IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, WYETH PHARMACEUTICALS INC., and PF PRISM C.V.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 12-808-SLR (Consolidated)
LUPIN PHARMACEUTICALS, INC., et al.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 2nd day of December, 2013, having reviewed *in camera* certain documents that defendant Lupin Pharmaceuticals, Inc. ("Lupin") wants to claw back, having produced them initially without claiming protection from disclosure under either the attorney-client privilege or the work product doctrine;

IT IS ORDERED that Lupin's request is denied, for the reasons that follow:

1. **Background.** The patent in suit, U.S. Patent No. 6,673,838 ("the '838 patent"), issued January 6, 2004 and relates to a novel salt of 0-desmethyl venlafaxine, that is, 0-desmethyl venlafaxine succinate, which salt has "properties which are particularly suitable for use as a drug, including improved solubility, permeability, and bioavailability." ('838 patent, col. 1:51-56) The '838 patent is listed in the Orange Book for "Pristiq," a drug listed since February 2008 for the treatment of major depressive disorder.

2. By letter dated May 11, 2012, Lupin notified plaintiffs Pfizer, Inc., Wyeth Pharmaceuticals, Inc. and Wyeth LLC, of the filing of its Abbreviated New Drug Application ("ANDA") No. 204-172, and its intention to engage in the commercial manufacture, use or sale of desvenlafaxine succinate extended-release tablets. The instant lawsuit was filed on June 22, 2012.

3. **Dispute.** During the course of discovery, Lupin produced more than 100 documents related to experiments conducted by scientists in Lupin's Intellectual Property Management Group between January and November 2011, which documents Lupin now wants to claw back as protected by either the attorney-client privilege or the work product doctrine. None of the documents bear any indication that they were shared with, or created under the direction of, an attorney. Indeed, it is evident that Lupin's outside counsel[1] had no knowledge whatsoever of the experiments as they were being conducted. Lupin, instead, depends on email exchanges with outside counsel at either end of the experimental study to justify protection from production.[2]

4. **Analysis.** Clearly, these documents are not protected under the attorney-client privilege, as they were neither created with the knowledge of outside counsel, nor were they shared with outside counsel contemporaneously. *See Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, Civ. No. 09-1685, 2010 WL 4537002, at *1 (M.D. Pa. Nov. 3, 2010) (citations omitted).

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[1]Apparently Lupin had no in-house counsel during the relevant period of time.

[2]More specifically, an email inquiry from outside counsel in April 2010 to see if Lupin needed counsel to work on desvenlafaxine, and an email inquiry from Lupin to outside counsel in October 2011 to see if counsel were available to do so, along with notice that Lupin had been working on a different salt of desvenlafaxine.

5. The harder question is whether they are protected by the work product doctrine. Pursuant to Fed. R. Civ. P. 26(b)(3), "[o]rdinarily, **a party may not discover documents** and tangible things **that are prepared in anticipation of litigation** . . . **by** or for **another party** or its representative (including the other party's attorney . . .)." Fed.R.Civ.P. 26(b)(3)(A) (emphasis added). By its plain language, an attorney need not be involved in the preparation of documents in order for such documents to be protected. *See, e.g., Spaulding v. Denton*, 68 F.R.D. 342 (D. Del. 1975). Instead,

> [t]he test for determining whether a document was prepared in anticipation of litigation is "where in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation." . . . Courts generally divide this test into two prongs: the documents were prepared (1) at a time when litigation was reasonably foreseeable; and (2) primarily for the purpose of litigation. . . . [T]he Third Circuit makes clear that the materials must be prepared in anticipation of litigation, and not in the ordinary course of business. . . . Otherwise, the privilege does not apply.

Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC, 2010 WL 4537002, at *2 (citations omitted).

6. I recognize that the documents at issue were generated under the complex administrative paradigm created under the Hatch-Waxman Act. Prior to market entry of a generic drug, the generic drug manufacturer must certify that a patent "is invalid or will not be infringed by the manufacture, use, or sale of the" generic drug; the holder of the patent has 45 days in which to file suit to resolve the issues of infringement and/or invalidity. If suit is filed, the FDA may not approve the ANDA until expiration of the patent, resolution of the lawsuit, or 30 months after the patentee's receipt of the notice,

whichever is earlier. *See generally* 21 U.S.C. §§ 271(e)(1), 355(b)(2)(A) and 355(j)(2)(A)(vii).

7. In other words, litigating the validity of patents is contemplated under the statute. Nevertheless, I decline to equate the ordinary course of business of a generic manufacturer (testing compounds in order to develop bioequivalent drugs) with the more specific conduct associated with anticipation of litigation (e.g., testing the compounds of the prior art in order to invalidate a patent), especially where, as here, there is no indication that the Lupin scientists were doing anything other than pursuing general scientific research on Lupin's prospective drug(s).[3] It is Lupin's burden to demonstrate that the documents at issue are protected from disclosure under Fed.R.Civ.P. 26(b)(3)(A). Lupin has failed to do so.

United States District Judge

[3]There are no declarations of record, nor any specific language in the documents themselves of what the goals of the scientists were. The only guidance as to the purpose of such testing is found in the email chain that directly preceded the testing, in which three questions are posed. Two of the questions relate to the status of certain of Wyeth's claims to desvenlafaxine succinate and crystalline desvenlafaxine succinate, with the third question directed to which polymorph Lupin could prepare. A general summary of the testing is found in the October 2011 email generated close to the conclusion of the testing, that is, Lupin had been "working on a different salt of desvenlafaxine."