

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,)

Plaintiff,)

v.)

F. HOFFMANN-LA ROCHE LTD, a)

Swiss Company, ROCHE DIAGNOSTICS)

GMBH, a German Company, and)

HOFFMANN LA ROCHE INC., a New)

Jersey Corporation,)

Defendants.)

Civil Action No.: 1:05-cv-12237 WGY

**AMGEN INC.'S EMERGENCY MOTION TO DISMISS FOR LACK OF SUBJECT
MATTER JURISDICTION**

I. INTRODUCTION

Amgen Inc. (“Amgen”) files this motion seeking to dismiss the claims of defendants, F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH and Hoffmann La Roche, Inc. (collectively “Roche”), regarding the invalidity of claims 4 and 5 of the United States Patent No. 5,618,698 (the “‘698 Patent”) for lack of subject matter jurisdiction.¹ On or about August 2, 2007 Amgen sent a letter to Roche indicating that Amgen would not be proceeding against them on claims 4 and 5 of the ‘698 Patent.² Indeed, Roche acknowledged Amgen’s statement in the Trial Brief it filed with the Court in this matter.³ Notwithstanding Amgen’s statement, it has become clear from this same Trial Brief that Roche intends to proceed forward on its counterclaims that claims 4 and 5 of the ‘698 Patent are invalid.⁴ Accordingly, Amgen is herewith filing a Covenant Not to Sue (“Covenant”) which confirms its prior agreement not to sue Roche for infringement of claims 4 and 5 of the ‘698 Patent. The effect of this Covenant, as a matter of settled Federal Circuit law, is to eliminate any case or controversy over the validity, enforceability or infringement of claims 4 and 5 of the ‘698 Patent. Accordingly, Roche’s claims challenging the validity, enforceability and infringement of claims 4 and 5 of the ‘698 Patent are non-justiciable and must be dismissed for lack of subject matter jurisdiction.

II. STATEMENT OF FACTS

Amgen filed this action seeking a declaratory judgment that Roche infringed a number of

¹ By this motion, Amgen is not withdrawing its claims with respect to any other claims of the ‘698 patent or its claims with respect to any other patents at issue in this litigation. Amgen in no way concedes Defendants’ allegations that claims 4 and 5 or that any claim of the ‘698 patent is invalid, unenforceable, or not infringed.

² A copy of this letter is attached as Exhibit A to the Affidavit of Patricia R. Rich filed herewith.

³ See Roche’s Trial Brief [DN 919] , p.18, fn 7.

⁴ See Roche’s Trial Brief at pp. 44-49 [DN 919].

Amgen's patents. Included in the patents asserted is the '698 Patent. In its Complaint, Amgen sought, among other things, a declaratory judgment that Roche infringed claims 4-9 of the '698 Patent. However, on or about August 2, 2007, Amgen sent a letter to Roche which stated that "Amgen will not assert '698 claims 4 and 5 at trial."⁵

Roche acknowledged Amgen's statement in the Trial Brief Roche filed with this Court on August 31, 2007. Specifically, Roche stated that Amgen's claim for declaratory relief with respect to claims 4 and 5 of the '698 patent were no longer to be decided by the Court.

Now, in confirmation of its statement to Roche in the August 2, 2007 letter, Amgen files the Covenant herewith. Specifically, the Covenant provides, in part, that:

Amgen, Inc., on behalf of itself and any successor-in-interest to United States Patent No. 5,618,698 (the "'698 Patent'"), hereby unconditionally and irrevocably covenants (1) not to assert claims 4 and 5 of patent infringement (including direct infringement, contributory infringement, and inducing infringement) against F. Hoffmann-La Roche Ltd., a Swiss Company, Roche Diagnostics GmbH, a German Company, and Hoffmann La Roche, Inc., a New Jersey Corporation (collectively "Defendants") under the '698 Patent. This covenant covers any and all methods, processes, and products made, used, offered for sale, sold, or imported by any Defendants, at any time, whether before or after the date of this covenant. As used in this covenant, "products" broadly includes any glycosylated erythropoietin polypeptide (whether or not such polypeptide has polyethyleneglycol attached to it). This covenant does not extend to any affiliate or customer of Defendants.

⁵ See *Rich Aff. at Ex. A.*

III. ARGUMENT

A. Subject Matter Jurisdiction Requires An Actual Case or Controversy

The Declaratory Judgment Act requires that there must be the existence of an actual case or controversy to meet the prerequisite for subject matter jurisdiction.⁶ An actual controversy must exist through all stages of the litigation, not merely at the time the action was filed.⁷ Accordingly, a party or the Court can raise the issue of subject matter jurisdiction at any time prior to final judgment.⁸ Moreover, “[s]imply because there is an actual controversy between the parties does not mean that the district court is required to exercise that jurisdiction.”⁹ Courts have held that even where an actual case or controversy exists, the court must still use “reasoned judgment” to determine if the investment of its resources would be “worthwhile.”¹⁰ As the United States Supreme Court recently decided in *MedImmune, Inc. v. Genetech, Inc.*, in order for a court to have jurisdiction over a declaratory judgment action the facts alleged must “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.”¹¹

B. In Light Of Amgen’s Covenant Not To Sue, There is No Actual Case or Controversy and, Therefore, No Subject Matter Jurisdiction.

The Federal Circuit has held that a patent owner’s covenant not to sue divests the district

⁶ 28 U.S.C. §§ 2201-2202;

⁷ *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975).

⁸ *Grupo Dataflux v. Atlas Global Grp., L.P.*, 14 S.Ct. 1920, 1924 (2004).

⁹ *Emc Corp. v. Norand Corp.*, 89 F. 3d 807, 813 (Fed. Cir. 1996).

¹⁰ *Id.*

¹¹ 127 S.Ct. 764, 771 (2007).

court of subject matter jurisdiction over claims for declaratory judgments of patent invalidity and unenforceability.¹² In *Super Sack*, the patent owner provided a covenant not to sue, similar to the one provided by Amgen here, and based on that the Federal Circuit held that by promising not to sue, Super Sack had eliminated “the existence of an actual controversy,” which thereby rendered the declaratory judgment claim nonjusticiable.¹³

The Federal Circuit made a similar finding in *Amana Refrigeration, Inc. v. Quadlux, Inc.*¹⁴ In that case, the Federal Circuit found that subject matter jurisdiction had been destroyed as a result of “Quadlux’s promise not to assert any infringement claim against Amana under the patent as it presently reads, with respect to any product previously or currently advertised, manufactured, marketed, or sold by Amana.”¹⁵

More recently, in *Benitec Australia, Ltd. v. Nucleonics, Inc.*¹⁶, the Federal Circuit, applying the United States Supreme Court’s standard for declaratory judgment jurisdiction from *MedImmune*, held that Nucleonics did not make a “showing of ‘sufficient immediacy and reality’ to support declaratory judgment jurisdiction” for its counterclaims where the patentee promised not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date of dismissal in the action.¹⁷

Here, Amgen has not only provided Roche with a letter indicating that it will not pursue

¹² See *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F. 3d 1054, 1058 (Fed. Cir. 1995).

¹³ *Id.* at 1055, 1060

¹⁴ 172 F.3d 852 (Fed. Cir. 1999).

¹⁵ *Id.* at 855.

¹⁶ 2007 U.S. App. LEXIS 17299 (Fed. Cir. 2007)

¹⁷ *Id.* at *24-25.

declaratory judgment relief concerning infringement of claims 4 and 5 of the '698 Patent, it has also provided Roche with the Covenant, which expressly provides that Amgen will not now or in the future sue Roche for infringement of claim 4 or 5 of '698 Patent. Having provided this covenant not to sue, Roche can no longer, as a matter of law, establish a "substantial controversy, between parties having adverse legal interests" necessary to for subject matter jurisdiction.¹⁸ Roche can have "no cause for concern that it can be held liable for any infringing acts" involving its products vis a vis claims 4 and 5 of '698 Patent.

¹⁸ *MedImmune*, 127 S.Ct. at 771.

III. CONCLUSION

Based on the foregoing, Amgen's covenant not to sue Roche for patent infringement of claims 4 or 5 of the '698 Patent has extinguished any justiciable controversy regarding the invalidity, unenforceability and non-infringement of claims 4 or 5 of the '698 Patent, and vitiated the subject matter of this Court as to those counterclaims. Accordingly, Amgen respectfully requests that the Court grant this motion to dismiss Roche's counterclaims regarding the invalidity, unenforceability and non-infringement of claims 4 or 5 of the '698 Patent.

Dated: September 3, 2007

Respectfully Submitted,

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By its attorneys,

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Patricia R. Rich

Patricia R. Rich

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Patricia R. Rich

Patricia R. Rich