IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and ELAN PHARMA INTERNATIONAL LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-552-SLR
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

ELAN'S MOTION TO DISMISS COUNTS III AND VI OF TEVA PHARMACEUTICALS USA, INC.'S COUNTERCLAIMS AND TO STRIKE ITS THIRD AND SIXTH AFFIRMATIVE DEFENSES

Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd. (collectively "Elan") move pursuant to Rule 12(b)(6) to dismiss Counts III and VI of Teva Pharmaceuticals USA, Inc.'s ("Teva") counterclaims, and pursuant to Rule 12(f) to strike Teva's Third and Sixth Affirmative Defenses. These counterclaims and defenses are based on the allegation that Elan committed inequitable conduct through its purportedly false and misleading characterization of a prior art reference that was before the patent examiner during prosecution of the patents-in-suit. Federal Circuit precedent makes clear, however, that an applicant's characterization of prior art before the examiner cannot constitute inequitable conduct, as a matter of law.

1. This is one of several related actions[1] in this Court alleging infringement of two Elan patents – United States Patent Nos. 6,228,398 ("the '398 patent") and 6,730,325 ("the '325 patent") (collectively the "patents-in-suit") – by generic drug manufacturers seeking to market generic versions of FOCALIN XR, a once-a-day treatment for Attention Deficit Hyperactivity Disorder. (*See* D.I. 7 ¶ 15; Exs. A & B).

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[1] *See Elan Corporation, plc, et al. v. Intellipharmaceutics Corporation, et al.*, C.A. No. 07-603 (SLR); *Elan Corporation, plc, et al. v. Actavis South Atlantic LLC*, 07-679 (SLR) and *Elan Corporation, plc, et al. v. Barr Laboratories, Inc.*, 07-736 (SLR)

2. Teva answered the complaint on November 9, 2007, asserting six affirmative defenses and six counterclaims. (D.I. 9). Count III of Teva's counterclaims, directed to purported unenforceability of the '398 patent, alleges (¶¶ 14-18):

> 14. Based on information and belief, during the prosecution of the '398 patent, those involved with the prosecution of the '398 patent and having a duty of candor to the Patent Office under 37 CFR 1.56, including the ***patent applicants and their patent counsel, falsely and misleadingly characterized a piece of prior art before the Patent Office***, with the intent to deceive the Patent Office in granting the '398 patent over the prior art reference.
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> 15. Specifically, in a paper entitled "Petition of Accelerated Examination," filed in June 2000 on behalf of the patent applicants by their counsel Leona G. Young, ***the patent applicants, through counsel, characterized prior art reference U.S. Patent No. 5,837,284, Mehta et al***, as "disclos[ing] a formulation that is capable of a delayed release profile *in vitro*, but there is not disclosure of a formulation that produces an *in vivo* pulsed release profile.
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> 16. ***The characterization of U.S. Patent No. 5,837,284, Mehta et al***, including that U.S. Patent No. 5,837,284, Mehta et al, does not disclose a formulation that produces an in vivo pulsed release profile, ***was false and misleading***.
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> 17. Based on information and belief, ***the characterization of U.S. Patent No. 5,837,284, Mehta et al***, including that U.S. Patent No. 5,837,284, Mehta et al, does not disclose a formulation the products an in vivo pulsed release profile, ***was made with the intent to deceive the Patent Office***.
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> 18. ***As a result, the '398 patent is unenforceable*** in its entirety due to inequitable conduct.

3. Count VI of Teva's counterclaims, directed to enforceability of the '325 patent, is also based on Elan's characterization of the Mehta patent during prosecution. Count VI alleges that the '325 patent is a continuation of the application that became the '398 patent and "[a]s a result of the unenforceability of the '398 patent, the '325 patent is unenforceable under the doctrine 'infectious unenforceability' and 'unclean hands.'" (D.I. 9, ¶¶ 24-25).

4. Teva's Third and Sixth affirmative defenses simply refer to the allegations in Counts III and VI. (D.I. 9, pp. 4-5, 7-9).

5. Teva's unenforceability allegations in Counts III and VI of its counterclaims and in its Third and Sixth affirmative defenses are based solely on Elan's alleged characterization of the Mehta patent, which was before the examiner during prosecution. As a matter of law, such allegations cannot constitute inequitable conduct. *See, e.g. Genzyme Corp. v. Transkaryotic Therapies, Inc.,* No. 00-677-GMS, 2004 WL 2239248, at *2 (D. Del. Sept. 27, 2004) (***"mischaracterization of [prior art] is not actionable 'because the examiner was free to reach his own conclusion regarding . . . the art in front of him'"***) (quoting *Semiconductor Energy Lab. Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1482 (Fed. Cir. 2000).

6. Indeed, it is clear that "'[a]n applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.'" *Bayer AG v. Dr. Reddy's Labs. Ltd.*, No. 04-179-SLR, 2007 WL 3120794 at *11 (D. Del. Oct. 25, 2007) (quoting *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000)); *see also Molins PLC v. Textron*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

7. Moreover, the Federal Circuit has held that merely attempting to distinguish prior art "does not constitute a material omission or misrepresentation" because an "examiner was free to reach his own conclusion regarding [the prior art] based on the art in front of him." *Akzo, N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986); *see also Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007) (reversing grant of summary judgment of inequitable conduct based on an attorney's characterization of prior art in front of the examiner, explaining that, "the examiner was free to reach his own conclusions and accept or reject [patentee's] arguments"); *Life Techs., Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1325-26 (Fed. Cir. 2000) (holding that applicants "merely advocated a particular interpretation of the

teachings of [the article]. . ., which the Examiner was free to accept or reject," and such arguments "were not affirmative misrepresentations and cannot give rise to a determination of inequitable conduct").

8. Numerous district courts have similarly held that a "mischaracterization of [prior art] is not actionable because the examiner was free to reach his own conclusion regarding the art in front of him." *Genzyme Corp.,* No. 00-677-GMS, 2004 WL 2239248, at *2; *see, also, Semiconductor Energy Lab. Co. Ltd. v. Chi Mei Optoelectronics Corp.*, No. 04-4675-MHP, 2007 WL 1793770 at *8 (N.D. Cal. June 19, 2007) ("[Accused infringer's] assertion that [patentee] somehow duped the examiner into misinterpreting [the prior art] when the examiner was able to perform his or her own independent analysis of the reference cannot support an inequitable conduct defense."); *Blackhawk Molding Co. v. Portola Packaging, Inc.*, 422 F. Supp. 2d 948, 964 (N.D. Ill. 2006); *Bayer Healthcare LLC v. Abbott Labs.*, No. 03-189-GMS, 2004 WL 2862267, at *2 (D. Del. Dec. 10, 2004) ("[W]here all the pertinent information was available to the examiner, the defendant's inequitable conduct defense may fail as a matter of law for lack of materiality."); *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 386 (D. Del. 2000) (Farnan, J.) (holding that "even if Plaintiff's characterization of the [prior art] patents was inaccurate, . . . this characterization would not rise to the level of a material misrepresentation" because plaintiff "submitted the [prior art] patents with the IDS for the Examiner's review").

9. The Court may dismiss a counterclaim for "failure to state a claim upon which relief can be granted" and strike "any insufficient defense" when a pleading does not "contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory." *Bell Atl. Corp. v. Twombly*, __ U.S. ___, 127 S. Ct. 1955, 1969 (2007). Here, Teva's allegations of unenforceability in Counts III and VI of its counterclaims and in its Third and Sixth affirmative defenses are based solely on Elan's

characterization of prior art that was admittedly before the patent examiner. Such allegations cannot as a matter of law constitute inequitable conduct and thus Counts III and VI should be dismissed and Teva's Third and Sixth affirmative defenses stricken.[2]

CONCLUSION

For the foregoing reasons, Elan requests that Counts III and VI of Teva's counterclaims be dismissed for failing to state a claim upon which relief can be granted, and its Third and Sixth Affirmative Defenses be stricken.

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[2] Teva's counterclaims and affirmative defenses of inequitable conduct and infectious unenforceability also fail as they are not pleaded with the particularity required by Fed R. Civ. P. 9(b). Count III of Teva's Counterclaims does not allege any facts showing that anything, was false or misleading about the characterization of the Mehta patent. *See Reid-Ashman Mfg. v. Swanson Semiconductor Serv. LLC,* No. 06-4693-JCS, 2007 WL 1394427 (N.D. Cal. May 10, 2007). Count VI similarly fails to identify any conduct by Elan, much less "shocking" conduct that could implicate a charge of "unclean hands." *American Top English v. Lexicon Marketing (USA), Inc.*, No. 03 C 7021, 2004 WL 2271838, at *11 (N.D. Ill. Oct. 4, 2004) ("Unclean hands is an equitable defense that must be pled with the specific elements required to establish the defense."). These counterclaims, and the defenses based on them, should be dismissed and stricken pursuant to Fed. R. Civ. P. 12(f) and 12(b)(6).

RULE 7.1.1. CERTIFICATE

Pursuant to D. Del. LR 7.1.1, counsel for Plaintiffs certifies that the subject of this motion has been raised with counsel for Defendant, and that the parties have not reached an agreement.

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Thomas G. Whalen, Jr., Esquire
STEVENS & LEE, P.C.

I further certify that I caused to be served copies of the foregoing document on December 3, 2007 upon the following in the manner indicated:

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VIA ELECTRONIC MAIL and HAND DELIVERY

/s/ Maryellen Noreika

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