

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CONNECTICS CORPORATION, *et al.*,

Plaintiff,

v.

PENTECH PHARMACEUTICALS, INC.,

Defendant.

Case No. 08 C 2230

Hon. Harry D. Leinenweber

MEMORANDUM OPINION AND ORDER

This suit began on April 18, 2008, when Plaintiffs Connetics Corporation and Stiefel Research Australia Pty. Ltd. (collectively, the "Plaintiffs") alleged that Defendants Pentech Pharmaceuticals, Inc., Cobrek Pharmaceuticals, Inc., and Cipla, Ltd. (collectively, the "Defendants") had infringed a patent they own. Now before the Court is Defendants' Motion for Leave to File an Amended Answer, Affirmative Defenses, and Counterclaims (Docket No. 56, which corrects the main document in Docket No. 53). For the following reasons, the motion is **granted**.

I. FACTUAL AND PROCEDURAL BACKGROUND

In October 2000, Plaintiffs' predecessors received Patent No. 6,126,920 ("the '920 patent") on the drug OLUX®, which is used for the treatment of scalp dermatoses and non-scalp psoriasis. See Am. Compl. ¶¶ 13-16. Defendant Pentech filed an Abbreviated New Drug Application (the "ANDA") with the Food and Drug Administration

under 21 U.S.C. § 355(j) seeking approval to market a generic version of OLUX® before the expiration of the '920 patent. *Id.* at ¶ 17. In April 2008, after learning of the ANDA application, Plaintiffs brought this suit against Defendants for infringing the '920 patent. Plaintiffs filed an amended complaint on September 23, 2008, and Defendants filed an amended answer containing affirmative defenses and counterclaims on October 24, 2008.

On February 11, 2009, Defendants filed a motion to amend the answer to add two new defenses and counterclaims: (1) invalidity pursuant to 35 U.S.C. § 112 ¶ 1 (35 U.S.C. § 112 ¶ 1 states "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."); and (2) unenforceability due to inequitable conduct before the United States Patent and Trademark Office (the "USPTO"). These amendments are based on information that Defendants obtained in depositions of two of Plaintiffs' witnesses, Albert Abram, a scientist involved in the development of the patented formulation, and Julie Jones, an inventor, which took place on December 4 and 9, 2008. In those depositions, Defendants learned that Abram and

Jones were aware of a 1981 article in the *International Journal of Pharmaceutics* by Hans Bundgaard and Jens Hansen entitled *Studies on the Stability of Corticosteroids VI. Kinetics of the Rearrangement of Betamethasone-17-Valerate to the 21-Valerate Ester in Aqueous Solution*, 7(3) *Int'l J. of Pharmaceutics* 197-203 (1981) ("the Bundgaard Article") that was not disclosed to the USPTO during the application process for the '920 patent. Based on this revelation, Defendants claim that Plaintiffs' attorneys or agents made material misrepresentations, submitted false information to the USPTO, and/or failed to disclose material information to the USPTO, including material prior art in the form of Bundgaard Article. See Defs.' Mem. in Support of their Mot. for Leave to File their Am. Answer, Aff. Defenses and Counterclaims ("Defs.' Mem.") at 6. Defendants state that they also learned in these depositions that the patent failed to meet the requirements of 35 U.S.C. § 112 ¶ 1, and is therefore invalid.

On July 22, 2008, Judge James Moran issued a discovery schedule setting deadlines of February 7, 2009 to amend the pleadings and June 12, 2009 for the close of fact discovery. See Docket No. 31. On July 29, 2008, Docket No. 31 was corrected, moving back the deadline to amend the pleadings to February 27, 2009. See Docket No. 33. On April 21, 2009, the parties' joint motion to extend fact discovery until August 14, 2009 was granted.

See Docket No. 63. On April 24, 2009, the case was reassigned to this Court for all further proceedings. See Docket No. 68.

Defendants filed the instant motion on February 11, 2009, in advance of the deadline to amend the pleadings pursuant to Judge Moran's corrected order. Evidently neither party noticed the correction to the docket, and their briefs assume that the motion was filed after the applicable deadline. Because the appropriate standard is less stringent than that discussed in the briefs, this Court will decide the motion based on the existing briefs.

II. DISCUSSION

Federal Rule of Civil Procedure 15 provides that a party may amend its pleading after a responsive pleading has been served with the opposing party's written consent or the court's leave. FED. R. CIV. P. 15(a). "The court should freely give leave when justice so requires." *Id.* Although the rule reflects a liberal attitude toward the amendment of pleadings, courts have the discretion to deny a proposed amendment if the moving party has unduly delayed in filing the motion, if the opposing party would suffer undue prejudice, or if the pleading is futile. *Campania Management Co., Inc. v. Rooks, Pitts & Poust*, 290 F.3d 843, 849-50 (7th Cir., 2002) (citing *Foman v. Davis*, 371 U.S. 178, 181-82 (1962)). Here, Defendants contend that they should be permitted to amend their answer because of the information they learned in the two

depositions taken in December 2008. Plaintiffs oppose the motion on the grounds of undue delay, prejudice, and futility.

A. Delay

Delay alone is typically not a sufficient reason to deny a motion to amend. *Dubicz v. Commonwealth Edison Co.*, 377 F.3d 787, 792 (7th Cir., 2004). However, delay may suffice if the effect of granting the motion would be to prejudice other party. See 6 CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1488, at 661-62 (2d Ed. 1990) ("FEDERAL PRACTICE AND PROCEDURE"); *Park v. City of Chicago*, 297 F.3d 606, 613 (7th Cir., 2002).

Plaintiffs claim that the depositions revealed no new information because neither Abram nor Jones could recall specific facts about how they used the Bundgaard Article before the patent application was filed. Pls.' Resp. in Opp'n at 6. Plaintiffs further argue that they produced the Bundgaard Article and documents relating to the container for the patented formulation (which relate to Defendants' added claims of invalidity) on May 12, 2008 as part of discovery in a related case in this judicial district involving the same patent and parties, but a different generic drug. See *Connetics Corp., et al. v. Pentech Pharms., Inc. et al.*, Case No. 07-CV-6297 (Gottschall, J.). The parties have agreed that discovery from the case before Judge Gottschall may be used in this case. Defendants have therefore been on notice for

seven months of the material underlying the amendments they now seek.

Defendants admit that Plaintiffs produced the relevant documents before the depositions, but contend that only after they took the two depositions did the new defenses and counterclaims "crystallize." Defs.' Reply at 4-7. Defendants point to portions of the testimony in which the deponents acknowledged discussing and/or using information from the Bundgaard Article prior to the filing of the patent application. *Id.* at 5-6. The depositions assured them of the evidentiary support they needed to include these new counts, particularly in light of the requirement that the elements of inequitable conduct must be pled with particularity. *See, Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir., 2003).

The Court finds that Defendants have not unduly delayed in filing their motion to amend their answer. Defendants requested dates to depose Plaintiffs' witnesses in September 2008, but did not receive confirmation of dates from Plaintiffs until November, and did not take the depositions until December. Defendants have incorporated information they learned in the depositions into their additional affirmative defenses and counterclaims, as the deponents admitted having knowledge of the article before the application for the '920 patent was filed. As Defendants state, they would not have been able to plead materiality and intent to deceive - two

elements of inequitable conduct - with sufficient particularity prior to obtaining witness testimony. The Court agrees that Defendants needed to depose certain fact witnesses, and find that they have provided a credible explanation for the delay. Compare, *Doe v. Howe Military School*, 227 F.3d 981, 989-90 (7th Cir., 2000) (denying leave to amend the complaint where the plaintiffs did not provide any facts explaining the delay).

In addition, the litigation is still in its early stages. The cases Plaintiffs cite in which the courts did not allow amendments were much further along in the litigation process. See *Optivus Technology, Inc. v. Ion Beam Applications, S.A.*, No. CV 03-2052, 2004 WL 5543277, *4 (C.D.Cal., Dec. 29, 2004), *aff'd*, 469 F.3d 978 (Fed. Cir., 2006) (discovery and motion cut-off deadlines had passed, and the trial date was close); *Remington Arms Co., Inc. v. Modern Muzzleloading, Inc.*, No. 2:97-CV-660, 1998 WL 1040949, *2 (M.D.N.C., Dec. 17, 1998) (discovery had closed, dispositive motions had been filed, the *Markman* hearing had taken place, and a trial date had been set). None of the steps completed in *Remington Arms* have been completed in this case; indeed, Plaintiffs have taken no depositions, expert discovery has not yet begun, and dispositive motion deadlines have not yet been set. The purpose of Rule 15(a) is to provide the maximum opportunity for each claim to be heard on the merits. See 6 FEDERAL PRACTICE AND PROCEDURE § 1471 at

505-06. Defendants have not delayed to such an extent they should be denied the opportunity to be heard.

B. Prejudice

Plaintiffs argue that allowing Defendants' new defenses and counterclaims would prejudice them because it would be difficult to investigate and rebut the new claims before the June 12, 2009 fact discovery deadline. Plaintiffs provide no specifics on the additional discovery they need to conduct, but argue that the "parties already have a tremendous amount of work to complete" in both this case and the case before Judge Gottschall. This explanation fails to give the Court an understanding of how Plaintiffs would be unduly prejudiced by the amendment. See *Medtronic, Inc. v. AGA Medical Corp.*, No. CV-07-567, 2008 WL 5245896, *2 (N.D.Cal., Dec. 17, 2008) (defendants permitted to amend answer where plaintiffs failed to show how they would be prejudiced by the amendment). In light of the April 21, 2009 order extending the deadline for fact discovery, the Court finds that Plaintiffs will not be prejudiced by Defendants' amendments.

C. Futility of the Invalidity Claims

Lastly, Plaintiffs argue that Defendants' motion should be denied because the additional invalidity claims under 35 U.S.C. § 112 ¶ 1 are futile. Plaintiffs do not argue that the inequitable conduct claims are futile. Amendments are futile if "the complaint, as amended, would fail to state a claim upon which

relief could be granted.” *General Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1085 (7th Cir., 1997). The legal standard for sufficiency is therefore the same as that for a Rule 12(b)(6) motion, *id.*, which means that Defendants’ allegations must raise the right to relief above a speculative level. See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Pursuant to 35 U.S.C. § 112 ¶ 1, the specification of a patent “shall set forth the best mode contemplated by the inventor of carrying out his invention.” The best mode of making or using the invention must “be disclosed if it materially affects the properties of the claimed invention itself.” *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306, 1319-20 (Fed. Cir., 2002). The purpose of the requirement is to ensure that the public receives a full disclosure of the inventor’s preferred embodiment of the invention in exchange for the rights conferred under patent law. *Id.* (citing *DeGeorge v. Bernier*, 768 F.2d 1318, 1324-25 (Fed. Cir., 1985)). The scope of the best-mode requirement is limited to the invention as claimed. *AllVoice Computing PLC v. Nuance Communications, Inc.*, 504 F.3d 1236, 1246 (Fed. Cir., 2007) (citing *DeGeorge*, 768 F.2d at 1325). The Federal Circuit has stated, however, that, “[n]otwithstanding that the best mode requirement keys only on carrying out the claimed invention, ‘we have found violations of the best mode requirement for failure to disclose subject matter not strictly within the bounds of the claims.’”

Bayer, 301 F.3d at 1316 (quoting *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1331 (Fed. Cir., 2002)).

Defendants' invalidity claims center on the inventors' failure to disclose the best-mode requirements related to the container holding the patented formulation under pressure. Defendants claim that certain requirements for the containers, which were omitted from the patent application, are necessary to ensure the stability of the patented formulation. These requirements materially affect the properties of the claimed invention, and therefore, their omission provides the basis for Defendants' additional invalidity claims. Defs.' Reply at 14-15. Plaintiffs dispute Defendants' contention and argue that the invalidity claims and defenses "relate to a feature that is not part of the claimed invention (the cans and can lining)." Pls.' Mem. at 12. Because Plaintiffs have not run afoul of the best-mode disclosure requirements, they argue that the claims and defenses fail to state a claim for relief under 35 U.S.C. § 112 ¶ 1.

The Court believes that it is premature to deny the motion to amend on this ground. Defendants point to a portion of the '920 Patent application that describes the need for a container "capable of withstanding the pressure of the propellant gas and having an appropriate valve/nozzle for dispensing the composition as a foam under pressure." Defendants also cite Jones' testimony that she acknowledged the need for a container to store the patented

formulation. See Defs.' Reply, Ex. R, at 53. As such, Defendants have put forth allegations sufficient to raise their right to relief above a speculative level. At this early stage in the case, that is enough. Defendants' motion will not be denied as futile.

IV. CONCLUSION

For the reasons stated herein, Defendants' Motion for Leave to File an Amended Answer, Affirmative Defenses, and Counterclaims (as corrected in Docket 56) is **granted**.

IT IS SO ORDERED.



Harry D. Leinenweber, Judge
United States District Court

DATE: 5/8/2009