

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BENITEC AUSTRALIA LTD.,                     :  
  :  
                          Plaintiff,                     :  
  :  
                  v.                                     : Civil Action No. 04-0174 JJF  
  :  
NUCLEONICS, INC.,                               :  
  :  
                          Defendant.                     :

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**MEMORANDUM OPINION**

September 29, 2005  
Wilmington, Delaware

*Joseph J. Farnan Jr.*  
FARNAN, District Judge

Pending before the Court is the Motion For Voluntary Dismissal Without Prejudice (D.I. 108) filed by Plaintiff, Benitec Australia, Ltd. ("Benitec").<sup>1</sup> For the reasons discussed, the Court will grant Benitec's motion.

#### BACKGROUND

The parties are engaged in conducting research and developing technologies to create therapeutics to treat disease using gene silencing technologies. On March 22, 2004, Benitec filed its Complaint (D.I. 1), alleging that Defendant, Nucleonics, Inc. ("Nucleonics"), infringes U.S. Patent No. 6,573,099 ("the '099 patent").

On February 16, 2005, Nucleonics files a Motion To Amend Its Answer to add seven declaratory judgment counterclaims of non-infringement, patent invalidity under 35 U.S.C. § 102, patent invalidity under 35 U.S.C. § 103, patent invalidity under 35 U.S.C. § 112(1), patent invalidity under 35 U.S.C. § 112(2), patent invalidity under 35 U.S.C. § 116, and patent unenforceability. (D.I. 91). On September 14, 2005, the Court issued an Order granting Nucleonics' Motion To Amend Its Answer

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<sup>1</sup> Defendant Nucleonics, Inc. filed an Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117). The Court will grant the Motion, and the Surreply will be deemed filed.

(D.I. 119).

The parties have not yet completed discovery.

#### **PARTIES' CONTENTIONS**

By its motion, Benitec contends that this case should be dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a) because of a substantive change in the law with regard to the scope of the exemption set forth in 35 U.S.C. § 271(e)(1). Specifically, Benitec contends that the recent decision of the United States Supreme Court in Merck KGAA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005), had the effect of negating the case or controversy before the Court with regard to infringement of Benitec's patents and, therefore, dismissal is warranted.

In response, Nucleonics contends that the Court retains jurisdiction to decide its counterclaims for invalidity, unenforceability, and non-infringement because Nucleonics has a reasonable apprehension of being sued by Benitec in the future. Nucleonics argues that, because Benitec filed a lawsuit for patent infringement against Nucleonics and Benitec has not provided Nucleonics with a covenant not to sue for past, present, and future acts, jurisdiction over the declaratory judgment counterclaims exists.

### LEGAL STANDARD

When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court. Buse v. Vanguard Group of Inv. Co., No. 91-3560, 1994 WL 111359, at \*2 (E.D. Pa Apr. 1 1994). Specifically, Rule 41(a)(2) provides: "[A]n action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper. If a counterclaim has been pleaded by a defendant . . . the action shall not be dismissed against the defendant's objection unless the counterclaim can remain pending for independent adjudication by the court. Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice." Fed. R. Civ. P. 41(a)(2)(2004). A Rule 41(a)(2) motion "will be determined after attempting to secure substantial justice to both parties." DuToit v. Strategic Minerals Corp., 136 F.R.D. 82 (D. Del. 1991) citing Lunn v. United Aircraft Corp., 26 F.R.D. 12, 14 (D. Del. 1960). Moreover, while considering the legitimate interests of both parties, the Court must bear in mind that a plaintiff's motion should be granted absent substantial prejudice to the defendant. Id. at 10.

## DISCUSSION

The Court concludes that dismissing Benitec's action would not cause substantial prejudice to Nucleonics because no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgment claims against Benitec.

Nucleonics objects to dismissing Benitec's action without prejudice because Nucleonics contends that Benitec's action "brought a public cloud of uncertainty" over Nucleonics. (D.I. 110 at 2.) Thus, Nucleonics contends that Benitec should not now be allowed to leave the playing field, keeping its patent safe from scrutiny with regard to invalidity or unenforceability, while continuing to taint Nucleonic's current and future business and technology with the threat of another lawsuit. Nucleonics argues that the Declaratory Judgment Act, 28 U.S.C. § 2201, permits the Court to independently adjudicate Nucleonics' counterclaims.

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996). Nucleonics has the burden of establishing the existence of an actual case or controversy. See Cardinal Chemical Co. v. Morton Intern., Inc., 508 U.S. 83, 95 (1993). When a party has

actually been charged with infringement of a patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a counterclaim pursuant to the Declaratory Judgment Act. Id. at 96. Furthermore, a counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement. Id. The issue before the Court, then, is whether an actual controversy sufficient to support the Court's jurisdiction over Nucleonics' declaratory judgment counterclaims continues to exist if Benitec's patent infringement claim is dismissed.

Benitec contends that dismissing its infringement claim divests the Court of jurisdiction to hear the counterclaims. However, a number of courts have held that withdrawing a charge of infringement will not necessarily preclude the existence of an actual controversy, especially if, as here, the withdrawal occurs after the filing of the declaratory judgment action. See, e.g., C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 881 (Fed. Cir. 1983); Societe de Conditionnement v. Hunter Eng'g, 655 F.2d 938 (9th Cir. 1981). In turn, Nucleonics contends that, because Benitec has refused to enter into a covenant not to sue for enforcement of the '099 patent against Nuceonics at a later time, an actual controversy necessarily exists. However, a patentee's refusal to promise not to enforce the patent, while "relevant to the [actual

controversy] determination," is "not dispositive." BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 980 (Fed. Cir. 1993).

In the alternative, Nucleonics contends that it has a reasonable apprehension of suit because Benitec has already sued Nucleonics and others for patent infringement, Benitec has not promised not to assert the '099 patent against Nucleonics in the future, and Benitec has requested a voluntary dismissal of its action without prejudice. In reply, Benitec contends that Nucleonics has nothing to fear because Nucleonics' research activities are exempt from infringement liability pursuant to §271(e)(1) and the Supreme Court's decision in Integra.

The test for determining whether an actual case or controversy exists in a declaratory judgment action involving patents is two-pronged. First, the defendant's conduct must have created on the part of the plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the product or have prepared to produce that product. Indium Corp. v. Semi-Alloys, Inc., 781 F.2d 879 (Fed. Cir. 1985)

With regard to the first prong, the Court concludes that Nucleonics has demonstrated a reasonable apprehension of suit. The factual background in this case is such that Nucleonics could

be concerned that Benitec would, at some time, file a patent infringement suit against it. By suing Nucleonics and alleging that Nucleonics' technology is now covered by the Benitec's patent, Benitec has engaged in a course of conduct that shows a willingness to protect that technology. See, e.g., C.R. Bard v. Schwartz, 716 F.2d 874, 880-81 (Fed. Cir. 1983); Int'l Medical Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575, 229 U.S.P.Q. 278, 281 (Fed. Cir. 1986)

With regard to the second prong, production or preparation of a product, Nucleonics contends that its entire research effort is devoted to the RNAi area of technology and its activities will ultimately leave the safe harbor created by Integra. Nucleonics further alleges that it anticipates beginning research on livestock diseases, which are unprotected by the safe harbor. In response, Benitec argues that future infringement is not ripe for adjudication because Benitec's product may never be approved by the FDA or may be approved in a form that does not implicate the claims of the '099 patent. (D.I. 115 at 18.)

The declaratory judgment plaintiff carries the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. Jervis B. Webb Co., 742 F.2d 1388, 1399 (Fed. Cir. 1984). On the record before it, the Court concludes that Nucleonics 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. At the time this lawsuit was filed, Nucleonics was several years away from obtaining FDA approval. Further, as argued by Benitec, there is no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed. And finally, Nucleonics has adduced no evidence that it has undertaken sales or marketing activity with regard to any product. For these reasons, the Court concludes that any threat of litigation that may have existed now lacks sufficient immediacy and reality to support declaratory judgment jurisdiction.

#### **CONCLUSION**

In the circumstances presented here, the Court concludes that no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonic's declaratory judgment claims against Benitec with regard to the '099 patent. Accordingly, the Court will grant Benitec's Motion For Voluntary Dismissal Without Prejudice (D.I. 108).

An appropriate Order will be issued.

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FOR THE DISTRICT OF DELAWARE

BENITEC AUSTRALIA LTD., :  
 :  
 Plaintiff, :  
 :  
 v. : Civil Action No. 04-0174 JJF  
 :  
 NUCLEONICS, INC., :  
 :  
 Defendant. :

O R D E R

At Wilmington, this 29th day of September 2005, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. The Motion For Voluntary Dismissal Without Prejudice (D.I. 108) filed by Plaintiff, Benitec Australia, Ltd. is GRANTED.
2. Defendant Nucleonics, Inc.'s Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117) is GRANTED.
3. The Surreply attached as Exhibit 1 to the Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117) is deemed filed.

  
UNITED STATES DISTRICT JUDGE