

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)
)
 Plaintiff,)
)
 v.) C.A. No. 06-230 (GMS)
)
 APOTEX, INC.,)
)
)
 Defendant.)
)
)

**MERCK & CO., INC.’S MOTION TO DISMISS FOR LACK OF SUBJECT
MATTER JURISDICTION IN LIGHT OF MERCK’S COVENANT NOT TO SUE**

Plaintiff Merck & Co., Inc. (“Merck”) moves for an order in the form attached (Exhibit A) dismissing this action for lack of subject matter jurisdiction because the covenant not to sue (Exhibit B) that Merck has given Defendant Apotex, Inc. (“Apotex”) removed the controversy between the parties and has mooted this case. *Super Sack Manf. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995).

BACKGROUND

This is an action for patent infringement based upon Apotex’s filing of an Abbreviated New Drug Application (“ANDA”), which is directed to a generic version of Merck’s FOSAMAX® tablets. Apotex sent a “Paragraph IV” letter to Merck dated February 24, 2006, which notified Merck: that Apotex had filed ANDA No. 077-982 for a generic version of Merck’s FOSAMAX® tablets, that Apotex intended to market such generic tablets before the expiration of nine Merck patents listed in the FDA’s Orange Book for FOSAMAX® tablets, and that the ANDA certified that Merck’s patents are invalid, unenforceable and/or will not be

infringed by the commercial manufacture, use, or sale of Apotex's alendronate sodium tablets before their expiration.¹

Merck filed its complaint on April 7, 2006, and alleged patent infringement by Apotex of these nine patents pursuant to 35 U.S.C. § 271(e)(2)(A) based upon Apotex's filing of the ANDA (D.I. 1). On May 9, 2006, Apotex answered the complaint by denying the infringement allegations and asserting a counterclaim seeking a declaration of invalidity and noninfringement of the nine patents (D.I. 8). Merck answered Apotex's counterclaim on May 30, 2006 (D.I. 11).

Pursuant to a Confidentiality Agreement, Apotex forwarded to Merck excerpts of the ANDA. After reviewing these excerpts, Merck notified Apotex in early July 2006 that it would grant a covenant not to sue on all claims of the patents in suit. Merck forwarded a copy of the covenant not to sue on August 7, 2006 (Exhibit C).

At the scheduling conference held on August 8, 2006, Apotex indicated that it would contest dismissal based upon Merck's covenant not to sue (Exhibit D at 3-4). Following the scheduling conference, Merck sent a proposed order of dismissal to Apotex, and invited Apotex to explain any disagreement (Exhibit E). Apotex responded that the proposed order was "unacceptable," but failed to explain its position (Exhibit F).

ARGUMENT

As a result of Merck's covenant not to sue, this action is moot and the Court lacks subject matter jurisdiction over the purported controversy. *See Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631 (Fed. Cir. 1991); *Super Sack v. Chase*, 57 F.3d 1054 (Fed. Cir. 1995). In particular, there is no subject matter jurisdiction over Apotex's counterclaim because Merck's

¹ These nine patents are U.S. Patent Nos. 5,358,941; 5,681,590; 5,849,726; 6,008,207; 6,090,410; 6,194,004; 5,994,329; 6,015,801; and 6,225,294.

covenant not to sue moots Apotex's counterclaim. *Super Sack*, 57 F.3d at 1059 (Although defendant "may have some cause to fear an infringement under the [patents in suit] based on products that it may develop in the future," there is no subject matter jurisdiction over defendant's counterclaims where plaintiff's covenant not to sue removed any "cause for concern that [defendant] can be held liable for any infringing acts involving products that it made, sold, or used on or before [the date of any covenant not to sue]."). As in *Super Sack*, Merck's covenant not to sue has removed any cause for concern that Apotex could be held liable for infringement of the patents in suit in connection with its generic tablets in the form they are now contemplated (which Apotex has represented is reflected in the excerpts of the ANDA produced to Merck under the confidentiality agreement). Thus, the Court lacks subject matter jurisdiction over this action, including Apotex's counterclaim, and this action should be dismissed.

The Court addressed a virtually identical situation in another case earlier this year. In *Merck & Co., Inc. v. Watson Laboratories, Inc.*, C.A. No. 05-658 (GMS), Merck asserted the same nine patents against Watson, another generics company that also filed an ANDA for generic versions of Merck's FOSAMAX® tablets. Watson asserted counterclaims seeking similar relief. After reviewing excerpts of Watson's ANDA, Merck also granted a covenant not to sue to Watson. Although Watson contested Merck's motion to dismiss, the Court dismissed Merck's claims and Watson's counterclaims in light of *Super Sack*. *Merck & Co., Inc. v. Watson Laboratories, Inc.*, 2006 WL 1537375 (D. Del. 2006). Like *Super Sack* and *Merck v. Watson*, this case should also be dismissed.

CONCLUSION

Accordingly, Merck requests that the Court enter its proposed form of dismissal (Exhibit A) at the Court's earliest convenience.

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/s/ Mary B. Graham

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Dated: August 16, 2006
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CERTIFICATE OF SERVICE

I hereby certify that on August 16, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Richard L. Horwitz, Esquire
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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on August 16, 2006 upon the following individuals in the manner indicated:

BY E-MAIL AND HAND DELIVERY

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