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REPLY TO Wilmington Office

July 27, 2007

Honorable Joseph J. Farnan, Jr.
U. S. District Court for the
District of Delaware
844 North King Street
Wilmington, DE 19801

Re: Pfizer Inc v. Ranbaxy, Inc., Case 1:07-cv-00138-JJF

Dear Judge Farnan:

Pursuant to Local Rule 7.1.2 (b), Pfizer brings to the attention of the Court the recent decision of the Federal Circuit dated July 20, 2007 in the case captioned *Benitec Australia, Ltd v. Nucleonics, Inc.*, --- F.3d ----, 2007 WL 2069646 (Fed. Cir. 2007). A copy is attached. The opinion is relevant to Pfizer's Motion to Dismiss Ranbaxy's Counterclaims with respect to the '995 patent [D.I. 14]. As the Court may already know, the opinion addresses the impact of the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007) on *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995) and its progeny concerning declaratory judgment jurisdiction when a covenant not to sue is provided.

If the Court has any questions, please do not hesitate to contact me.

Very truly yours,

Rudolf E. Hutz
Connolly Bove Lodge & Hutz LLP

REH.bjh
enclosure

cc: Frederick L. Cottrell III, Esquire
William R. Zimmerman, Esquire

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United States Court of Appeals for the Federal Circuit

06-1122

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

Scott A.M. Chambers, Patton Boggs, LLP, of McLean, Virginia, argued for plaintiff-appellee. On the brief were Marc R. Labgold, Kevin M. Bell, and Richard J. Oparil, of Washington, DC.

Jason A. Lief, McDermott, Will & Emery, of New York, New York, argued for defendant-appellant. With him on the brief were Dennis J. Mondolino, and Christine A. Pepe.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

United States Court of Appeals for the Federal Circuit

06-1122

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

DECIDED: July 20, 2007

Before RADER and DYK, Circuit Judges, and WHYTE, District Judge*.

Opinion for the court filed by District Judge WHYTE. Dissenting opinion filed by Circuit Judge DYK.

WHYTE, District Judge.

Nucleonics, Inc. ("Nucleonics") appeals from the judgment of dismissal for lack of subject matter jurisdiction entered by the United States District Court for the District of Delaware on Nucleonics's declaratory judgment counterclaims against Benitec Australia, Ltd. ("Benitec"). We affirm.

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* Honorable Ronald M. Whyte, District Judge, United States District Court for the Northern District of California, sitting by designation.

I. BACKGROUND

On March 22, 2004, Benitec sued Nucleonics for infringing U.S. Patent No. 6,573,099 ("'099 patent"), which relates to RNA-based disease therapy. Both parties are biotechnology companies that are engaged in gene silencing, which involves silencing the expression of disease-causing genes. A cell is exposed to a piece of foreign DNA that is specifically engineered to contain certain portions or copies of the target gene to be silenced. The foreign DNA then produces other molecules (double-stranded RNA) that shut down the expression of the target gene. This technology is known as RNA interference ("RNAi") gene silencing.

Nucleonics filed a timely answer to the complaint on March 24, 2004. On July 13, 2004, Nucleonics moved to dismiss Benitec's complaint and argued:

> Nucleonics now moves to dismiss Benitec's complaint for lack of jurisdiction and failure to state a claim upon which relief can be granted. . . . Simply stated, Benitec has shot before there is even a target. Nucleonics' accused activities are directed to developing and submitting information to the U.S. Food and Drug Administration . . . and are therefore exempt from infringement under 35 U.S.C. § 271(e)(1). . . .

Further, Nucleonics contended that:

> it [would] not be ready to file a New Drug Application to manufacture and market a new drug product until at least 2010-2012, if ever, depending on the progress of its clinical trials. . . . As a result, Benitec lacks a statutory basis to sue for infringement at this time, and it is premature for this Court even to entertain such a claim.

The court denied the motion, but without prejudice to reconsideration depending upon the outcome of the Supreme Court's review of Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003).

On October 4, 2004, Nucleonics filed a request with the U.S. Patent and Trademark Office ("PTO") for reexamination of the '099 patent.[1]

In 2005, Benitec encountered a pair of obstacles. First, Nucleonics received evidence indicating that the inventor named in the '099 patent may have misappropriated the idea for the invention from others, or at least should have named others as co-inventors on the patent application. On February 16, 2005, Nucleonics sought leave of court to amend its answer and add declaratory relief counterclaims of invalidity and unenforceability based upon alleged inventorship fraud. After some discovery skirmishes, Nucleonics obtained testimony in June 2005 from Australian scientists Peter Waterhouse and Ming-Bo Wang that they had contributed to the subject matter of the '099 patent. Neither, however, is named as an inventor in the '099 patent.

Second, and in the same month, the Supreme Court decided Merck KGaA v. Integra Lifesciences I, Ltd., reading expansively the pharmaceutical research exception of § 271(e)(1). 545 U.S. 193 (2005).

On August 1, 2005, Benitec moved to dismiss its complaint without prejudice under Federal Rule of Civil Procedure 41(a)(2). Benitec claims it sought dismissal only because the Merck decision indicated that it had no presently viable infringement claim against Nucleonics. Nucleonics, on the other hand, claims Benitec sought dismissal in an attempt to prevent the district court from declaring the '099 patent invalid.

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[1] Nucleonics filed a second request for reexamination on May 18, 2006. In both instances, the PTO ordered reexamination of the '099 patent. The PTO recently merged the two proceedings. Benitec canceled claims 1, 2, and 8 during the reexamination. In April 2006, the examiner rejected all other claims of the patent in a non-final office action. In June 2006, Benitec submitted argument in an attempt to overcome the rejection, to which the examiner had not substantively responded as of December 13, 2006.

The district court granted Nucleonics's motion to amend its answer on September 14, 2005. Two weeks later, however, the court granted Benitec's motion to dismiss its complaint without prejudice and dismissed Nucleonics's counterclaims for lack of jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

During the time between the filing of Nucleonics's motion to amend to assert its counterclaims and the court's dismissal of those counterclaims, Nucleonics allegedly began discussing expanding its efforts beyond human health to animal husbandry and veterinary products.

Nucleonics appeals the dismissal of its declaratory judgment counterclaims. In its appellee's brief, Benitec "covenants and promises not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action—September 29, 2005."

The critical question on appeal is whether, in light of the circumstances, the court at this time has declaratory judgment jurisdiction over Nucleonics's counterclaims seeking declarations of invalidity and unenforceability of Benitec's '099 patent.

II. ANALYSIS

A. Developments Following Notice of Appeal

Subsequent to the oral argument in this case, the Supreme Court decided MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007). In view of that decision, particularly footnote 11 expressing disapproval of our previously used "reasonable apprehension of imminent suit" test for determining declaratory judgment jurisdiction,[2]

[2] The *MedImmune* Court noted that the "reasonable apprehension of imminent suit" test is an evolved form of the "reasonable apprehension of suit" test, which the Court also rejected.

we requested further briefing. The court has considered that briefing and is now also informed by this court's recent decisions in Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330 (Fed. Cir. 2007), and Sandisk Corp. v. STMicroelectronics NV, 480 F.3d 1372 (Fed. Cir. 2007), both of which involve the application of the standards set forth in MedImmune for determining declaratory judgment jurisdiction.

B. Standard for Determining Declaratory Relief Jurisdiction

A party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, "'under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" MedImmune, 127 S. Ct. at 771 (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)). Prior to MedImmune, our case law required that there be "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." See, e.g., BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993). However, "[t]he Supreme Court's opinion in MedImmune represents a rejection of our reasonable apprehension of suit test." Sandisk, 480 F.3d at 1380; see also Teva, 482 F.3d at 1339. In MedImmune, the Supreme Court held that in order for a court to have jurisdiction over a declaratory judgment action:

> the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and

> admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

127 S. Ct. at 771 (internal citation and quotations omitted).

In Sandisk, we further explain:

> Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. . . . We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

Sandisk, 480 F.3d at 1381. A useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff:

> The concepts of "adverse legal rights" and "legal risk," used in [prior] cases to describe the standard for jurisdiction require that there be an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring, if not for the fact that the declaratory plaintiff has preempted it. Without an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction.

Microchip Tech. Inc. v. Chamberlain Group, Inc., 441 F.3d 936, 943 (Fed. Cir. 2006).

The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since. See Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974); Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995); Int'l

Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed. Cir. 1986). "If . . . a party has actually been charged with infringement of the patent, there is, necessarily, a case or controversy adequate to support jurisdiction" at that time. Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 96 (1993). Further, once that burden has been met, absent further information, that jurisdiction continues. Id. at 98. The burden of bringing forth such further information may logically rest with the party challenging jurisdiction, see id. at 98, but the actual burden of proof remains with the party seeking to invoke jurisdiction. See Super Sack, 57 F.3d at 1058; Int'l Med. Prosthetics Research Assocs., 787 F.2d at 575. "The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint [was] filed." Steffel, 415 U.S. at 459 n.10.

The dissent's view that Cardinal Chemical holds that "the burden shifts to the party seeking to divest the court of jurisdiction to prove there is no longer a current case or controversy" reads more into the language of Cardinal Chemical than is justified. First, the Supreme Court makes clear at the outset of its opinion that "[the] practice [the Federal Circuit's uniform practice of declaring the issue of validity moot if it affirms the district court's finding of noninfringement], and the issue before us, therefore concern the jurisdiction of an intermediate appellate court—not the jurisdiction of either a trial court or this Court. In the trial court, of course, a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy." 508 U.S. at 95. Further, the Court only said that "[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the burden of coming forward with subsequent events that have produced that

alleged result." Id. at 98 (emphasis added). The Court did not hold that the ultimate burden of proof in the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction.

With the basic principles for determining declaratory judgment jurisdiction in mind, we analyze the question of whether the court currently has declaratory judgment jurisdiction over Nucleonics's counterclaims.

C. Application of Standard for Declaratory Judgment Jurisdiction

1. Declaratory Judgment Jurisdiction Existed at the Time Nucleonics Filed it Counterclaims

At the time Nucleonics filed its counterclaims for declarations of invalidity and unenforceability, Benitec's patent infringement claims were pending. Because Nucleonics had been charged with infringement of the '099 patent, there was, as dictated by Cardinal Chemical, necessarily a case or controversy adequate to support jurisdiction at that time. See id.

2. Declaratory Judgment Jurisdiction at the Present Time

a. Human Application of RNAi

Cardinal Chemical, however, does not address whether subsequent events can divest the district court of jurisdiction, specifically here, over Nucleonics's counterclaims. This court has rejected the argument that subsequent events cannot divest the trial court of jurisdiction, noting that Cardinal Chemical dealt primarily with this court's previous practice of vacating findings of patent invalidity as moot in light of non-infringement. Super Sack, 57 F.3d at 1060; see also Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999).

In Super Sack, we found that Super Sack's unconditional agreement "not to sue Chase for infringement as to any claim of the patents-in-suit based upon the products currently manufactured and sold by Chase" was sufficient to divest the court of jurisdiction over Chase's counterclaims for non-infringement, invalidity and unenforceability because Chase was engaged in no "present activity" placing it at risk of an infringement suit and Chase did not claim it was planning to make any new infringing product. 57 F.3d at 1059-60 (quoting BP Chems., 4 F.3d at 978). We further explained that "[t]he residual possibility of a future infringement suit based on Chase's future acts is simply too speculative a basis for jurisdiction over Chase's counterclaim for declaratory judgments of invalidity." Id. at 1060.

In Amana Refrigeration, Amana sued Quadlux for "declaratory judgments of patent invalidity and noninfringement." 172 F.3d at 855. Quadlux responded with a promise not to sue Amana for patent infringement based on the patent-in-suit "as it presently reads, with respect to any product currently advertised, manufactured, marketed or sold by Amana, or any product which was advertised, manufactured, marketed or sold by Amana prior to the date of" the promise. Id. We held that this promise divested the district court of jurisdiction, notwithstanding that at some indefinite point in the future, Amana might develop new products or the PTO might reissue the patent-in-suit with altered claims. Id. at 855-56.

Although neither Super Sack nor Amana has been expressly overruled, both applied the disapproved "reasonable apprehension of imminent suit" test. Therefore, although the holdings in both cases are not necessarily dependent on the "reasonable apprehension of imminent suit" requirement, we nevertheless base our analysis of

whether jurisdiction currently exists over Nucleonics's declaratory judgment counterclaims strictly on the framework of MedImmune.

Nucleonics is currently researching applications of RNAi with an eye to treating human diseases, such as hepatitis B. Section 271(e)(1) of Title 35 of the United States Code provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The parties have now both taken the position that Nucleonics's present activities related to the human medical application of RNAi are, in light of § 271 and the Supreme Court's decision in Merck, not infringing and cannot become infringing until after Nucleonics files a new drug application ("NDA") with the U.S. Food and Drug Administration ("FDA"). Nucleonics took this position, which the dissent does not mention, even before the decision in Merck. Benitec acknowledged lack of infringement later when it moved to dismiss its infringement claims. Nucleonics does not even anticipate filing an NDA before "at least 2010-2012, if ever." Therefore, Nucleonics's activities of developing and submitting information to the FDA related to human application of RNAi does not present a case or controversy of sufficient immediacy and reality to warrant declaratory judgment jurisdiction over the enforceability of the '099 patent. The fact that Nucleonics may file an NDA in a few years does not provide the immediacy and reality required for a declaratory judgment. The situation is analogous to that in Telectronics Pacing

Systems, Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992), where we affirmed the district court finding that a defibrillator component manufacturer's claim for future patent infringement lacked a sufficient allegation of immediacy to support a declaratory judgment action since the potentially infringing defibrillator had only recently begun clinical trials and was years away from possible FDA approval.

Nucleonics argues that Fort James Corp. v. Solo Cup Co., 412 F.3d 1340, 1342 (Fed. Cir. 2005), supports its position that the court has jurisdiction. In Fort James, the plaintiff sued Solo Cup for infringement of three patents. Solo Cup "counterclaimed for declarations that the patents were invalid, unenforceable, and not infringed." Id. at 1343. The district court bifurcated the proceedings; all issues were to be tried to a jury first, except Solo Cup's unenforceability counterclaim, which was to be tried by the court following the jury trial. Id. at 1344. The jury found that one of the patents-in-suit was neither invalid nor infringed. Id. at 1345. Fort James then promised not to sue Solo Cup on any of the three patents for any product Solo Cup currently or previously manufactured and to "not seek to overturn the jury's verdict." Id. Solo Cup nonetheless wished to press forward with its declaratory claim for invalidity of one of the patents. Id. We held that there was still declaratory judgment jurisdiction over Solo Cup's counterclaim. Id. at 1349. The majority stated that Fort James's promise not to sue "had no effect on Fort James's claim for infringement, because that controversy had already been resolved by the jury's verdict." Id. at 1348. The majority concluded that "the jury verdict holding that Solo Cup did not infringe Fort James's patents did not moot Solo Cup's counterclaim for unenforceability nor did it act to divest the district court of jurisdiction to hear that unlitigated counterclaim." Id.

Contrary to Nucleonic's assertions, Fort James does not compel jurisdiction here. The instant setting is different because no trial of the infringement issue has taken place. Benitec instead had its claims dismissed at its request before a trial and the considerable effort connected therewith had taken place. The court in Fort James distinguished Super Sack on this "unique procedural posture":

> In Super Sack and its progeny, the patentee's covenant not to sue was filed prior to consideration or resolution of the underlying infringement claim. In such circumstances, the promise not to sue obviated any reasonable apprehension that the declaratory judgment plaintiff might have of being held liable for its acts of infringement. . . . Here, however, the Post-Verdict Covenant had no effect on Fort James's claim for infringement, because that controversy had already been resolved by the jury's verdict.

Id. at 1348.

In SanDisk, we did hold that the statement of STMicroelectronics NV's ("ST") vice president of intellectual property and licensing that "ST has absolutely no plan whatsoever to sue SanDisk" did not eliminate the justiciable controversy created by ST's actions. 480 F.3d at 1382. However, ST's statement was made when ST had engaged in a course of conduct that showed a willingness to enforce its patent rights despite its vice-president's statement. ST had approached SanDisk having made a studied and considered determination of infringement by SanDisk and having communicated that determination to SanDisk. It then only stated that it did not intend to sue SanDisk; it did not say it would not sue SanDisk in the future for its alleged infringement. Id. at 1382-83. In the instant case, Benitec made its covenant and sought dismissal of its infringement claim after it concluded that the Merck decision precluded an infringement claim based upon the activities of Nucleonics on which it, Benitec, had instituted its suit. Under these circumstances, there is no controversy between the

parties concerning infringement by Nucleonics in its development of human applications of RNAi technology.

b. Animal Application of RNAi

Nucleonics now states, however, that it wishes to expand into animal RNAi products. Such products presumably would not be protected from infringement by § 271(e)(1) because they would appear to fall within its parenthetical exception to the safe harbor that excepts from infringement protection any "new animal drug or veterinary biological product . . . which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques."

Nucleonics submitted to the district court the declaration of its president[3] who stated:

> Nucleonics wishes to expand its efforts beyond human health to animal husbandry and veterinary products. To this end, Nucleonics has entered into discussion with a large supplier of breeding stock for a variety of livestock food species regarding their needs and how RNA interference might be utilized to provide them a competitive advantage. These discussions began around May 25 of 2005; a meeting was held in Nashville on July 27. Nucleonics has executed a confidentiality agreement between the parties, which is a prerequisite to detailed technical discussions. Nucleonics expects work and research involving RNAi technology will commence shortly.

Nucleonics argues that the evidence offered by its president shows a justiciable case or controversy that supports declaratory judgment jurisdiction over its potential expansion to animal husbandry and veterinary products. To be liable as an infringer, Nucleonics must be one who "without authority makes, uses, offers to sell, or sells" a

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[3] Benitec did not raise evidentiary objections to the declaration before the district court and therefore will not be heard to object now.

product that infringes the '099 patent. See 35 U.S.C. § 271(a). There was no evidence before the district court that Nucleonics had made or sold any infringing product.[4]

The meaning of "offer to sell" in § 271(a) is the offer of common law contracts. Rotec Indus. v. Mitsubishi Corp., 215 F.3d 1246, 1254-55 (Fed. Cir. 2000). The declaration of Nucleonics's president does not indicate that Nucleonics's desire to expand into animal markets has yet produced any definite offer which the unnamed "supplier of breeding stock" could accept. Nucleonics has not shown that it is engaged in any "use" of the patented invention that could subject it to an infringement suit by Benitec. Nucleonics has therefore not met its burden of showing that it is engaged in any present activity that could subject it to a claim of infringement by Benitec. See Microchip Tech., 441 F.3d at 943. In other words, Nucleonics has not shown that its discussions regarding expansion into animal husbandry and veterinary products meet the immediacy and reality requirement of MedImmune. See MedImmune, 127 S. Ct. at 771.

Nucleonics has also failed to show that its future plans meet the immediacy and reality requirement of MedImmune necessary to support a justiciable controversy. Three reasons compel the conclusion that Nucleonics has not done so.

First, Nucleonics's only steps toward potentially-infringing animal research are discussions with an unnamed potential customer and execution of an undescribed confidentiality agreement. Nucleonics merely "expects" to begin work "shortly." We do not doubt the veracity of Nucleonics's president's statements—indeed, there is no

[4] In fact, when Nucleonics moved for leave to file its counterclaims of invalidity and unenforceability on January 16, 2005, it apparently had not even begun discussions about expanding into animal husbandry and veterinary products.

evidence to the contrary. However, to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent.

Second, and particularly given the uncertain contours of § 271(e)(1), see Merck, 545 U.S. at 202, Nucleonics has provided insufficient information for a court to assess whether Nucleonics's possible future animal work would be infringing or not. The Supreme Court in Merck held that § 271(e)(1) "exempted from infringement all uses of patented compounds 'reasonably related' to the process of developing information for submission under any federal law regulating the manufacture, use, or distribution of drugs." 545 U.S. at 206 (emphases in original). Although the allegedly infringing activity at issue in Merck did not implicate § 271(e)(1)'s parenthetical exception for animal drugs, here, based on the evidence Nucleonics has presented, one cannot tell if Nucleonics intends to undertake activity that would fall within § 271(e)(1)'s parenthetical exception or would otherwise be infringing.

Third, although Benitec originally argued that animal testing for human use was infringing activity, it has now concluded that such testing falls within § 271(e)(1)'s protection. Benitec has never challenged use of the technology in testing in animals for animal use and claims another company owns any right to do so. In any event, there is no evidence of a justiciable controversy between Benitec and Nucleonics over Nucleonics's vaguely defined potential expansion to animal husbandry and veterinary products.

We recognize that Nucleonics would like to remove any concerns it or its potential investors might have over possible infringement of the Benitec patent. We do

not express an opinion on whether Nucleonics's animal work could ever be the subject of an infringement suit. We merely hold that Nucleonics did not carry its burden of showing an existing justiciable controversy. As we observed in Teva:

> federal courts are to decide only actual controversies by judgment which can be carried into effect, and not to give opinions on moot questions or abstract propositions. . . . Although there can be a fine line between declaratory judgments and advisory opinions, the Supreme Court maintains the necessity of avoiding issuing advisory opinions on hypothetical facts.

482 F.3d at 1338-39 (internal quotations and citation omitted). We also recognize that Nucleonics wishes to receive the benefit of a ruling on the validity and scope of Benitec's patent now, while Nucleonics undertakes any nascent animal work. There is currently, however, no "substantial controversy, between [Benitec and Nucleonics], of sufficient immediacy and reality to warrant the issusance of a declaratory judgment." MedImmune, 127 S. Ct. at 771. And there may never be.

III. CONCLUSION

Nucleonics has not made a showing of "sufficient immediacy and reality" to support declaratory judgment jurisdiction. The district court's judgment of dismissal for lack of jurisdiction is affirmed.

AFFIRMED

United States Court of Appeals for the Federal Circuit

06-1122

BENITEC AUSTRALIA, LTD.,

Plaintiff-Appellee,

v.

NUCLEONICS, INC.,

Defendant-Appellant.

DYK, Circuit Judge, dissenting.

If this declaratory judgment action were filed today, I would agree with the majority that the required case or controversy had not been established. I also agree that there must be a case or controversy at all stages of the litigation. See Steffel v. Thompson, 415 U.S. 452, 459 n.10 (1974). However, in my view, a different test for determining whether there is a case or controversy applies when the allegation of infringement is withdrawn during the course of litigation. Supreme Court precedent requires that, if a patentee files an infringement lawsuit and the particular claim of infringement is mooted, a counterclaim for invalidity should not be dismissed unless the patentee demonstrates that there is no possibility of a future controversy with respect to invalidity. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 98 (1993). In my view, Benitec made no such showing.

I

There is a strong public interest in permitting accused infringers to challenge invalid or unenforceable patents. See Cardinal Chem., 508 U.S. at 100; Blonder-

Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 345-47 (1971); Lear, Inc. v. Adkins, 395 U.S. 653, 663-64 (1969); Altvater v. Freeman, 319 U.S. 359, 364-65 (1943). The Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 (1934), plays an important role in facilitating such challenges, in particular by preventing patent holders from threatening enforcement while avoiding litigation that might render the patent invalid or unenforceable. See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 734-35 (Fed. Cir. 1988). The Supreme Court in MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007), has recently emphasized the importance the Declaratory Judgment Act plays in protecting against the Hobson's choice of abandoning lawful endeavors or risking liability for infringement.[1] Id. at 772-73.

Here Benitec sued Nucleonics for infringement of Benitec's patent, broadly alleging that Nucleonics is "engaged in making, using, offering to sell, and selling gene silencing technologies that are the same or equivalent to the technologies claimed in the Benitec patent." J.A. at 71. Nucleonics timely answered the complaint, denying infringement and, nearly ten months later, moved to add declaratory judgment counterclaims asserting invalidity and unenforceability. At the time of Nucleonics's counterclaim filing, it was clear that there was declaratory jurisdiction because "[i]f . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a

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[1] The Advisory Committee Notes accompanying the 1937 adoption of Federal Rule of Civil Procedure 57 explain that

> [t]he controversy must necessarily be of a justiciable nature, thus excluding an advisory decree upon a hypothetical state of facts. . . . The existence or non-existence of any right, duty, power, liability, privilege, disability, or immunity or of any fact upon which such legal relations depend, or of a status, may be declared.

(internal quotation marks and citations omitted).

case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the Act." Cardinal Chem., 508 U.S. at 96 (emphasis in original); see also Arrowhead, 846 F.2d at 736.

Nonetheless, the majority holds that when the accused infringer has been sued "[t]he burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." Slip op. at 6. In my view, the majority's approach erroneously applies the same standard for judging continuing declaratory jurisdiction as for judging original declaratory jurisdiction.

II

Here the patentee's manipulative efforts to defeat declaratory jurisdiction are clear enough. After Nucleonics moved to add the counterclaims, the Supreme Court decided Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005), which addressed the 35 U.S.C. § 271(e)(1) safe harbor for research.[2] In Merck, the Supreme Court clarified that the safe harbor protects any research using a patented compound where the "drugmaker has a reasonable basis for believing that [the] patented compound may work . . . to produce a particular physiological effect, and uses the

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[2] Section 271(e)(1) provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product . . . which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

compound in research that, if successful, would be appropriate to include in a submission to the FDA." Merck, 545 U.S. at 207. The patentee does not claim that Merck provides any protection for commercial production of compounds for humans or production of or, even research for, animal compounds.

Following the Merck decision, Benitec, suggesting that it was unlikely to prevail on infringement claims directed to research on medical compounds for humans, filed a motion to dismiss the case without prejudice under Federal Rule of Civil Procedure 41(a)(2), asserting that there was no longer a continuing case or controversy. As the majority appears to recognize, slip op. at 3, the motion may well have been motivated by a desire to avoid a patent invalidity determination.

Benitec did not offer a formal covenant not to sue before the district court. Rather, it stated in its motion to dismiss that it "could only bring new claims if Nucleonics is ultimately successful in obtaining FDA approval for its infringing products or otherwise engages in infringing activities not otherwise permitted under the § 271(e) exemption." J.A. at 1379. Nucleonics opposed the motion to dismiss on several grounds, including that there was a continuing controversy because it had taken "concrete steps . . . with the intent to conduct" allegedly infringing activity, including research on drugs for animals. BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993).[3]

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[3] Nucleonics submitted the declaration of Robert J. Towarnicki, Nucleonics's president and CEO, stating that:

> Nucleonics wishes to expand its efforts beyond human health to animal husbandry and veterinary products. To this end, Nucleonics has entered into discussion with a large supplier of breeding stock for a variety of livestock food species regarding their needs and how RNA interference might be utilized to provide them a competitive advantage. These discussions began around May 25 of 2005; a meeting was held in

The district court granted the motion to dismiss without prejudice finding that, although "Nucleonics has demonstrated a reasonable apprehension of suit," it "has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec." Benitec Austl. Ltd. v. Nucleonics, Inc., No. 04-0174, slip op. at 6-8 (D. Del. Sept. 29, 2005).

Nucleonics filed this appeal, arguing that Benitec's statement was insufficient to eliminate declaratory jurisdiction. In an effort to defeat jurisdiction, Benitec expanded its representation, stating that its argument to the district court included—and was intended to include—a promise "not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action—September 29, 2005." Appellee's Br. 45. At oral argument, Benitec again purported to clarify its covenant. Benitec stated that it would not sue "for any research that was going on prior to the dismissal" or "for animal research that was done at the time of the dismissal." Notably, Benitec offered no covenant with respect to future human or animal products or animal research.

The majority holds that Nucleonics has the burden of demonstrating a continuing case or controversy as narrowed by Benitec's promises. Slip op. at 6. It concludes that Nucleonics has not met this burden as to either its human application of RNAi or its animal application of RNAi. Slip op. at 12, 15. In my view, the majority applies an erroneous test.

> Nashville on July 27. Nucleonics has executed a confidentiality agreement between the parties, which is a prerequisite to detailed technical discussions. Nucleonics expects work and research involving RNAi technology will commence shortly.

J.A. at 1412.

III

The Supreme Court has clearly established that once declaratory jurisdiction has been established, the burden shifts to the party seeking to divest the court of jurisdiction to prove that there is no longer a current case or controversy. See Cardinal Chem., 508 U.S. at 98. In Cardinal Chemical, we initially held that a finding of non-infringement moots a declaratory counterclaim for invalidity. Id. at 87. The Supreme Court reversed finding that "it is perfectly clear that the District Court had jurisdiction to entertain Cardinal's counterclaim" because "if . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the Act." Id. at 96 (emphasis in original). The Court explained that while the initial burden of establishing declaratory judgment jurisdiction rests on the party seeking a declaratory judgment, "once that burden has been met courts are entitled to presume, absent further information, that jurisdiction continues." Id. at 98.

In explaining the policy reasons for shifting the burden, the Court stated that "[a] company once charged with infringement must remain concerned about the risk of similar charges if it develops and markets similar products in the future." Id. at 99-100. Moreover, declining jurisdiction over invalidity counterclaims "creates [the] potential for relitigation and imposes ongoing burdens on competitors who are convinced that a patent [is] invalid." Id. at 101; see also Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace and Agric. Implement Workers of Am., 523 U.S. 653, 660 (1998) ("[T]he only question is whether the parties had any concrete dispute over the contract's voidability at the time the suit was filed." (emphasis added)). Nothing

in the Supreme Court's recent MedImmune decision, 127 S. Ct. 764, suggests that the same test for determining whether a case or controversy exists applies throughout the lawsuit.

The majority distinguishes Cardinal Chemical as resting on the fact that at the time of the alleged mootness the case was on appeal after a judgment of non-infringement, but there is nothing in the Supreme Court's decision that restricts its burden-shifting holding to that limited context. Slip op. at 7. Contrary to the majority, Cardinal Chemical cannot be limited to mootness at the court of appeals level. If a case is not moot when the case is on appeal, it can hardly be moot in identical circumstances at the district court level. Our decisions holding that Cardinal Chemical does not compel a district court to decide an invalidity counterclaim after entering a judgment of non-infringement are best understood as recognizing district court discretion under the Declaratory Judgment Act.[4] Indeed, in repeatedly recognizing that a district court may decide the invalidity issue after a judgment of non-infringement, we have confirmed that such cases are not moot in the Article III sense of the term.

In any event, this is not a case in which the patentee suffered an adverse judgment, but rather one in which it voluntarily abandoned its infringement suit in the light of unfavorable developments. It is particularly inappropriate to place the burden of establishing continuing jurisdiction on declaratory plaintiffs where, as here, the claim of

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[4] See, e.g., Liquid Dynamics v. Vaughan Co., Inc., 355 F.3d 1361, 1371 (Fed. Cir. 2004) ("A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed may either hear the claim or dismiss it without prejudice, subject to review only for abuse of discretion."); see also Cardinal Chemical, 508 U.S. at 95 n.17 ("[T]he Declaratory Judgment Act affords the district court some discretion in determining whether or not to exercise that jurisdiction, even when it has been established.").

mootness is the result of the opposing party's acts designed, at least in part, to defeat declaratory jurisdiction. "[T]here is an important public interest in protecting the legal system against manipulation by parties, especially those prone to involvement in repeat litigation, who might contrive to moot cases that otherwise would be likely to produce unfavorable precedents." Hart and Wechsler, The Federal Courts and the Federal System 204 (5th ed. 2003); see also Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("[O]ne who may become liable for infringement should not be subject to manipulation by a patentee who uses careful phrases in order to avoid explicit threats, thus denying recourse to the courts while damages accrue.").

In the closely related injunction context, the Supreme Court has repeatedly held that the defendant carries a heavy burden of demonstrating that a case is moot when it voluntarily ceases the accused conduct. As the Supreme Court noted in Iron Arrow Honor Society v. Heckler, 464 U.S. 67, 72 (1983), "[d]efendants face a heavy burden to establish mootness in such cases because otherwise they would simply be free to 'return to [their] old ways' after the threat of a lawsuit had passed. . . . Thus they must establish that 'there is no reasonable likelihood that the wrong will be repeated.'" (quoting United States v. W.T. Grant Co., 345 U.S. 629, 632 (1953)); see also Public Serv. Co. of Colo. v. Shoshone-Bannock Tribes, 30 F.3d 1203, 1206 n.3 (9th Cir. 1994). Similarly in Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc., 528 U.S. 167, 189 (2000), the Supreme Court again concluded that "[t]he heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again lies with the party asserting mootness." (internal quotation marks

omitted).[5] Cardinal Chemical confirms that the same rule governs in the declaratory context and requires a showing by the patentee that there is no reasonable likelihood that the controversy over the patent's validity and enforceability will recur.

IV

In my view, the patentee here has not come close to meeting its burden to show that there will be no future controversy. Even if we were to assume that there is no longer any possible controversy concerning Nucleonics's research on human drugs, there is a possibility that Nucleonics may in the future make human drugs that Benitec would challenge as infringing. Nucleonics has also stated that it intends to pursue animal research. While I agree with the majority that the future controversy would not satisfy the sufficient immediacy and reality test for the filing of a new suit today, Benitec has made no effort to demonstrate that the controversy between the parties will not recur. In fact, when asked at oral argument whether Benitec was "promising not to sue [Nucleonics] for animal product research that they begin" the day after argument, Benitec's counsel responded, "We have not made that statement that we would forebear suing them." Here Benitec's success in defeating declaratory jurisdiction will have the effect of inhibiting Nucleonics's ability to raise funds and conduct research and development. Nucleonics has stated that the threat of litigation has "hampered its efforts to obtain funding and to continue its business activities." Appellant's Br. 45 n.19.

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[5] See also Buckhannon Bd. & Care Home v. West Virginia Dep't Health and Human Res., 532 U.S. 598, 609 (2001) (stating that "[i]t is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur").

Benitec has not satisfied its burden to eliminate any future controversy concerning infringement of the '099 patent.

V

The majority's decision here is not only inconsistent with the Supreme Court precedent; it exposes an inconsistency in this court's own jurisprudence. We have twice previously addressed the question of continuing declaratory jurisdiction in suits for infringement where the patent holder has attempted to defeat continuing jurisdiction by a covenant not to sue. See Fort James Corp. v. Solo Cup Co., 412 F.3d 1340 (Fed. Cir. 2005); Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054 (Fed. Cir. 1995). As the majority recognizes, slip op. at 9, those cases rested on our now-rejected reasonable apprehension test, and may no longer be good law after MedImmune. 127 S. Ct. at 774 n.11. But assuming that they are still good law, they in fact conflict with each other.

In Super Sack, 57 F.3d 1054, we held that a covenant not to sue defeated jurisdiction, though we noted that the accused infringer "never contended that it ha[d] taken meaningful preparatory steps toward an infringing activity by planning to make a new product that may later be said to infringe," and that "[t]he residual possibility of a future infringement suit based on [the accused infringer's] future acts is simply too speculative a basis for jurisdiction over [the] counterclaim for declaratory judgments of invalidity." Id. at 1059-60.[6] In Fort James, 412 F.3d 1340, even though the accused infringer did not prove a controversy that would satisfy the sufficient immediacy and

[6] In Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999), we applied the same test to a covenant not to sue filed after the commencement of a declaratory action where no infringement action had been commenced.

reality test, we held the opposite—that a covenant not to sue for existing products did not render the declaratory claim moot, even though there was no evidence of a future controversy. Id. at 1348. While the majority here attempts to reconcile the two cases on the ground that the covenant in Super Sack came before a judgment of non-infringement, whereas in Fort James it came after a judgment of non-infringement, I fail to see why this should make any difference, nor did the dissent in Fort James itself. See id. at 1354 (Schall, J., dissenting).

VI

The effect of today's decision is to limit the availability of declaratory jurisdiction to challenge invalid and unenforceable patents by allowing patentees to moot such controversies by dismissing the original infringement action and covenanting not to bring suit on existing products, without any showing that the controversy will not recur in the future. I respectfully dissent.