parties had been altered. The Court in Christianson v. Colt confirmed that jurisdiction "is determined by reference to the well-pleaded complaint, not the well tried case." 486 U.S. at 814; see also Holmes Group v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 832, n.3 (2002). The purpose of the rule is to determine jurisdiction at the outset of litigation, to avoid throwing the parties into "a perpetual game of jurisdictional ping-pong." Id. at 818. To bifurcate an appeal after some of the issues are decided offers the worst of all possibilities, for it would not be known whether some issues would be shipped elsewhere, to be redocketed and rebriefed and reargued and reappealed, until after the Federal Circuit decided other issues. Such a situation is devoid of support.

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CLEVENGER, Circuit Judge, dissenting in part.

MedImmune, Inc. ("MedImmune") paid, and continues to pay, royalties under a 1997 licensing agreement with Genentech, Inc. ("Genentech"), which entitles MedImmune to produce and sell its humanized monoclonal antibody, Synagis®, free from liability under U.S. Patent No. 6,331,415 ("Cabilly II" or "the '415 patent"). Because MedImmune's good standing under the agreement necessarily quells any reasonable apprehension of an infringement suit brought by Genentech pursuant to the '415 patent, I agree with the court that the declaratory judgment claims properly were

dismissed for want of jurisdiction. Indeed, the district court's dismissal is required by our prior decisions in Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004) and MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376 (Fed. Cir. 2005). I write separately, however, to voice my disagreement with the court's refusal to transfer the remainder of the case to the Court of Appeals for the Ninth Circuit, pursuant to 28 U.S.C. § 1631, for a determination as to whether the district court properly granted summary judgment regarding MedImmune's antitrust and unfair competition claims.

Under 28 U.S.C. § 1295(a)(1), this court has exclusive jurisdiction over an appeal from a final decision of a district court, so long as the district court's jurisdiction was based in whole or in part upon 28 U.S.C. § 1338. See Apotex, Inc. v. Thompson, 347 F.3d 1335, 1342 (Fed. Cir. 2003) (stating that if the district court had jurisdiction over at least one claim in the case under section 1338, then this court has appellate jurisdiction over the entire case). Section 1338(a) in turn provides that a district court shall have original jurisdiction over any civil action arising under an Act of Congress relating to patents. The "well-pleaded complaint" rule defines what "arising under" means. See Holmes Group v. Vornado Air Circulation Sys., Inc., 535 U.S. 826, 833-34 (2002). "Under the well-pleaded complaint rule, as appropriately adapted to § 1338(a), whether a claim 'arises under' patent law must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose." Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809 (1988) (internal quotation marks omitted). The focus of our jurisdictional inquiry should thus be upon MedImmune's complaint and whether, as ultimately

amended, it arises under an Act of Congress relating to patents. See Chamberlain Group v. Skylink Tech., Inc., 381 F.3d 1178, 1189 (Fed. Cir. 2004). As ultimately amended, I would hold that it does not.

Our precedent mandates this conclusion. First, we have stated that a dismissal for lack of subject matter jurisdiction is usually one without prejudice because the dismissing court has no power to render a judgment on the merits of the dismissed claim. Textile Prods., Inc. v. Mead Corp., 134 F.3d 1481, 1486 (Fed. Cir. 1998). Such is the case here, and nothing about the district court's dismissal bars MedImmune from refiling its complaint. See Semtek Int'l Inc. v. Lockheed Martin Corp., 531 U.S. 497, 505-06 (2001) ("The primary meaning of 'dismissal without prejudice,' we think, is dismissal without barring the defendant from returning later, to the same court, with the same underlying claim."). Second, we have held, in a decision that binds this panel, that dismissals without prejudice are "de facto amendments," or "constructive amendments," to the complaint. See Nilssen v. Motorola, Inc., 203 F.3d 782, 784-85 (Fed. Cir. 2000) (noting that regardless of whether the patent claims were dismissed without prejudice or extinguished by amendment, the effect is the same because in either case the parties are left in the same legal position with respect to the patent claims as if they had never been filed); Gronholz v. Sears, Roebuck & Co., 836 F.2d 515, 516, 518 (Fed. Cir. 1987) (holding that plaintiff's voluntary dismissal of the patent claim without prejudice constituted an amendment to the complaint and that the suit no longer arose under the patent laws for jurisdictional purposes). Third, for jurisdictional determinations, we do not differentiate between actual and constructive amendments—

"both divest us of jurisdiction if they eliminate all issues of patent law." Chamberlain Group, 381 F.3d at 1189.

Therefore, because the district court's dismissal of MedImmune's declaratory judgment claims without prejudice is equivalent for jurisdictional purposes to an amendment removing the declaratory judgment claims from the complaint, and because no other claims in MedImmune's complaint "arise under" patent law, the district court's dismissal eliminates all issues of patent law from MedImmune's well-pleaded complaint and thus divests this court of jurisdiction over the case. Where a plaintiff lacks standing to pursue a patent law claim, as in this case, we have no jurisdiction over the remaining claims and must transfer the case to an appropriate court of appeals. See Fieldturf v. Southwest Recreational Indus., 357 F.3d 1266, 1267 (Fed. Cir. 2004). Indeed, MedImmune itself understands that a transfer is required if we affirm the absence of jurisdiction over the declaratory judgment claims. (Appellant's Reply Br. at 12 n.8.)

Finding no jurisdiction, I would transfer the case to the Court of Appeals for the Ninth Circuit, pursuant to 28 U.S.C. § 1631, for a determination as to whether the district court properly granted summary judgment regarding MedImmune's antitrust and unfair competition claims. See Christianson, 486 U.S. at 818-19 (noting that the Federal Circuit erred in deciding to reach the merits of plaintiff's antitrust claims after concluding that it lacked jurisdiction).

As the majority correctly notes, our jurisdiction is determined by the complaint. Where a patent law issue permeates the complaint, the "case" is ours, and all "issues," including non-patent law issues, remain with us for decision. But when the complaint

contains nary a whiff of patent law, as is the situation with the amended complaint in this case, we are powerless to adjudicate the other issues in the case.

To be sure, transfer to another circuit court involves some inconvenience to the parties and a burden on the courts. But inconvenience and burden are insufficient reasons to violate a fundamental limitation on federal courts: the power of judicial review vests only where jurisdiction lies.