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

Teva's opposition largely ignores the narrow issue of law on which Elan's motion to dismiss and strike is based – that an applicant's characterization of prior art before the patent examiner cannot constitute a material misrepresentation, as a matter of law. Instead, Teva responds with a lengthy recitation of so-called "factual allegations" – many of which are inaccurate and irrelevant to the narrow legal issue presented by Elan's motion – and argues that "it suffices" that it pleaded in conclusory fashion that Elan "falsely characterized the Mehta reference." Teva's allegations, however, are not sufficient. The Mehta patent was before the examiner, who was free to agree or disagree with Elan's characterization of its disclosures. Moreover, although Teva alleges that Elan's characterization was "false and misleading," it has not alleged (and cannot allege) facts that support the threshold level of materiality. As a result, Teva's counterclaims and affirmative defenses of inequitable conduct fail to state a claim and should be dismissed and stricken from the pleadings.

1. To state a claim for inequitable conduct, Teva was required to allege facts, not merely conclusions, to support an "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information," and an "intent to

deceive." *Impax Labs., Inc. v. Aventis Pharms., Inc*., 468 F.3d 1366, 1374 (Fed. Cir. 2006); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc*., 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc). Teva's conclusory allegations, however, contain no facts to support the threshold levels of ***both*** materiality and deceptive intent. Instead, Teva argues that "it suffices that Teva has pled that Elan . . . falsely characterized the Mehta reference." (D.I. 14 at 15). Teva is wrong for at least two reasons.

2. First, as a matter of law, "[t]he essence of the duty of disclosure is to get relevant information before an examiner in time for him to act on it." *Young v. Lumenis, Inc*., 492 F.3d 1336, 1349 (Fed. Cir. 2007). Elan did that here.[1] When Elan characterized the Mehta patent, it "merely advocated a particular interpretation of the teachings" of the prior art "which the Examiner was free to accept or reject." *Life Techs., Inc. v. Clontech Labs., Inc*., 224 F.3d 1320, 1326 (Fed. Cir. 2000).

3. As discussed in Elan's motion (D.I. 12 ¶¶ 5-9), the case law makes clear that such advocacy cannot constitute an affirmative misrepresentation of material fact, even when an alleged infringer claims it to be a mischaracterization. *See Young*, 492 F.3d at 1349 ("We therefore fail to see how the statements [to the examiner] . . ., which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact."); *Life Techs*., 224 F.3d at 1326 ("[T]he inventors merely advocated a particular interpretation of the teachings of the [prior art]. . ., which the Examiner was free to accept or reject. This argument did not contain any factual assertions that could give rise to a finding of misrepresentation."); *Azko, N.V. v. United States Int'l Trade Comm'n*, 808

[1] Elan had disclosed the Mehta patent twice, discussing it in the specification of the patents-in-suit and in the Petition for Accelerated Examination. (*See* D.I. 8, Ex. A ('398 Patent, col. 3, ll. 27-31), Ex. B ('325 Patent, col. 3, ll. 27-31); D.I. 14 (Ex. B at 2)).

F.2d 1471, 1482 (Fed. Cir. 1986) ("The mere fact that [patentee] attempted to distinguish the [claimed] process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the [claimed] process based on the art in front of him.").[2]

4. Teva's attempts to qualify Federal Circuit precedent by discussing extensively the Eastern District of Virginia's decision in *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 4 F. Supp. 2d 477 (E.D. Va. 1998) ("*SEL*") (D.I. 14 at 9-11), are also unavailing.[3] The *SEL* decision is inapposite because Teva has not alleged that Elan intentionally

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[2] This Court has repeatedly followed this authority. *Bayer AG v. Dr. Reddy's Labs. Ltd*, No. 04-179-SLR, 2007 U.S. Dist. LEXIS 79108, at *36 (D. Del. Oct. 25, 2007) ("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner.") (citation omitted); *Bayer Healthcare LLC v. Abbott Labs*., No. 03-189-GMS, 2004 WL 2862267, at *2 (D. Del. Dec. 10, 2004) (information in front of the examiner "preclude[s] a finding of materiality") (citing *Akzo*, 808 F.2d at 1482); *Genzyme Corp. v. Transkaryotic Therapies, Inc.*, No. 00-677-GMS, 2004 U.S. Dist. LEXIS 19250, at *6 (D. Del. Sept. 27, 2004) ("[A]ny mischaracterization of [prior art] is not actionable 'because the examiner was free to render his own conclusion regarding . . . the art in front of him.'") (quoting *Akzo*, 808 F.2d at 1482)); *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 386 (D. Del. 2000) ("[E]ven if Plaintiff's characterization of the [prior art] patents was inaccurate. . . this characterization would not rise to the level of a material misrepresentation" because prior was submitted "for the Examiner's review.") (citing *Akzo*, 808 F.2d at 1471).

[3] Teva also argues that the "handful of district court cases" cited in Elan's motion misconstrue Federal Circuit precedent, but it makes no attempt to address the numerous decisions that have consistently held that alleged mischaracterizations of prior art cannot provide a basis for inequitable conduct where the prior art is before the examiner. *Innogenetics N.V. v. Abbott Labs*., No. 05-0575, 82 U.S.P.Q.2d (BNA) 1009, 2006 U.S. Dist. LEXIS 49422, at *29 (W.D. Wisc. 2006); *Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc*., No. 04-1689, 2006 U.S. Dist. LEXIS 34476, at *16-17 (D.N.J. May 30, 2006) ("[A]pplicants' efforts to argue that the claimed invention was not anticipated by the prior art does not rise to the level of a material misrepresentation.") (citing *Akzo*, 808 F.2d at 1482); *Rosco, Inc. v. Mirror Lite Co*., No. 96-5658-CPS, 2003 U.S. Dist. LEXIS 26209, at *59 (E.D.N.Y. July 8, 2003); *Emerson Elec. Co. v. Spartan Tool*, 223 F. Supp. 2d 856, 921 (N.D. Ohio 2002); *Environ Prods., Inc. v. Total Containment, Inc*., 951 F. Supp. 57, 61 (E.D.Pa. 1996) (striking inequitable conduct defense as legally insufficient, finding "there is no policy reason which would support the unprecedented expansion of the interpretation of 'material information' to include legal arguments"); *Al-Site Corp. v. Opti-Ray, Inc*., 1993 U.S. Dist. LEXIS 9807 (E.D.N.Y. May 28, 1993) ("The examiner, once aware of the prior art, is free to draw his or her own conclusions with regard to its materiality. Advocacy, even if somewhat overzealous, will not alone amount to inequitable conduct.").

withheld material information from the PTO. In *SEL*, the court found inequitable conduct on two grounds: first, the applicant withheld material information by submitting a one-page, partial English translation of a 29-page Japanese patent application that misleadingly omitted the material portions; and second, the applicant misrepresented another prior art reference that was "contrary to its own knowledge and inconsistent with its own previously stated position on an important issue before the PTO." *Id*. at 482-83, 486. The Federal Circuit affirmed only on the basis of applicant's submission of the materially incomplete, partial translation of the Japanese application, holding that it "deceived the examiner into thinking that [the Japanese application] was less relevant than it really was, and constructively withheld the reference from the PTO." 204 F.3d 1368, 1377 (Fed. Cir. 2000). Here, however, Teva does not dispute that Elan disclosed the Mehta patent not once, but twice, and provided a full copy of it to the PTO.[4]

5. Second, Teva fails to assert any facts supporting its assertions that Elan's characterization of the Mehta patent were, as Teva contends, a "deliberate mischaracterization," "flatly untrue," and "demonstrably false." Teva's inequitable conduct claim is based solely on a statement in the Petition for Accelerated Examination stating:

> Applicants would like to point out that the Mehta et al. reference discloses 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.

[4] Judge Jordan's decision in *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 417 F. Supp. 2d 580 (D. Del. 2006), *aff'd*, 480 F.3d 1129 (Fed Cir. 2007), is likewise inapposite. There, the court found inequitable conduct based on applicants' three declarations, which "amounted to over two thousand pages," and contained express misstatements of fact. *Id*. at 598. Indeed, the Federal Circuit found that "this case [wa]s similar to *Semiconductor Energy*," agreeing "with the district court that the 'blizzard of paper' submitted to the PTO . . . left the examiner with the impression that the examiner did not need to conduct any further investigation." 480 F.3d at 1138. In contrast, here Teva challenges a single sentence about a single prior art reference that was admittedly before the examiner.

(D.I. 14 at 4; Ex. B at 2)).[5] Teva claims that Elan's description is "demonstrably false" because, according to Teva, "[t]he Mehta reference discloses formulations ***capable of*** an *in vivo* pulsed release profile." (D.I. 14 at 4). Elan's statement to the Patent Office, however, said nothing about formulations "capable of" an *in vivo* pulsed release profile.

6. Teva offers no factual basis – or citation to the Mehta patent – supporting its conclusory allegations regarding the purported disclosures of Mehta. Teva also offers no explanation as to how Elan's statement constitutes a "gross mischaracterization" or is "flatly untrue," other than Teva's own say so. In fact, Teva does not even contend that the Mehta patent does, in fact, disclose a formulation that ***produces*** an *in vivo* pulsed release profile.[6]

7. Instead, Teva appears to argue that Elan had a duty to anticipate Teva's interpretation of the Mehta patent and address it during the prosecution of Elan's patents years earlier. Such a theory of inequitable conduct has, not surprisingly, been rejected. *See Innogenetics N.V. v. Abbott Labs.*, 82 U.S.P.Q.2d (BNA) 1009, 2006 U.S. Dist. LEXIS 49422, at *23-32 (W.D. Wisc. 2006). In *Innogenetics*, the defendant, like Teva here, alleged that the patent applicant falsely characterized prior art before the examiner. *Id*. at *26-27. Citing *Akzo*, the court dismissed those inequitable conduct charges for lack of materiality and deceptive intent (*id.* at *28-29):

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[5] Emphasis added unless otherwise noted.

[6] Teva suggests that "further inquiry during discovery" will uncover evidence of materiality (D.I. 14 at 7 n.7), but where, as here, "allegations in a [pleading], however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Bell Atlantic Corp. v. Twombley*, 127 S. Ct. 1955, 1967 (May 21, 2007) (citation omitted). Teva also puts the cart before the horse. Indeed, Teva previously asserted in the District of New Jersey that "a party acts properly when it uses discovery not only to identify but also to confirm factual support before bringing a claim of inequitable conduct." (*Wyeth v. Teva Pharms. USA, Inc.*, No. 03-1293-WJM (D.N.J.), D.I. 94, at 9 (June 20, 2006)).

> Plaintiff did not do anything impermissible in promulgating its view of the novelty of its claim before the USPTO. The doctrine of inequitable conduct prohibits only the intentional misrepresentation of facts to the USPTO. ***The law does not require an applicant to adopt and advance other parties' interpretation of prior art***.

The court even awarded the plaintiff attorney fees for having to defend against defendant's unfounded inequitable conduct allegations, holding (*id*. at *32):

> Defendant accuses plaintiff of not arguing its patent application before the USPTO in good faith, but it is actually defendant that could not possibly have brought this counterclaim in good faith. ***If defendant disagrees with plaintiff's reading of the [prior art], its recourse is a defense of invalidity***, not a charge of inequitable conduct.

8. Finally, Teva attempts to find materiality by arguing that statements in a Petition to Make Special "are afforded special consideration" and "independently support a finding of inequitable conduct" fail. (D.I. 14 at 11-12). In *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405 (Fed. Cir. 1994), the case on which Teva heavily relies, the Federal Circuit did not hold that every statement in Petition to Make Special is *per se* material. It found that, where an applicant falsely stated that a prior art search had been conducted in a petition to make special, such a statement is material because a thorough prior art search is necessary for expedited examination. *Id*. at 1411. Indeed, the Federal Circuit in *Regents of Univ. of Cal. v. Eli Lilly & Co*., 119 F.3d 1559, 1571 (Fed. Cir. 1997), refused to apply the broad dicta from *General Electro* to an "alleged mischaracterization," concluding that "the district court clearly erred" in finding it material to patentability. *Id*. at 1571.[7]

[7] Other district courts have treated statements in a petition to make special no differently. *See, e.g., Dimension One Spas, Inc. v. Coverplay, Inc.*, No. 03-1099-CAB, 2007 WL 2815042, at *2 (S.D. Cal. Sept. 25, 2007) (rejecting defendant's argument that a "heightened duty [of candor] applies when an applicant files a petition to make special"); *Kowalski v. Mommy Gina Tuna Res.*, No. 05-00679-BMK, 2007 WL 1118292, at *4 (D. Haw. Apr. 12, 2007) (dismissing inequitable conduct allegations based on statements about prior art made in Petition to Make Special because "[s]tatements to the USPTO are (Continued . . .)

CONCLUSION

Teva's allegation that Elan's characterization of a reference that was twice submitted to the Patent Office was false fails, as a matter of law, to state a claim or defense of inequitable conduct. Moreover, even assuming that pleading an intentional mischaracterization of a reference was sufficient (which it is not), Teva's allegations would still fail because Teva has not pleaded any facts sufficient to support its allegations of falsity. *Azko*, 808 F.2d at 1482 ("Nor does Du Pont's [*i.e.*, applicant's] affidavit, advocating a particular interpretation of the [two prior art patents] (albeit favorable to Du Pont's position), show any intent to mislead the PTO. Du Pont's intent was not to mislead, but rather to distinguish prior art from the [claimed] process and demonstrate to the examiner that the [claimed] process would not have been obvious."). Thus, Elan requests that Counts III and VI of Teva's counterclaims be dismissed for failure to state a claim upon which relief can be granted, and its Third and Sixth Affirmative Defenses be stricken.

(. . . continued)

not considered 'material information' when they are . . . are made to explicitly distinguish prior art") (citing *Akzo*, 808 F.2d at 1481-82); *Bayer Healthcare*, 2004 WL 2862267, at *2 n.1 ("[T]he court is not convinced that the duty is so heightened by [a petition to make special] that the applicant can no longer rely on the examiner to read and understand the [information before him]").

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CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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