UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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KING PHARMACEUTICALS, INC., KING PHARMACEUTICALS RESEARCH and DEVELOPMENT, INC.,

Plaintiffs/Counterclaim Defendants,

-against-

EON LABS, INC.,

Defendant/Counterclaim Plaintiff,

-against-

ELAN PHARMACEUTICALS, INC. and JONES PHARMA INC.

Counterclaim Defendants.

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MEMORANDUM AND ORDER

Civil Action No. 04-CV-5540(DGT)

Trager, J:

This opinion lays to rest the final issues in this case and a related case, No. 03-CV-0006 ("the 400 mg action"), which remained after this Court's January 20, 2009 Order granting summary judgment to defendant Eon Labs, Inc. ("Eon") on the grounds that the two patents at issue in these actions are invalid. The two patents – U.S. Patent Nos. 6,407,128 ("the '128 patent") and 6,683,102 ("the '102 patent") – both claim a new method of administering the muscle relaxant metaxalone with food in order to increase the bioavailability of the drug. This

Court's January 20, 2009 Order held that all of the claims in the two suit patents were invalid, either because they were anticipated under 35 U.S.C. § 102, failed for obviousness under 35 U.S.C. § 103 or claimed subject matter not patentable under 35 U.S.C. § 101. King Pharms., Inc. v. Eon Labs, Inc., 593 F. Supp. 2d 501 (E.D.N.Y. 2009). On August, 2, 2010, the Federal Circuit affirmed this Court's Order regarding invalidity, although on slightly different grounds for some claims. King Pharms., Inc. v. Eon Labs, Inc., Nos. 2009-1437, 2009-1438, 2010 WL 3001333 (Fed. Cir. Aug. 2, 2010).

This Court now addresses Eon's counterclaim against plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. and Jones Pharma Inc. (collectively "King") and counterclaim defendant Elan Pharmaceuticals, Inc. ("Elan") (collectively "counterclaim defendants") under 35 U.S.C. § 285 that this action and the related 400 mg action are exceptional cases entitling Eon to reasonable attorney's fees. Because Eon has failed to meet its burden of proving by clear and convincing evidence that this is an exceptional case, its motion is denied.

Overview and Procedural History

This case and the 400 mg action both arise from a dispute between brand name manufacturers of the drug metaxalone (Elan

and King) and a potential rival that wanted to market a generic version of the drug (Eon). The original patent on metaxalone issued in 1962 and expired long ago. See U.S. Patent No. 3,062,827. This dispute concerns the prosecution of two separate patent applications that Elan applied for in 2001 and 2002 respectively, and litigation based on those patents once they issued in 2002 and 2004 respectively. Both patent applications were based on a fed-fasted study that was arranged and conducted between June and September of 2001 ("Study 101"), through which Elan claims to have discovered that the bioavailability of metaxalone is greater when the drug is administered in the fed state than when it is administered in the fasted state. The patents claimed to protect a method for administering metaxalone with food to increase the bioavailability of the drug, and using that method in the treatment of musculoskeletal conditions.

(1)

The Suit Patents

a. Prosecution of the '128 patent

On December 3, 2001, two employees of Elan – Michael Scaife and Jaymin Shah – filed a patent application based on the

results of the 101 study ("the '128 application"[1]). The application claimed to patent a method for increasing the bioavailability of metaxalone by administering the drug with food. Eon Ex. 17. On December 23, 2001, the examining attorney in the Patent and Trademark Office ("PTO") issued an office action rejecting claims 1-8 and 17-19 of the '128 application. Eon Ex. 19 at 5. The office action stated that claims 1-8 "fail[ed] to particularly point out and distinctly claim the subject matter which applicant regards as the invention," and suggested that applicant could overcome these concerns by amending claim 1 to read: "A method of increasing the oral bioavailability." Id. at 1.

On January 31, 2002, Applicants[2] filed a petition to make

[1] Application number 09/998,206. The application would eventually issue as patent number 6,407,128.

[2] For ease of reference, employees of both Elan and King who participated in prosecuting the '128 and '102 patents as well as outside counsel who assisted them in their efforts are collectively referred to as "Applicants." Under PTO rules, the duty to disclose information material to patentability rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application. 37 C.F.R. 1.56. Scaife and Shah therefore had a duty to disclose known material references regardless of whether prosecution was handled by outside counsel.

special[3] with the PTO. Eon Ex. 19 at 8-21. In connection with the petition, Applicants stated that they had performed a preexamination search of U.S. patents in class 514, subclasses 161, 384, 457 and 558, and class 424, subclasses 464, 468, 469 and 484, as well as a keyword search of the Claims data base of the Dialog Information System using the key terms "metaxalone" and "food." Id. Based on the results of that search, Applicants referenced nine patents and one patent application that they deemed to be "the most closely related to the subject matter of the pending claim" in their petition to make special. Id. Applicants did not reference any prior art other than patents and the one patent application in the petition. Id.

On February 7, 2002, the PTO granted Applicants' petition to make special. Id. at 22. The next day, Applicants filed a response to the first office action in which they agreed to amend claim 1 in the manner suggested by the examining attorney, cancel claims 17-19 and add new claims 23-29 to the '128 application. Id. at 7, 23, 28. On March 4, 2002, the PTO accepted Applicants' response to the first office action and

[3] A petition to make special is a request to have a patent application reviewed on an expedited basis. See Manual of Patent Examining Procedure § 708.02.

issued a notice of allowance.[4] Id. at 31. On June 18, 2002, the PTO issued the patent as patent number 6,407,128. Eon Ex. 16.

b. Prosecution of the '102 patent

On March 25, 2002, Applicants filed a second patent application based on the 101 study ("the '102 application"[5]). The '102 application was a continuation of the '128 application that had the same specifications as the '128 application but differed in that it claimed to apply the '128 patent to the treatment of musculoskeletal conditions. On August 13, 2002, Applicants filed a petition to make special for the '102 application. King Ex. D at KG1186-1213. The petition stated that Applicants had conducted a preexamination search which was substantially similar to the one conducted for the petition filed in connection with the '128 application, and referenced fifteen patents or patent applications that Applicants deemed to be the "most closely related to the subject matter of the pending claims." Eon Ex. 20 at KG001187-001188.

On November 18, 2002, the patent examiner issued an office action rejecting claim 27 as being obvious over the Physician's

[4] On March 21, 2002, after the PTO issued a notice of allowance but before the patent issued, Scaife and Shah assigned the '128 patent to Elan. Eon Ex. 17 at KG001273.

[5] Application number 10/104,044. The application would eventually issue as patent number 6,683,102.

Desk Reference, 55th Ed., and all other pending claims under the doctrine of obviousness-type double patenting over claims 1-22 of the '128 patent. Id. at KG001219-001220. On November 27, 2002, Applicants responded to the office action by filing an amendment cancelling claim 27 and a terminal disclaimer obviating the double patenting rejection of the other pending claims. Id. at KG001226-001228.

(2)

Eon's ANDA

In late 2002, after the '128 patent had issued but while the '102 application was still pending, Eon filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking to market a generic version of metaxalone. King Ex. E. As part of its ANDA, Eon informed the FDA that, although it sought to manufacture the drug before expiration of the '128 and '102 patents, it believed that it would not infringe on the patents and, moreover, that the patents were invalid. Id. On November 7, 2002, Eon notified Elan of its ANDA and identified an article by Kazem Fathie, M.D. which Eon alleged was prior art that invalidated the '128 patent

because it referred to taking metaxalone "with food" ("Fathie II").[6] Id.

On November 27, 2002, Applicants filed an Information Disclosure Statement ("IDS") with the PTO identifying Fathie II. King Ex. D at KG1225. On December 13, 2002, Applicants filed a second IDS identifying a related article by the same author that recommended taking metaxalone "after each meal and at bedtime" ("Fathie I").[7] King Ex. D at KG1229-36. On January 9, 2003, after having received both IDSs, the PTO issued a notice of allowance for the '102 application. Id. at KG1246.

On February 7, 2003, Eon's counsel sent Elan a letter identifying additional references that Eon's counsel believed invalidated the '128 patent, namely, articles by Lloyd W. Morey

[6] "Musculoskeletal Disorders and Their Management with a New Relaxant," Clinical Medicine 678 Clinical Medicine 678 (Apr. 1965). Dr. Fathie describes a clinical study in which metaxalone was administered to patients with musculoskeletal disorders. Eon Ex. 4. The patients were prescribed 800 mg of metaxalone, to be taken three or four times daily. The article notes that "[metaxalone was well accepted and except for mild nausea in six cases, was apparently well tolerated. Nausea might have been less prominent if the medication had been taken with food." Id. at E003317 (emphasis added).

[7] "A Second Look at a Skeletal Muscle Relaxant: A Double-Blind Study of Metaxalone," 6 Current Therapeutic Research 677 (Nov. 1964). Eon Ex. 23 at E008653. The article describes two double-blind studies in which patients with "low-back pain and discomfort" were administered either metaxalone or placebo. Those who received metaxalone were prescribed a recommended dose of "two [400 mg] tablets after each meal and at bedtime." Id. at E008655 (emphasis added).

and Allan R. Crosby ("Morey")[8] and Julia Keio Elenbaas ("Elenbaas").[9] King Ex. F. Morey describes a study in which patients were given metaxalone "after meals and at bedtime," Eon Ex. 5 at E008795, and Elenbaas lists the half-life of metaxalone as "2-3 hours," Eon Ex. 36 at E003386. On March 4, 2003, Applicants filed another IDS with the PTO disclosing these two references. King Ex. D at KG1250. On March 26, 2003, after considering the references identified in the most recent IDS, the PTO again issued a notice of allowance for the '102 application. Id. at KG1251-1252.

Following additional disclosures by Applicants of newly released clinical study reports, patents and the litigation concerning the '128 patent, the PTO issued another notice of allowance on September 16, 2003, and on January 27, 2004, the PTO issued the '102 patent. Eon Ex. 18. Throughout the entire application process for the '102 patent, Applicants never disclosed to the PTO a number of references that Eon now argues are material.[10]

[8] "Metaxalone, a New Skeletal Muscle Relaxant," Journal of the American Osteopathic Association 517/61 (Feb. 1963). Eon Ex. 5 at E008794.

[9] "Centrally Acting Oral Skeletal Muscle Relaxants," American Journal of Hospital Pharmacy 1313, vol. 37. Eon Ex. 36.

[10] These references are discussed infra at 18-19.

(3)

Infringement Suits Brought by Elan

On January 2, 2003, in response to Eon's ANDA, Elan brought an infringement action against Eon seeking to enjoin Eon from manufacturing a 400 mg version of metaxalone (No. 03-cv-0006, or "the 400 mg action"). On January 23, 3004, Eon filed counterclaims alleging that the '128 patent was invalid, that Eon was not infringing on the patent and that the court should find this an exceptional case entitling Eon to attorney's fees and costs. See Doc. No. 5 (03-0006) at 4-6.[11]

On June 12, 2003, King acquired the Skelaxin® brand from Elan, including the '128 patent and '102 application. King Ex. D at KG1278. King then sought to intervene in the 400 mg action, which the court allowed. Doc. Nos. 45, 46 (3-0006). After King intervened, Elan made a motion to substitute King for Elan as plaintiff in the 400 mg action, Doc. No. 49, 150 (03-0006), which Eon opposed, Doc. No. 50 (03-0006), and which the court denied, Doc. No. 180 (03-0006). Despite being unable to substitute King for Elan in the 400 mg action, Elan covenanted never to assert any rights for past, present or future

[11] Docket entries refer to the instant matter, docket number 04-CV-5540, unless they are followed by "(03-0006)," in which case they refer to the separate 400 mg action, docket number 03-CV-0006.

infringement of the '128 patent. King Pharms., Inc., 2010 WL 3001333, at *15.

Eon later amended its ANDA to include an 800 mg version of metaxalone. Doc. No. 352 ¶ 16. In response, King filed the instant lawsuit on December 17, 2004 alleging that production of an 800 mg version of metaxalone by Eon would infringe King's '128 and '102 patents ("the 800 mg action"). Eon again filed counterclaims, this time against both King and Elan, arguing that the suit patents were invalid and asking for a determination that this is an exceptional case meriting an award of litigation expenses. Doc. No. 352 at 23-45.

On September 28, 2006, Eon notified King and Elan that it had withdrawn its 400 mg metaxalone ANDA. Elan Ex. 22. There is some dispute over why Eon withdrew its ANDA. Eon argues that Elan and King convinced the FDA that one 800 mg tablet was safer than two 400 mg tablets, thereby destroying the market for a generic 400 mg version of metaxalone. Eon Reply at 20 n.15. Elan argues that Eon was unable to gain approval for its 400 mg version of metaxalone. Elan Mem. Law. Opp. Eon's Mot. Determination of Exceptional Case ("Elan Opp.") at 27. Regardless of why Eon withdrew its ANDA, on March 19, 2007, Eon voluntarily agreed to dismiss all of its counterclaims in the 400 mg action as moot except for its claim that the case is an exceptional case under § 285. Doc. No. 181 (03-0006) at 3. The

court then severed Eon's exceptional case claim from the 400 mg action and consolidated it with Eon's exceptional case claim in the 800 mg. action. Doc. No. 187 (03-0006).

(4)

'128 and '102 Patents Invalidated

On April 16, 2008, Eon moved for summary judgment in the 800 mg action on the issue of patent validity, Doc. No. 118, which this Court granted in its January 20, 2009 Order. That Order held that all of the claims in plaintiffs' '128 and '102 patents were invalid, either because: (1) they were anticipated by Fathie II and two other pieces of prior art not at issue in this motion, (2) because they were obvious, or (3) because they covered unpatentable subject matter.

On appeal, the Federal Circuit affirmed this Court's Order in part and vacated it in part. The Federal Circuit agreed with this Court that all claims in the '128 and '102 patents were invalid, but found that some claims of the '128 and '102 patents, which this Court invalidated under 35 U.S.C. § 101, were instead invalid under 35 U.S.C. § 102 because they were anticipated by prior art. King Pharms., Inc., 2010 WL 3001333. The Federal Circuit also vacated this Court's entry of the Order against Elan, finding that this Court lacked jurisdiction to adjudicate the counterclaim against Elan because no case or

controversy existed between Elan and Eon when this Court entered its order. Id. at *14-15.

Discussion

(1)

Eon Is a Prevailing Party

Section 285 states that "[t]he court in exceptional cases may award reasonable attorneys fees to the prevailing party." Only a "prevailing" party is eligible to recover attorney fees under § 285. Manildra Milling Corp. v. Ogilvie Mills, Inc., 76 F.3d 1178, 1183 (Fed. Cir. 1996).

According to the Federal Circuit,[12] a party is a "prevailing" party for purposes of § 285 when it obtains a result in its favor that "has the necessary judicially sanctioned imprimatur to constitute a judicially sanctioned change in the legal relationship of the parties." Highway Equip. Co., Inc. v. FECO, Ltd., 469 F.3d 1027, 1035 (Fed. Cir. 2006). A plaintiff does not qualify as a prevailing party merely because the defendant voluntarily takes whatever action was requested by plaintiff, thus mooting plaintiff's claim. Id.

[12] Whether a party is a "prevailing" party for purposes of § 285 is governed by the law of the Federal Circuit. See Highway Equip. Co., Inc. v. FECO, Ltd., 469 F.3d 1027, 1032 (Fed. Cir. 2006).

at 1034-35 (citing Buckhannon Bd. and Care Home, Inc. v. W. Va. Dep't of Health and Human Res., 532 U.S. 598, 600 (2001)).

Eon clearly qualifies as a prevailing party in the 800 mg action, having succeeded on its counterclaim for invalidity against King.[13] But, despite the similarities between this action and the 400 mg action, Eon does not qualify as a prevailing party in the 400 mg action, which was dismissed as moot when Eon voluntarily withdrew its ANDA for a 400 mg version of metaxalone. While there is some disagreement over the reason for Eon's withdrawal of its petition for a 400 mg version of metaxalone, see supra at 11, the debate is of no consequence to determining whether Eon is a prevailing party in the 400 mg action. Even if Eon withdrew its 400 mg ANDA entirely due to Elan's conduct, and not because of Eon's inability to gain FDA approval for a 400 mg version of metaxalone, Eon would still not be considered a prevailing party for purposes of § 285. Any voluntary conduct on the part of Elan which may have mooted the 400 mg action does not constitute "a judicially sanctioned

[13] Because this is not an exceptional case, as explained infra at 15-35, it is unnecessary to decide whether Elan may be held liable for some or all of Eon's reasonable attorney's fees as the party that prosecuted the '128 patent and began prosecuting the '102 patent. See Evident Corp. v. Church & Dwight Co., 399 F.3d 1310, 1315-16 (Fed. Cir. 2005) (upholding district court's determination that counterclaim defendant was jointly and severally liable for attorney's fees because it "was the record owner of the patent application at issue during a significant period of time before [the patent] issued").

change in the legal relationship of the parties," and is therefore insufficient to entitle Eon to recover under § 285 as a prevailing party.

(2)

Exceptional Case

Because Eon qualifies as a prevailing party in the 800 mg action, it may be entitled to reasonable attorney's fees if this is an exceptional case. 35 U.S.C. § 285. A case may be exceptional under § 285 if it involves any of the following: one or more acts of inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, or otherwise bad faith litigation; a frivolous suit; and/or willful infringement. Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1380 (Fed. Cir. 2001).

"Inequitable conduct resides in [the] failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence." Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 872 (Fed. Cir. 1988) (en banc). Information is "material" when "there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue

as a patent." Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1575 (Fed. Cir. 1996). "Intent to deceive" means that the inventor withheld material information or submitted false material with the "intent to deceive or mislead the patent examiner into granting the patent." Therma-Tru Corp. v. Peachtree Doors Inc., 44 F.3d 988, 995 (Fed. Cir. 1995).

It is not enough to show that "art or information having some degree of materiality was not disclosed. To be guilty of inequitable conduct, one must have intended to act inequitably." FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987). Thus, "there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference." Baxter Int'l Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998). To make such a showing, it is not sufficient to show that an undisclosed material reference existed somewhere in the patent owner's files. Rather, it is necessary to prove that the applicant had "actual knowledge of the reference's existence," Nordberg, Inc. v. Telsmith, Inc., 82 F.3d 394, 397 (Fed. Cir. 1996), and that the applicant "knew or should have known of the materiality of the information," Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006).

Once the party asserting inequitable conduct has made a threshold showing of materiality and intent to deceive, the

court then must weigh both factors in light of all the circumstances to determine whether the questioned conduct amounts to inequitable conduct. A greater showing of one factor may allow for a lesser showing of the other factor. Ferring B.V., 437 F.3d at 1186.

Eon argues that counterclaim defendants acted inequitably by: (1) failing to disclose several pieces of prior art to the patent examiner during all or part of the prosecution of the '128 and '102 patents, and in the petitions to make special for those patents; (2) failing to perform an adequate preexamination search; and (3) initiating and litigating frivolous claims against Eon in this action and the 400 mg action.

a. Failure to Disclose Material Prior Art with Intent to Deceive

Eon argues that Applicants' failure to disclose material prior art to the PTO during the prosecution of the '128 and '102 patents constitutes inequitable conduct. Eon's Mem. Law Supp. of Eon's Mot. Determination Exceptional Case ("Eon Mem.") at 29-33. The prior art references that Eon claims were material and were intentionally withheld from the PTO fall into two groups: (1) references to taking metaxalone with food, after meals, or four times daily; and (2) references to the terminal half-life of metaxalone being two to three hours.

The references to taking metaxalone with food, after meals or four times daily include Fathie I, Fathie II and Morey, which King disclosed to the PTO in IDSs in connection with the '102 application, see supra at 7-9, as well as an article by R.W. Dent, Jr. and Dorothy K. Ervin from 1975 ("Dent") that Applicants did not disclose to the PTO during the prosecution of either the '128 or '102 applications. Dent describes a study where patients were given metaxalone "four times daily."[14]

The references to the half-life of metaxalone being two to three hours include Elenbaas, which King also disclosed to the PTO in an IDS in connection with the '102 application, see supra at 8-9, as well as several references that Applicants did not disclose to the PTO during the prosecution of either the '128 or '102 applications, namely: an article by Lawrence Gross, M.D. published in different journals in 1986 and 1998 (referred to by the parties as "Gross II" and "Gross I" respectively, despite the chronology of the articles),[15] an article by John Stanko from

[14] "A Study of Metaxalone (Skelaxin) vs. Placebo in Acute Musculoskeletal Disorders: A Cooperative Study," Current Therapeutic Research, vol. 18, no. 3. Eon Ex. 26 at E003348.

[15] "Metaxalone: A Review of Clinical Experience," Journal of Neurological and Orthopaedic Medicine and Surgery, vol. 18 (1998), Eon Ex. 35 at E011870, and Advances in Therapy (1986), Eon Ex. 23 at E008588.

July 1990,[16] an article by R. Norman Harden from 2000,[17] the 2001 version of the United States Pharmacopoeia Dispensing Information ("USP-DI")[18] and the 2001 version of the American Society of Health-System pharmacists AHFS Drug Information.[19]

i. Materiality of references to taking metaxalone with food

Eon argues that the references to taking metaxalone "with food," "after meals" or "four-times daily" are material because they disclose all of the limitations of the '128 and '102 patents, and, therefore, a reasonable examiner would have considered them important in deciding whether to grant those patents. Eon's Mem. at 29-30.

This Court's January 20, 2009 Order found that numerous claims of the '128 and '102 patents were anticipated by Fathie II (as well as two other prior art references not at issue here), King Pharms., Inc., 593 F. Supp. 2d 501, 506-515, and that finding was upheld by the Federal Circuit, King Pharms., Inc., 2010 WL 3001333, at *6-12. Based on that finding, there

[16] "A Review of Oral Skeletal Muscle Relaxants for the Craniomandibular Disorder (CMD) Practitioner," Journal of Craniomandibular Practice, vol. 8, no. 3. Eon Ex. 28.

[17] "A Review of Three Commonly Prescribed Skeletal Muscle Relaxants," Journal of Back and Musculoskeletal Rehabilitation, 15. Eon Ex. 29.

[18] Eon Ex. 27 at E028718.

[19] Eon Ex. 42 at EO6491.

is no doubt that a reasonable examiner would consider Fathie II material.

For the same reason, Fathie I and Morey are also material.[20] Both articles reference taking metaxalone "after meals." The '128 and '102 patents state that metaxalone should be administered "with food," but define "with food" to mean "about 30 minutes prior to about 2 hours after eating a meal," and state that "most advantageously the dosage is administered within 15 minutes of eating a meal." Eon Exs. 16, 18. Based on this definition, saying that metaxalone should be administered "after meals" is nearly identical to saying that it should be administered "with food," and in fact describes the "most advantageous[]" method of administering metaxalone with food, according to the '128 and '102 patents.

Unlike these references to taking metaxalone "with food" or "after meals," Dent makes no mention of food or meals. Instead, Dent states that metaxalone should be taken "four-times daily."

[20] Although this Court's January 20, 2009 Order did not find that the '128 and '102 patents were anticipated by Fathie I or Morey, it viewed the evidence in the light most favorable to plaintiffs because it was ruling on defendant's motion for summary judgment. Doing so, this Court credited the "highly improbable" testimony of King's expert that "'after meals' can mean anytime at all after a meal." 593 F. Supp. 2d at 509-10. In deciding the instant motion, this Court is not required to view the evidence in a light more favorable to either party, and instead must determine whether the moving party has met its burden of proving that this is an exceptional case by clear and convincing evidence.

Eon argues that "assuming normal eating patterns," taking metaxalone four-times daily "would likely, although not necessarily, lead to ingestion of metaxalone within at least three hours of consumption of food." Eon Mem. at 30. But while it is plausible to assume that taking metaxalone four-times daily would lead to sometimes taking it "with food," Dent does not require, or even suggest, that metaxalone must be taken with food. A patent application is anticipated by prior art when "each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference." In re Omeprazole Patent Litig., 483 F.3d 1364, 1377 (Fed. Cir. 2007). "It is not sufficient if a material element or limitation is merely probably or possibly present in the prior art." Id. at 1378 (internal quotation marks omitted). Because Dent does not expressly state that metaxalone should be taken with food, and because there is no evidence that someone experienced in the field would recognize the "with food" limitation as being more than "probably present in the prior art," Eon has not met its burden of proving that there is a substantial likelihood that a reasonable examiner would have considered the reference to taking metaxalone four-times daily important in deciding whether to allow the '128 and '102 patents.

Counterclaim defendants both argue that the above references to taking metaxalone "with food" or "after meals" are not material because (1) they made no reference to an increase in bioavailability of metaxalone caused by taking the drug with food; and (2) when the references were finally disclosed to the patent examiner during the prosecution of the '102 patent, the examiner proceeded to allow the '102 patent to register. King Opp. Eon's Mot. Determination Exceptional Case ("King Opp.") 12-13; Elan Opp. 34.

Counterclaim defendants' first argument fails because it is immaterial whether the prior art disclosed the result of taking metaxalone with food; it is sufficient that the prior art disclosed the process of taking metaxalone with food. As the Federal Circuit stated in finding the suit patents invalid, "it is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." King Pharms., Inc., 2010 WL 3001333, at *7 (quoting In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990)). Because "[a]n increase in metaxalone's bioavailability is . . . an inherent aspect of the prior art," id., the Federal Circuit found that nearly every single claim of the '128 and '102 patents were inherently anticipated by Fathie II and two other references, all of which reference taking metaxalone "with food."

Counterclaim defendants' second argument also fails. They argue that several of the above references were submitted to the patent examiner during the prosecution of the '102 patent, and the examiner still allowed the patent to issue. But the test for materiality is "not whether a particular examiner would consider the material to be important . . . ; rather it is that of a 'reasonable examiner.'" W. Elec. Co. v. Piezo Tech., Inc., 860 F.2d 428, 433 (Fed. Cir. 1988). Even if the particular examiner assigned to the '102 patent did not find the disclosed references to be material, a reasonable examiner would have found them to be material given that they disclosed all of the limitations of the patent.[21]

ii. Materiality of references to the terminal half-life of metaxalone

Eon next argues that references to metaxalone's half-life of two to three hours are material because they demonstrate that metaxalone was administered to the participants of the study in a fed state.

[21] In addition, the references to taking metaxalone with food were not cumulative with U.S. Patent Nos. 3,993,767 and 4,036,957, which disclose the administration of metaxalone with food for veterinary use. It is not difficult to imagine reasons why it might be beneficial to administer an oral medication to animals with food that would not apply to humans. See, e.g., "Giving Oral Medications to a Dog," http://www.vetmed.wsu.edu/cliented/dog_meds.aspx.

Elan's 101 study, which led to filing of the '128 and '102 patent applications, demonstrated several differences in the way the body responds to metaxalone when it is delivered in the fed state as compared to the fasted state. Two of these differences demonstrate that the bioavailability of metaxalone increases when the drug is administered with food. These differences are (1) an increase in the total extent of absorption into the blood plasma,[22] and (2) an increase in the rate of absorption.[23]

A third difference demonstrated by the 101 study was that the terminal half-life[24] of metaxalone in the fed state was 2.37 hours, while in the fasted state it was 9.04 hours. Although this difference in terminal half-life does not demonstrate that the bioavailability of metaxalone increases when administered with food,[25] it nonetheless demonstrates a significant difference

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[22] Extent of absorption into the blood plasma is measured by looking at the area under the plasma concentration/time curve ("AUC"). The '128 and '102 patents state that AUC for metaxalone is greater in the fed state than the fasted state, thus demonstrating a higher total extent of absorption in the fed state.

[23] Rate of absorption is measured by looking at the observed maximum concentration of the drug in the blood plasma ("Cmax"). The '128 and '102 patents claim that the Cmax for metaxalone is significantly greater in the fed state than the fasted state, thus demonstrating a higher rate of absorption in the fed state.

[24] Terminal half-life refers to the time required to divide the plasma concentration of a drug by two after reaching pseudo-equilibrium (i.e., once the plasma concentration/time curve begins to flatten out).

[25] The terminal half-life, by itself, demonstrates neither the extent nor the rate of absorption of a drug. Under certain

between how the body responds to the administration of metaxalone in the fed state versus the fasted state. The only known explanation for such a significant difference in the terminal half-life is the change in the rate of absorption of metaxalone when administered with food as compared to without food. King Ex. P at 159:19-1601:4.[26] Because of this significant difference between the terminal half-life of metaxalone when administered with and without food (2.37 hours versus 9.04 hours), it is highly likely that, for any study on

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circumstances (i.e., when the rate of absorption is a limiting factor, meaning that the absorption constant is much lower than the elimination constant), the rate of absorption of a drug can affect the terminal half-life; an increase in the rate of absorption could lead to a decrease in the terminal half-life. Therefore, it is possible that the decrease in terminal half-life of metaxalone when it is administered with food as compared to without food is caused by an increase in the absorption rate constant (a possibility that is supported by the significantly higher Cmax in the fed state over the fasted state). But, regardless of whether the decrease in terminal half-life of metaxalone when taken with food is caused by the increased rate of absorption, neither side appears to argue that the terminal half-life alone is sufficient to show that taking metaxalone with food increases the drug's bioavailability. Instead, Eon merely argue that, given the significant difference in the terminal half-life of metaxalone between the fed and fasted states, it is clear that studies in which metaxalone's terminal half-life was determined to be two to three hours were conducted by administering metaxalone in the fed state.

[26] Although individual differences between subjects could account for some difference in the terminal half-life for that subject, in a properly administered bioequivalence study, individual difference between subjects would be highly unlikely to account for such a significant difference in the mean terminal half-life. Decl. Dr. Michael Mayersohn Supp. Eon's Reply Mem. at ¶¶ 5-8.

metaxalone in which the terminal half-life was determined to be between two and three hours, the drug was administered in the fed state.

Nonetheless, such a finding is insufficient to show that references to metaxalone's half-life are material because it would not have been clear to someone of ordinary skill that those studies were conducted by administering metaxalone with food. An invention is not entitled to patent protection if it "was known or used by others in this country . . . before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). "For prior art to anticipate because it has been 'used,' the use must be accessible to the public." Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002); see also Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) ("[I]n order to invalidate a patent [under 102(a)] based on prior knowledge or use, that knowledge or use must have been available to the public."). In addition to being publically accessible, the prior art usage must also demonstrate "each and every limitation of the claim." Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995). "The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art." Id.

Here, there is no evidence that, prior to the 101 study, it would have been evident to someone of ordinary skill that scientific studies where the terminal half-life for metaxalone was determined to be two to three hours were conducted by administering metaxalone in a fed state. Although the 101 study found that the terminal half-life of metaxalone was 2.37 hours when taken with food and 9.04 hours when taken without food, there is no evidence that this information was generally known prior to the 101 study and the subsequent publication of the '128 patent. Without information about metaxalone's terminal half-life in both the fed and fasted states, it would have been impossible for someone of ordinary skill to determine that these studies were conducted in the fed state. Therefore, even if it is now clear from the results of the 101 study that previous studies on metaxalone were performed in the fed state, references to those studies are not material because, based on the information publically available when the '128 application was filed, it would not have been obvious to someone of ordinary skill that those studies were conducted in the fed state.

iii. Intent to deceive

Because Applicants failed to disclose Fathie I, Fathie II and Morey – all of which are material to the '128 and '102 patents – to the PTO during the prosecution of the '128 patent

and during a significant portion of the prosecution of the '102 patent, it is next necessary to decide whether Applicants were aware of the material references and intentionally failed to disclose them to the PTO.

Defendant points to several pieces of evidence that it claims demonstrate Scaife's and Shah's knowledge of the prior art references. With regard to Scaife, Eon argues that he would have been aware of Fathie II through his role as Elan's Vice President of Regulatory Affairs. In that role, he would have been in charge of submitting Form 2253s (titled Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) to the FDA for Skelaxin. The Form 2253s for Skelaxin filed in 2001 include advertisements that reference Fathie II. Eon Exs. 51 at 49:17-25; 56:12-59:12; 53. There is also some evidence that the regulatory affair group maintained a Skelaxin® Product Manual that referenced Fathie I, Fathie II and Morey in its bibliography and included copies of each of those articles. Eon Exs. 54, 55 at 8:1-5, 9:11-17, 61:16-62:11.

In addition, Eon points to an April 2, 2001 e-mail from Scaife to Elan employees Linda Fischer and Ed Bergeron that reads: "[W]e need to be able to critically review ALL data that are available on the safety and efficacy of metaxalone . . . . Could I ask your help in either collecting what data you have, and/or to tell where I can get the info (I will obviously ask

the library to conduct a lit. search)." Eon Ex. 37. In response, Fischer prepared a chart of the studies that dealt with the safety and efficacy of Skelaxin and gave the chart to Scaife "immediately after [she] finished putting it together." Eon Exs. 50, 51 at 96:16-97:11, 98:11-99:6. The chart included a brief description of Fathie I. Eon Ex. 50.

With regard to Shah, Eon cites to a "reference list" of "Skelaxin-P.K. and clinical studies" with Shah's name handwritten at the bottom of the document. The reference list includes Fathie I, Fathie II and Morey, and is followed by copies of each article. Eon Ex. 25. Defendant also points to a Medline search with a handwritten message that reads: "Jaymin [Shah], This was all that I could find in Medline from 1966-2007." In Elan's document production, the Medline search is followed immediately by copies of several articles about metaxalone. Although the Medline search does not reference Fathie I, a copy of Fathie I in among the articles directly following the search. Eon Ex. 23 at E008581, E008653-E008659. Finally, defendant points to a list of in-house references that includes both Fathie II and Morey, and that has a handwritten sticky note attached to it that reads: "Metaxalone (Skelaxin) References --> Jaymin, did you want/need these?" Eon Ex. 30.

In response, counterclaim defendants point to the deposition testimony of Scaife and Shah, in which both men

denied having any knowledge of the material references. Scaife testified that he had never reviewed Fathie II, and more generally that he "never read articles on Skelaxin." King Ex. L at 197:23-198:2, 238:17-22. Shah testified that he had no knowledge of Fathie I, Fathie II or Morey, and denied "ever [having] read any references to [metaxalone] at all." King Ex. M at 111:22-112:7, 389:3-391:2.

Although the evidence submitted by defendant strongly suggests that Scaife and Shah were generally aware of at least some of the material references, the evidence does not show that either Scaife or Shah reviewed the actual articles in such detail so as to be aware that they advised taking metaxalone either "with food" or "after meals." The advertisements that Scaife's Regulatory Affairs team submitted to the FDA accompanying the Form 2253s make general references to Fathie II, but they do not include copies of the article; nor do they make reference to the portion of Fathie II that suggests metaxalone should be taken "with food." Similarly, while the chart prepared by Fischer and delivered to Scaife lists Fathie I and generally describes the article's finding, it makes no reference to the portion of the article that advises taking metaxalone with food, and there is no evidence that a copy of Fathie I was delivered to Scaife along with the chart.

Although the evidence with regard to Shah strongly suggests that he was provided copies of Fathie I, Fathie II and Morey, there is no evidence that he personally reviewed these studies. He testified that he had never read any "any references to [metaxalone] at all," and defendant has not met its burden of proving that he was being untruthful. In addition, there is no evidence that Shah was aware that any of these articles made reference to taking metaxalone "with food" or "after meals." Therefore, defendant cannot prove that Shah was aware of the materiality of Fathie I, Fathie II or Morey, even if he was aware of the articles generally.

But even if Scaife and Shah were aware that some or all of the material references listed above advised taking metaxalone "with food" or "after meals," Eon has failed to meet its burden of proving by clear and convincing evidence that Scaife and Shah failed to submit these references to the PTO with the intent to defraud the PTO.

Defendant points to the following pieces of evidence that suggest that the 101 study and the '128 and '102 patents were part of a larger plan to hold off competition from producers of a generic version of metaxalone.

In 2001, Elan established the Skelaxin Life Cycle Management ("LCM") team and appointed Scaife as the head of that team. Eon Ex. 6 at 23:22-24:6, 28:14-29:5. The LCM team was

tasked with "maintain[ing] product sales of Skelaxin® by delaying generic entry, and obtaining approval for 800 mg product." Eon Ex. 9. It is clear from e-mails between Scaife and Elan's CEO Daniel Welch that the possibility of generic competition for Skelaxin® was an issue of "enormous importance" to Welch, Eon Ex. 8, and one that would have significant financial repercussions on Elan, Eon Exs. 3, 7, 8.

It is also clear that the LCM team was more concerned with preventing generic competition for Skelaxin® than it was for improving the safety or efficacy of the drug, despite Elan's outward appearance that its primary concern was for "good science." In response to a July 2001 e-mail where an Elan employee described one of the "key objective[s]" of the LCM team as "delaying generic entry," Scaife responded that such a description was "legally unacceptable and MUST be changed." Eon Ex. 9. Scaife's boss, Lars Ekman, then responded: "Mike, you are absolutely on target. We have to get this thinking established and explain why. We can think it, say it, but not write it." Id. And when Mutual Pharmaceutical Co., a company seeking to collaborate with Elan, informed Elan that bioequivalence studies "would effectively give Elan another year of exclusivity on the [Skelaxin] product," Eon Ex. 5 at E063318, Elan internally referred to the study as "another grenade to throw in front of generic companies," Eon Ex. 15, while

notifying the FDA that the study would be conducted "in the interest of good science," Eon Ex. 2 at E029277.

But despite Elan's overriding concern for protecting Skelaxin® from generic competition, and disingenuous public statements that its actions were based on a concern for "good science," Eon has failed to prove by clear and convincing evidence that Applicants contemplated using illegitimate means to forestall competition from generics. Patent protection is, by its very nature, anti-competitive in that it grants a monopoly of limited duration to the patent holder. Even if Applicants prosecuted the '128 and '102 patents for the sole purpose of holding off generic competition, that conduct does not prove that they intended to defraud the PTO by filing and prosecuting those applications. Because there is insufficient evidence to prove that Applicants withheld the material references during the prosecution of the '128 and '102 patents with intent to defraud the PTO, Eon has failed to meet its burden of proving by clear and convincing evidence that counterclaim defendants acted inequitably.

b. Inadequate Preexamination Search

Eon argues that counterclaim defendants also engaged in inequitable conduct by performing an inadequate preexamination search. Eon Mem. at 34-35. But Eon's brief fails to cite any

cases where a court has found inequitable conduct based on an applicant's preexamination search absent a materially false statement regarding the nature of the search that was conducted. In this case, Applicants disclosed the specific details of the preexamination searches that were conducted for both the '128 and the '102 patents, including the specific classes and subclasses of patents that were searched and the search terms that were used. Because there is no evidence that Applicants' description of these searches was materially false, their conduct does not rise to the level of inequitable conduct. See Flex-Rest, LLC v. Steelcase, Inc., 455 F.3d 1351, 1363 (Fed. Cir. 2006).

c. Litigation of Frivolous Claims

Finally, Eon argues that King engaged in inequitable conduct by initiating and litigating frivolous claims in this action.[27] Eon Mem. at 37-39. "A frivolous infringement suit is one which the patentee knew or, on reasonable investigation, should have known, was baseless." Haynes Int'l Inc. v. Jessop Steel Co., 8 F.3d 1573, 1579 (Fed. Cir. 1993), reh'g granted on other grounds, 15 F.3d 1076 (Fed. Cir. 1994).

[27] Because Eon was not a prevailing party in the 400 mg action, litigation misconduct in that action, if any, could not serve as the basis for a claim under § 285.

Given the statutory presumption of validity for issued patents, 35 U.S.C. § 282, the Federal Circuit has held that more than the mere fact that a patent was ultimately held invalid is required to prove that a case is exceptional. In McNeil-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362 (Fed. Cir. 2003), the Federal Circuit stated that it had "not previously held any party liable for attorney fees for . . . enforcing a presumptively valid patent, even where that patent was later invalidated, in the absence of clear and convincing evidence of inequitable conduct or misconduct during litigation," and declined to do so on the facts presented. Id. at 1371-72.

Eon has failed to prove by clear and convincing evidence that King initiated and litigated the 800 mg action despite knowing that its claims were frivolous. Eon argues that King was aware of several prior art references, but nonetheless proceeded to sue for infringement of patents that were later invalidated by those references. But the eventual success of Eon's position is insufficient to prove that King knew its suit was baseless, especially given the presumption of validity of the suit patents and the fact that the examining attorney had reviewed several of the same prior art references and still allowed the '102 patent to register.

Conclusion

For the foregoing reasons, defendant's motion for determination of exceptional case and request for reasonable attorney's fees is denied.

Dated: Brooklyn, New York
September 28, 2010

SO ORDERED:

/s/
David G. Trager
United States District Judge