

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EURAND INC., CEPHALON INC., and)
ANESTA AG,)
)
Plaintiffs,)
)
v.) Civ. No. 08-889-SLR
)
MYLAN PHARMACEUTICALS INC.,)
MYLAN INC., BARR)
PHARMACEUTICALS INC., and BARR)
LABORATORIES INC.,)
)
Defendants.)

MEMORANDUM ORDER

At Wilmington this 1st day of October, 2009, having considered the materials in connection with plaintiffs'¹ motion to bifurcate (D.I. 31, 36, 48);

IT IS ORDERED that plaintiffs' motion to sever and stay discovery on defendants' antitrust and patent misuse counterclaims and related affirmative defense (D.I. 30) is granted.

1. Background. Eurand is the owner of U.S. Patent No. 7,387,793 ("the '793 patent"), which is directed to a skeletal muscle relaxant. Cephalon, the exclusive licensee of the '793 patent, is the holder of a Food and Drug Administration ("FDA")-approved New Drug Application² ("NDA") for cyclobenzaprine hydrochloride capsules sold under the tradename AMRIX®. The '793 patent is listed in the FDA's Orange

¹Cephalon, Inc., Anesta AG (collectively "Cephalon") and Eurand, Inc., ("Eurand").

²No. 21-777.

Book for AMRIX®. On September 29, 2008, Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively “defendants”) filed an Abbreviated New Drug Application (“ANDA”) with the FDA, seeking approval to market a generic version of the drug AMRIX®.

Defendants subsequently notified plaintiffs of the ANDA. In this communication, defendants stated an intent to rely upon the bioequivalence data of AMRIX® and also certified that defendants’ generic copy of AMRIX® would not infringe the ‘793 patent. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

a. Plaintiffs filed a patent infringement suit pursuant to 35 U.S.C. § 271(e)(2)(A),³ triggering a 30-month stay on the FDA’s approval of defendants’ ANDA. Defendants’ answer included, inter alia, the affirmative defense of patent misuse and counterclaims based on theories of patent misuse and antitrust. (D.I. 20 at 13, 17-23) Plaintiffs subsequently moved to sever and stay discovery on defendants’ antitrust and patent misuse counterclaims and affirmative defense pursuant to Fed. R. Civ. P. 42(b). (D.I. 30) Defendants oppose the motion only to the extent that plaintiffs seek bifurcation of the patent misuse affirmative defense and counterclaim. (D.I. 36 at 7)

2. Bifurcation. A court is authorized to bifurcate any issue or counterclaim “[f]or convenience, to avoid prejudice, or to expedite and economize” Fed. R. Civ. P. 42(b). The Federal Circuit has recognized that “[district courts] are afforded broad discretion to control and manage their dockets, including the authority to decide the order in which they hear and decide issues pending before them.” *Amado v. Microsoft*

³“(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]”

Corp., 517 F.3d 1353, 1362 (Fed. Cir. 2008). District courts have properly exercised this discretion through the “standard practice” of separating patent issues from related antitrust issues. *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed. Cir. 1986). Indeed, courts may realize economy and convenience in first trying the less complex⁴ patent issues. *See id.* at 1085.

3. Discussion. Plaintiffs seek to have two separate phases of trial, the first to determine issues of patent infringement, and the second, if necessary, to determine issues of patent misuse and antitrust violation. The court finds that this request is supported by the promotion of judicial economy and avoiding the injection of complex, unrelated and perhaps unnecessary issues into the patent infringement case.

a. With respect to conserving judicial economy, defendants’ antitrust and patent misuse claims may be rendered moot by resolution of the patent infringement issues. Plaintiffs point to defendants’ burden in showing that the infringement suit is “objectively baseless” to have any chance in succeeding on its theories of antitrust violation⁵ and patent misuse. *Prof'l Real Estate Investors v. Columbia Pictures Indus.*,

⁴“Less” is used in a strict comparative sense; the complicated legal concepts and technologies at issue in patent infringement and validity disputes provide an ample source of confusion for juries. Such confusion would only be magnified by the esoteric commercial complexities introduced by simultaneously trying an antitrust claim.

⁵Defendants’ antitrust counterclaim relies upon the “sham litigation” exception to the *Noerr-Pennington* doctrine. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). Pursuant to this doctrine, a patentee may enforce its patent without fear of antitrust liability. *See C.R. Bard v. M3 Sys.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998). To pierce this general immunity, a litigant must show, by clear and convincing evidence, that the infringement suit was “a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.” *Noerr*, 365 U.S. at 144.

508 U.S. 49, 60-61 (U.S. 1993). A finding that plaintiffs' suit is "objectively baseless" would require the court to accept that no reasonable patent owner, aware of defendants' intent to rely upon the bioequivalence data of AMRIX®, could believe that the defendants' generic product infringes the '793 patent. Even if plaintiffs do not succeed in proving infringement,⁶ the court could still determine that plaintiffs "realistically expect[ed] success on the merits," thus obviating the need to adjudicate time consuming and complex antitrust and patent misuse issues. *Id.*

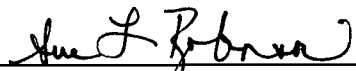
b. Defendants do not oppose bifurcation of the antitrust counterclaims. However, while a finding of patent misuse does not mandate a similar finding of antitrust violation, the issues are closely aligned as both inquire into anticompetitive behavior. *See Hunter Douglas, Inc. v. Comfortex Corp.*, 44 F. Supp. 2d 145, 156 (N.D.N.Y. 1999) (discussing *Hensley Equip. Co. v. Esco Corp.*, 383 F.2d 252, 261 (5th Cir. 1967)). Thus, any economies derived from severing the antitrust issues from the case at bar would be minimized by failing to also sever the issues of patent misuse. *Hunter Douglas*, 44 F. Supp. 2d at 157.

c. Further militating toward bifurcation of these issues is the distinct lack of evidentiary overlap between issues of patent validity and infringement and issues of patent misuse and antitrust. Indeed, assuming defendants can first show that plaintiffs' suit is "objectively baseless," defendants must still establish the substantive elements of patent misuse and antitrust violation. An antitrust action requires proof of elements such as antitrust injury and market power. A patent misuse claimant must establish the

⁶A successful infringement suit "is by definition a reasonable effort at petitioning for redress" *Profl Real Estate Investors*, 508 U.S. at 61 n.5.

patentee's bad faith and anticompetitive purpose. This evidence is largely, if not totally, irrelevant to discerning the existence of patent infringement or validity. Allowing defendants to introduce such evidence will serve only to distract the jury from the complicated, primary, and potentially dispositive issue of patent infringement.

4. Conclusion. After balancing the equities, the court finds that bifurcation of the patent infringement action from defendants' antitrust counterclaims and patent misuse affirmative defense and counterclaim is warranted. For the foregoing reasons, the court grants plaintiffs' motion to sever and stay discovery on defendants' antitrust and patent misuse counterclaims and related affirmative defense.


United States District Judge