

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)
)
 Plaintiff,)
)
 v.) C.A. No. 05-658 (GMS)
)
 WATSON LABORATORIES, INC.,)
)
 Defendant.)

MEMORANDUM

In the above-captioned action for patent infringement, plaintiff Merck & Co., Inc. (“Merck”) accuses defendant Watson Laboratories, Inc. (“Watson”) of infringing several patents by filing Abbreviated New Drug Application (“ANDA”) No. 76-768, which is directed to a generic version of one of Merck’s brand-name drugs. For reasons that are not important here, Merck decided it does not wish to continue prosecuting this action. Thus, Merck gave Watson a covenant not to sue in which “Merck unconditionally represents, stipulates, agrees, and covenants that it will not sue Watson for infringement of, or otherwise assert, enforce, or hold Watson liable for infringement of [the patents in suit] based on the importation, manufacture, use, sale, or offer for sale of the . . . tablets that are the subject of and described in Watson’s ANDA No. 76-768 . . .” (D.I. 17, Ex. B at 2.) Presently before the court is Merck’s motion to dismiss with prejudice for lack of subject matter jurisdiction.

In *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, the plaintiff in a patent infringement action decided it did not wish to continue prosecuting its claims against the defendant. 57 F.3d 1054, 1056 (Fed. Cir. 1995). Although the plaintiff did not take the step of delivering a separately-executed covenant to the defendant, the plaintiff did state in its briefing to the district court that it would “unconditionally agree not to sue [the defendant] for infringement as to any claim of the

patents-in-suit based upon the products currently manufactured and sold by [the defendant].” *Id.* Based on this representation, the district court dismissed the case for lack of subject matter jurisdiction. *Id.* at 1057. On appeal, the defendant argued that the plaintiff’s promise was legally powerless because it was merely a promise made by counsel in the course of briefing that would be unenforceable against the plaintiff in a future action. *Id.* at 1059. The Federal Circuit disagreed, holding that the counsel’s unconditional promise on behalf of the plaintiff was sufficient to bind the plaintiff “both now and in the future, by its promise not to sue [the defendant],” and thereby eliminated any “reasonable apprehension” the defendant may have had of facing an infringement suit. *Id.* As such, the district court had correctly determined that subject matter jurisdiction was lacking. *Id.* at 1060.

In this case, Watson argues that the covenant was “void upon execution” because, although Merck unconditionally promised not to sue Watson, Merck continued to assert its infringement claims against Watson. Thus, according to Watson, Merck’s promise not to sue does not remove any “reasonable apprehension” of an infringement suit so long as this suit remains pending. Suffice it to say, Watson’s argument is completely at odds with *Super Sack*. There, as here, the suit was still pending when the plaintiff promised not to sue the defendant, and yet the court held that the promise was sufficient to remove any “reasonable apprehension” of an infringement suit. Watson further argues that Merck’s covenant is unenforceable due to a lack of consideration. However, as far as the court is able to discern, the promise upheld in *Super Sack* was similarly unaccompanied by consideration. Watson also contends – somewhat confusingly – that because the covenant does not provide for dismissal of the complaint, this court has no jurisdiction to enforce the covenant. Again, the promise by the plaintiff in *Super Sack* seems to have suffered from the same alleged infirmity,

and yet it was upheld. Moreover, because any dismissal pursuant to Merck's covenant would be with prejudice, *res judicata* will likely prevent Merck from re-filing this suit regardless of the enforceability of the covenant. Therefore, the covenant is sufficient to remove any "reasonable apprehension" Watson may have of being sued for infringement by Merck.¹

Watson argues that even if the covenant is sufficient, the court retains jurisdiction to resolve the parties' dispute over the form of dismissal because this case involves the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, "which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282." *Minn. Mining and Mfg. Co. v. Riker Labs., Inc.*, 289 F.3d 775, 776-77 (Fed. Cir. 2002) ("3M"). In 3M, the plaintiff argued that the district court lacked subject matter jurisdiction to hear the plaintiff's patent infringement claims because information previously withheld and later disclosed by the defendant revealed that no infringement had actually occurred, thereby eliminating the existence of a case or controversy. *Id.* at 780. Moreover, because the defendant had withheld the exculpatory information, the plaintiff argued that there never was a case or controversy, and therefore, the case should be dismissed without prejudice. *Id.* The defendant disagreed, and argued that the case should be dismissed with prejudice. *Id.* The district court sided with the defendant, and the plaintiff appealed. *Id.* at 779. After explaining that the form of dismissal may have a significant effect on subsequent FDA proceedings due to the Hatch-Waxman Amendments, *i.e.*, possibly triggering a 180-day period

¹Watson contends that the covenant does not eliminate its apprehension because the covenant is only directed toward the "importation, manufacture, use, sale or offer for sale" of the tablets described in ANDA No. 76-768, but not the infringing act of filing the ANDA in the first place. (D.I. 22 at 9.) However, in its reply brief, Merck concedes that its covenant would indeed prevent it from accusing Watson of infringement by filing the ANDA. (D.I. 23 at 6 n.1.)

of market exclusivity for the first ANDA filer, the Federal Circuit held that the district court did in fact have jurisdiction to resolve the parties' dispute over the form of dismissal. *Id.* at 780. The Federal Circuit further held that the district court was correct to dismiss the plaintiff's claims with prejudice. *Id.* at 783-84.

In this case, Merck and Watson have both submitted proposed orders of dismissal. Merck's proposed order would have the court (1) dismiss all claims and counterclaims with prejudice, (2) order Watson to notify Merck of any changes to ANDA No. 76-768, and reserve the rights of the parties to reinstate their claims and counterclaims in the event that Watson acts outside the scope of Merck's covenant, (3) order each party to bear its own fees and costs, and (4) declare that the dismissal of Merck's claims has no bearing on whether Watson infringes Merck's patents, or on whether Merck's patents are valid and enforceable. (D.I. 17, Ex. A.) Watson's proposed order, on the other hand, would have the court (1) declare that ANDA No. 76-768 does not infringe any of the patents in suit, (2) reserve for Merck the right to file a later infringement suit "if Watson seeks approval for or sells a drug product other than the one presently described in" ANDA No. 76-768, (3) dismiss all claims (with prejudice) and counterclaims, (4) announce that it (the court) retains jurisdiction to enforce Merck's covenant, and (5) order each party to bear its own fees and costs. (D.I. 22, Ex. F.)

Although these very different proposed orders demonstrate sharp differences of opinion between the parties, the court is unable to resolve those differences in this case. The court's jurisdiction over Watson's declaratory judgment counterclaims is dependent upon a "reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit." *Super Sack*, 57 F.3d at 1058 (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed Cir.

1993)) (emphasis in original). However, the parties' agreement that Merck's claims should be dismissed with prejudice eliminates any "reasonable apprehension" of an infringement suit against Watson. Thus, the court has no subject matter jurisdiction to declare that ANDA No. 76-768 does not infringe any of the patents in suit. Moreover, given this court's inability and unwillingness to issue advisory opinions, the court cannot declare that the dismissal of Merck's claims has no bearing on whether Watson infringes Merck's patents, or on whether Merck's patents are valid and enforceable. Furthermore, the court cannot reserve the rights of the parties to reinstate their claims at a later date, because such rulings would prematurely resolve potential disputes between these parties, or between future parties to future lawsuits. Thus, the effect of dismissing Merck's claims with prejudice must be left for another day. The court also believes it would be imprudent to order Watson to notify Merck of any changes to ANDA No. 76-768. If Watson or any other ANDA filer is required by statute, regulation, or rule to provide such notification, then it should do so. However, this court will not create an additional obligation for Watson when others similarly situated may not be constrained by such an obligation. The court concludes it would be likewise imprudent to announce that it retains jurisdiction to enforce Merck's covenant in the absence of some alleged violation of that covenant.²

Watson's final argument is that permitting Merck to withdraw its claims at this stage would be improperly prejudicial under Fed. R. Civ. P. 41(a)(2) because such a withdrawal would require

²Watson argues that the court retains jurisdiction over Watson's demand for attorneys' fees. However, the seriousness with which Watson makes this argument is belied by the fact that Watson's proposed order of dismissal provides that each party should bear its own fees and costs. Moreover, the stated basis for attorneys' fees – in large part, that Merck filed suit on invalid patent claims – is unconvincing because Merck's petition for *writ of certiorari* seeking to overturn invalidation was denied *after* suit was filed. Merck filed its motion to dismiss only four months later. This sequence of events does not, in the court's opinion, warrant the award of attorneys' fees.

Watson to wait until both the expiration of Merck's patents and the expiration of the 180-day exclusivity period before marketing its generic.³ Watson's argument is flawed for at least two obvious reasons. First, dismissal of this case is required under Article III of the United States Constitution, which trumps the Federal Rules of Civil Procedure. Second, it is not clear that Watson will be prejudiced because not all of the patent claims asserted by Merck have been invalidated. Thus, even if the case were to proceed, Watson may not succeed in freeing itself from the reach Merck's intellectual property rights. Therefore, this argument does not warrant denying Merck's motion.

Dated: June 2, 2006

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE

³Watson was not the first ANDA filer.

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ORDER

IT IS HEREBY ORDERED THAT:

1. Merck's motion to dismiss (D.I. 17) be GRANTED;
2. All claims of Merck's complaint (D.I. 1) be DISMISSED with prejudice;
3. All counterclaims of Watson's answer (D.I. 5) be DISMISSED for lack of subject matter jurisdiction; and
4. Watson's motion for leave to file a motion for summary judgment (D.I. 20) be DENIED.

Dated: June 2, 2006

/s/ Gregory M. Sleet _____
UNITED STATES DISTRICT JUDGE