IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| LEO PHARMA A/S, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civ. No. 10-269-SLR |
| | ) | |
| TOLMAR, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**MEMORANDUM ORDER**

At Wilmington this 27th day of October, 2011, having reviewed plaintiff's motions to amend and to extend time;

IT IS ORDERED that plaintiff's motion to amend (D.I. 55) is granted in part and denied in part, for the reasons that follow:

1. Plaintiff LEO Pharma A/S ("plaintiff") is the owner of the two patents-in-suit, U.S. Patent No. 6,753,013 (the "'013 patent") and Reissued Patent No. RE 39,706 (the "RE '706 patent"). Tolmar has submitted to the FDA ANDA Nos. 20-935 and 20-1615 ("the ANDAs") containing certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications"), certifying that, in Tolmar's opinion and to the best of its knowledge, the "013 patent and the RE '706 patent are invalid or will not be infringed by the manufacture, use, or sale of the new products for which the ANDAs were submitted ("the ANDA products"). Plaintiff thereafter filed suit alleging infringement of the RE'706 patent, pursuant to 35 U.S.C. § 271(e)(2).

2. In its motion to amend, plaintiff contends that Tolmar's proposed ANDA products will also infringe the '013 patent and proposes to add claims for infringement of such patent. The motion is granted as to this request. In this regard, plaintiff's second motion to amend (D.I. 70) is denied as moot.

3. Plaintiff also contends that Teva Pharmaceutical Industries Ltd. ("Teva") should be added as a defendant. More specifically, in counts IV through VII of the proposed amended complaint, plaintiff asserts that Teva manufactures the active pharmaceutical ingredient ("API") for use in Tolmar's proposed ANDA products and has submitted the Drug Master File to the FDA for the purpose of manufacturing the API for any subsequent commercial use in the United States. (D.I. 55, ex. 1) Based on these facts, plaintiff contends that Teva is jointly and severally liable for infringement: (a) pursuant to 35 U.S.C. § 271(e), because Teva participated in, contributed to, aided, abetted and/or induced the submission of Tolmar's ANDAs (*id.* at ¶¶ 44, 46, 51, 56, 61); (b) pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (g), if Teva "commercially manufactures, uses, offers for sale or sells," or "imports . . . into the United States, or induces or contributes to any such conduct," the API of the ANDA products (*id.* at ¶¶ 47 and 48); and (c) pursuant to 35 U.S.C. § 271(b), because Teva has "engag[ed] in a cooperative venture with Tolmar to submit the ANDA and [has] incorporate[d] by reference Teva's DMF thereto to the FDA to obtain approval to engage in the commercial manufacture, use, sale and/or importation" of Tolmar's ANDA products (*id.* at ¶¶ 54, 59 and 64).

4. The motion is denied insofar as plaintiff's claims of infringement relate to the

filing of the ANDAs.[1] Although "[p]arties 'actively involved' in preparing an ANDA are deemed to have 'submit[ted]' the ANDA," *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009), I decline to extend liability under § 271(e)(2) to third parties for work protected under § 271(e)(1). In this regard, I conclude that the allegation that Teva "participated in the work related to the submission" is distinguishable from actually preparing the ANDA.[2]

5. Moreover, it is apparent that an API manufacturer like Teva cannot be held liable for "inducing" the submission of the ANDAs. As explained by the Federal Circuit in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003),

> 35 U.S.C. § 271(e)(2)(A) simply provides an "artificial" act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product. . . . Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed. . . . **The proper inquiry under § 271(e)(2)(A) is "whether, if a particular drug were put on the market, it would infringe the relevant patent."** *Bristol-Myers Squibb Co. v. Royce Labs, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

---

[1]In other words, paragraphs 44, 46, 49, 51, 52, 56, 57, 61 and 62 are stricken from the proposed amended and consolidated complaint. With respect to paragraphs 53-54, 58-59, and 63-64, it is not apparent that there are any allegations of infringement based upon the future sale of the ANDA products separate and distinct from the underlying factual underpinning that Teva "engaged in a cooperative venture with Tolmar to submit the ANDA;" therefore, these paragraphs shall also be stricken.

[2]I recognize, however, that the line between engaging in protected work under § 271(e)(1), which "enables generic manufacturers to test and seek approval to market" ANDA products, *Warner-Lambert*, 316 F.3d at 1358, and being "'actively involved' in preparing the ANDA," e.g., by "contributing employees to the various teams responsible for preparing the ANDA," and having employees of each prepare and execute ANDA-related documents, *Cephalon,* 629 F. Supp. 2d at 349, is a fine one.

*Id.* at 1365-66 (emphasis added). In sum, while Federal Circuit precedent indicates that inducement of infringement is a cause of action under Hatch-Waxman, such precedent "provide[s] no support for the notion that inducement of the filing of an ANDA can be a cause of action." *AstraZeneca AB v. Mylan Laboratories, Inc.*, 265 F. Supp. 2d 213, 218 n.5 (S.D.N.Y. 2003).

6. Based on the above precedent, the motion is granted to the extent plaintiff adds claims of infringement against Teva based on the allegations contained in ¶¶ 47-48 in count IV. I am aware that this decision comes after the close of fact discovery and, therefore, will conduct a telephonic status conference on **November 3, 2011 at 10:00 a.m.**, in order to determine how the case should proceed.

IT IS FURTHER ORDERED that plaintiff's motion to extend time for joinder of parties (D.I. 53) is denied, as the court is not prepared to further delay this litigation for the addition of a third party who is not an indispensable party.[3]

United States District Judge

[3]Indeed, except to pursue discovery more easily, I am not sure why it makes sense to join the API manufacturers or similarly situated third parties at this juncture since, if the ANDA products are deemed to infringe the patents-in-suit, no third party may make, use, sell, or offer to sell such products without similarly infringing the patents-in-suit.