

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

CONNETICS CORPORATION and STIEFEL)		
RESEARCH AUSTRALIA PTY, LTD.,))	
)	
Plaintiffs,))	Case No. 07 C 6297
)	
v.))	Judge Joan B. Gottschall
)	
PENTECH PHARMACEUTICALS, INC.,))	
COBREK PHARMACEUTICALS, INC., and))	
CIPLA LTD.,))	
)	
Defendants.))	

MEMORANDUM OPINION AND ORDER

Defendants Pentech Pharmaceuticals, Inc., Cobrek Pharmaceuticals, Inc. and CIPLA Ltd. (collectively “Defendants”) have filed a motion for leave to file an Amended Answer, Affirmative Defenses and Counterclaims. Plaintiffs Connetics Corporation and Stiefel Research Australia Pty, Ltd. (collectively “Plaintiffs”) object to Defendants’ motion. For the reasons set forth below, Defendants’ motion for leave to amend is granted.

I. Factual Background

Plaintiffs produce a drug known as LUXIQ which is a betamethasone valerate foam used to treat scalp dermatoses and non-scalp psoriasis. LUXIQ is protected by two patents. U.S. Patent No. 7,078,058 (filed Sep. 27, 2002) (“the ’058 patent”); U.S. Patent No. 6,126,920 (filed Mar. 1, 1996) (“the ’920 patent”). In late September 2007, Plaintiffs received notice that Defendants had filed an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to market a generic copy of LUXIQ. In response, Plaintiffs filed this lawsuit on November 6, 2007, alleging the technical act of patent infringement of the ’920 patent and the ’058 patent.

On January 30, 2008, the court entered an initial scheduling order (Docket No. 31). That initial scheduling order allowed the parties until August 1, 2008 to amend their pleadings. Discovery was ordered closed by December 15, 2008. Pursuant to the initial scheduling order, Plaintiff Connetics filed an Amended Complaint on August 1, 2008 naming two new Defendants, Cobrek Pharmaceuticals and CIPLA Ltd. On November 20, 2008, the court entered a revised scheduling order (Docket No. 86). The revised scheduling order established the following new deadlines: document discovery by February 15, 2009, fact depositions by March 31, 2009, and answers to contention interrogatories by April 7, 2009.

On January 26, 2009, Defendants filed the instant motion for leave to file an Amended Answer, Affirmative Defenses and Counterclaims pursuant to Fed. R. Civ. P. 13(f), 15(a), and 16(b). Specifically, Defendants seek to add affirmative defenses and counterclaims relating to invalidity under 35 U.S.C. § 112, ¶ 1 and unenforceability due to inequitable conduct.

Defendants' invalidity claims under 35 U.S.C. § 112, ¶ 1 relate to information Defendants learned during depositions taken on December 4, 2008 and December 9, 2008. In those depositions, the inventors testified that an epoxy/phenolic-lined can was the best can in which to store the patented foam. Because neither the '920 patent nor the '058 patent mentions an epoxy/phenolic-lined can, Defendants assert that the '920 and '058 patents are invalid for failure to satisfy the requirements of 35 U.S.C. § 112, ¶ 1.

Defendants' new claim of unenforceability due to inequitable conduct relates to an article 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* ("Bundgaard article"). The '920 and '058 patents indicate that the Bundgaard article was not cited to the U.S. Patent & Trademark Office ("USPTO") during prosecution of

either patent. Plaintiffs produced to Defendants communications between some of the named inventors of the '920 and '058 patents regarding the Bundgaard article on May 12, 2008. During the December 4, 2008 and December 9, 2008 depositions, Defendants asked the inventors about the Bundgaard article. Neither deponent recalled specific facts about the Bundgaard article during prosecution of the '920 and '058 patents. Defendants claim that the Bundgaard article was material to the patentability of both the '920 and '058 patents and, therefore, should have been disclosed to the USPTO.

Plaintiffs object to the proposed amendments, arguing that they are futile, that there is no good cause for the delay in seeking an amendment, and that permitting amendments now would prejudice Plaintiffs.

II. Legal Standard

The decision of whether to allow a party to amend its pleading is within the discretion of the district court judge. *Zenith Radio Corp. v. Hazeltine Res., Inc.*, 401 U.S. 321, 330 (1971) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *Pugh v. Tribune Co.*, 521 F.3d 686, 698 (7th Cir. 2008) (reviewed for abuse of discretion); *Campania Mgmt. Co. v. Rooks, Pitts & Poust*, 290 F.3d 843, 848–49 (7th Cir. 2002). “[A] party may amend its pleading only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). Defendants filed the instant motion seeking leave to file an amendment because Plaintiffs refused to consent to Defendants’ amendment. “The court should freely give leave when justice so requires.” *Id.* “In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be ‘freely given.’” *Foman*,

371 U.S. at 182; *see Bower v. Jones*, 978 F.2d 1004, 1008 (7th Cir. 1992) (reversing denial of leave to amend where new facts discovered near end of discovery).

Plaintiffs allege that Defendants' new claims are futile. An amendment is futile if it would not survive a motion to dismiss. *Crestview Vill. Apartments v. U.S. Dep't of Hous. & Urban Dev.*, 383 F.3d 552, 558 (7th Cir. 2004); *Barry Aviation, Inc. v. Land O'Lakes Mun. Airport Comm'n*, 377 F.3d 682, 687 (7th Cir. 2004); *Garcia v. City of Chi.*, 24 F.3d 966, 970 (7th Cir. 1994); *Duthie v. Matria Healthcare, Inc.*, 254 F.R.D. 90, 95 (N.D. Ill. 2008).¹

Because the court has entered a scheduling order, and Defendants are moving to amend after the period for amending pleadings has closed, Rule 16(b) also applies and requires a party to show "good cause" for the tardy amendment. *Trustmark Ins. Co. v. Gen. & Cologne Life Re of Am.*, 424 F.3d 542, 553 (7th Cir. 2005). The Seventh Circuit has adopted the position of the Ninth Circuit that "'Rule 16(b)'s 'good cause' standard primarily considers the diligence of the party seeking amendment.'" *Id.* (quoting *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 609 (9th Cir. 1992)); *Connell v. KLn Steel Prods. Co.*, No. 04 C 0194, 2006 WL 1120514, at *4 (N.D. Ill. Apr. 25, 2006) (quoting *Trustmark Ins.*, 424 F.3d at 553).

¹ Many decisions of the United States Court of Appeals for the Seventh Circuit state that an amendment is futile if it would not survive a motion for summary judgment. *See, e.g., Dewitt v. Proctor Hosp.*, 517 F.3d 944, 949 (7th Cir. 2008); *King ex rel. King v. E. St. Louis Sch. Dist. 189*, 496 F.3d 812, 819 (7th Cir. 2007); *Sound of Music Co. v. Minn. Mining & Mfg. Co.*, 477 F.3d 910, 923 (7th Cir. 2007); *Bethany Pharm. Co. v. QVC, Inc.*, 241 F.3d 854, 856, 861–62 (7th Cir. 2001). These cases all involved motions to amend when the cases had progressed to the summary judgment stage. For example, in *King*, motions for summary judgment had been filed and briefed before the motion to amend was filed. *King*, 496 F.3d at 814. Similarly, in *Dewitt*, the district court had already granted summary judgment when it decided the motion to amend. *Dewitt*, 517 F.3d at 946. In both *Sound of Music* and *Bethany*, discovery had closed and motions for summary judgment had already been briefed. *Sound of Music*, 477 F.3d at 923; *Bethany*, 241 F.3d at 861–62. As Magistrate Judge Cole recently explained, "it would have been incongruous [in these cases] for the court to have defined futility in terms other than the capacity of the amendment to survive summary judgment." *Duthie*, 254 F.R.D. at 95. But where, as here, neither party has moved for summary judgment, the applicable standard is whether the amendment can withstand a motion to dismiss. *See id.*

Thus, there are two hurdles Defendants must overcome to prevail in their motion for leave to amend their pleadings. First, Defendants must show “good cause” to amend their pleadings. Second, Defendants must show that the new claims are not futile.

III. Analysis

Defendants’ proposed amendment includes two new claims. First, Defendants claim that the ’058 and ’920 patents are invalid for failure to satisfy the requirements of 35 U.S.C. § 112, ¶ 1. Second, Defendants claim that the ’058 and ’920 patents are unenforceable due to inequitable conduct. The court will address the merits of these two new claims in turn.

A. Invalidity Claims and Defenses Based on 35 U.S.C. § 112, ¶ 1

Under section 112, ¶ 1, a patent must satisfy the “written description,” “enablement,” and “best mode” requirements.

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.

35 U.S.C. § 112, ¶ 1 (2006). Defendants’ new claim does not differentiate among these requirements; it merely asserts that the patents at suit are invalid under section 112. In their briefs, however, the parties address the best mode requirement in detail. Therefore the court will focus its attention on the best mode requirement of section 112.

“A holding of invalidity for failure to disclose the best mode requires clear and convincing evidence that the inventor both knew of and concealed a better mode of carrying out the claimed invention than that set forth in the specification.” *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002) (citing *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 560 (Fed. Cir. 1994)). “Compliance with the best mode requirement is a question of fact which involves a two-pronged inquiry.” *Id.* (citing *N. Telecom*

Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1286 (Fed. Cir. 2000)). “The first prong is subjective, focusing on the inventor’s state of mind at the time he filed the patent application, and asks whether the inventor considered a particular mode of practicing the invention to be superior to all other modes at the time of filing. *Id.* (citing *N. Telecom*, 215 F.3d at 1286). The second prong is objective and asks whether the inventor adequately disclosed the mode he considered to be superior. *Id.* (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991)).

Defendants satisfy the “good cause” requirement to amend their pleadings to include a new claim that the ’058 and ’920 patents are invalid for failure to meet the requirements of 35 U.S.C. § 112, ¶ 1. Defendants discovered the basis for this new claim at depositions on December 4, 2008 and December 9, 2008. Defendants moved for leave to amend on January 26, 2009, less than seven weeks later. Nothing in this timeline of events suggests undue delay or a lack of diligence.

Plaintiffs argue that, even if Defendants have good cause to include their section 112 claim, the claim is futile, citing *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). In *Bayer*, the Federal Circuit examined a number of its prior decisions and came to the following conclusion regarding the scope of the required best mode disclosures:

Thus, we have held a patent invalid for failure to satisfy the best mode requirement in two situations. First, we have invalidated patents when they do not adequately disclose a preferred embodiment of the invention. . . . Consequently, if an inventor fails to disclose the preferred embodiment of the invention, the best mode requirement is not satisfied.

Second, we have invalidated patents when the patentee failed to disclose aspects of making or using the claimed invention and the undisclosed matter materially affected the properties of the claimed invention.

Id. at 1319. In other words, the best mode requirement of section 112 requires the inventor to disclose the best mode of carrying out the *claimed* invention and any unclaimed subject matter that *materially affects* making or using the claimed invention itself. *Id.*; *Teleflex*, 299 F.3d at 1330–31 (“[T]he best mode inquiry is directed to what the applicant regards as the invention, which in turn is measured by the claims.’ . . . [W]e have found violations of the best mode requirement for failure to disclose subject matter not strictly within the bounds of the claims . . .”).

Claims 1 and 4 of the ’920 patent, the only independent claims, refer to “a propellant.” ’920 patent, col. 5, ll. 51, 66. The specification states that “[t]he propellant is . . . added under pressure . . .” *Id.* at col. 3, l. 66. Furthermore, the specification discloses a container. *See id.* at col. 4, ll. 11–31. Indeed, the specification states, “If the container is made of a metal material likely to suffer corrosion under the action of the composition, the composition may include a corrosion inhibitor as an additive.” *Id.* at col. 4, ll. 15–18.

Viewing all of the evidence in the light most favorable to Defendants and drawing all inferences in their favor, Defendants’ new section 112 claim could survive a motion to dismiss. Viewed in this light, the inventors had a subjective belief that a specific epoxy/phenolic-lined can was the best to use because the patented foam did not corrode it very easily. Furthermore, drawing all reasonable inferences in Defendants’ favor, the epoxy/phenolic-lined can materially affected using the claimed invention because it allowed the patented foam to be stored in a container for longer periods of time without degradation of the container. Consequently, viewed in the context of a motion to dismiss, the inventors were required to disclose the epoxy/phenolic-lined can. There is, however, no reference to the specific epoxy/phenolic-lined can anywhere in

the '058 or '920 patents. Thus, Defendants' new claim could withstand a motion to dismiss and, therefore, it is not futile.

Because Defendants have good cause to amend their answer to include their new section 112 claim and because the section 112 claim is not futile, Defendants' motion for leave to file an amended answer including the section 112 claim is granted.

B. Unenforceability Claims and Defenses Based on Inequitable Conduct

An inequitable conduct claims requires Defendants to show that the patentee “(1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO].” *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (quoting *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007) (citing *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006))). Defendants' new claim is based on the patentee's failure to disclose the Bundgaard article to the USPTO during prosecution of the '058 and '920 patents. Accepting Defendants' allegations regarding the Bundgaard article as true, the proposed new claim of inequitable conduct is capable of withstanding a motion to dismiss and, therefore, is not futile.

The issue of good cause for delay is a closer question. On May 12, 2008, Plaintiffs produced documents indicating that the patentees were aware of the Bundgaard article. Defendants waited more than eight months to file the present motion for leave to amend. The United States Court of Appeals for the Seventh Circuit has made spoken to the issue of delay and amendments to the pleadings. “Some delay of trial therefore is inevitable—a natural consequence of allowing claims to be brought at all. In this sense, delay alone is not a sufficient basis for refusing an amendment.” *Feldman v. Allegheny Intern., Inc.*, 850 F.2d 1217, 1225 (7th

Cir. 1988). Thus, it is the delay of the trial that is important, not a party's delay in bringing the claim.

Defendants' new claim will probably require the parties to engage in some discovery, including expert discovery to address, at the very least, whether the Bundgaard article was "material information." That discovery may delay the trial somewhat; however, the trial date has not yet been set, minimizing that concern.² The court also recently entered an amended discovery schedule. The court cannot agree that the need to undertake additional discovery will be unduly prejudicial.

Plaintiffs nevertheless also claim that they will be prejudiced by any delay in this case. This argument is not persuasive. First, Plaintiffs stand to benefit from any delay in this case because it can only delay the time when Defendants may proceed with their Abbreviated New Drug Application. Second, Plaintiffs have already sought one discovery extensions, and the parties just agreed to a new extension because of delays during settlement negotiations.

Plaintiffs cite to cases in support of their position, but these are distinguishable. The first is *Remington Arms Co. v. Modern Muzzleloading, Inc.*, No. 97 C 660, 1998 WL 1040949, at *2 (M.D.N.C. Dec. 17, 1998). In *Remington Arms*, the defendant sought to amend its answer and counterclaim to add a claim of inequitable conduct. *Remington Arms*, 1998 WL 1040949, at *1. The defendant alleged that the patentee had withheld a particular document from the USPTO. *See id.* at *2. The district court noted that there was evidence that the defendant was aware of the document at issue as much as five or six months before it sought to amend its answer. *Id.* at

² Of course, filing a patent infringement case upon notice of an ANDA filing automatically stays the FDA's proceedings until the patent's expiration, the resolution of the suit, or thirty months have passed, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii) (2006); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 2009-1071, 2009 WL 440569, at *2 (Fed. Cir. Feb. 24, 2009). This case was filed on November 6, 2007. Thus, more than half of the statutory stay period has already expired.

*1–2. The defendant’s delay, however, was not the only reason the court denied the defendant’s motion for leave to amend. In *Remington Arms*, extensive discovery had already closed, a *Markman* hearing had already been held, dispositive motions had already been briefed and filed, and a trial date had already been set. *Id.* at *1–3.

Plaintiffs also cite to *Optivus Tech., Inc. v. Ion Beam App. S.A.*, No. 03 C 2052, 2004 WL 5543277 (C.D. Cal. Dec. 29, 2004), *aff’d*, 469 F.3d 978 (Fed. Cir. 2006)). In *Optivus*, the defendant sought to amend its answer to include a claim of inequitable conduct. *Optivus*, 2004 WL 5543277, at *1. It appears that the defendant was aware of sufficient facts supporting an inference of inequitable conduct for nearly two and one half months. *Id.* at *5. The court found that delay “inexcusable.” *Id.* Again, however, like *Remington Arms*, the defendant’s delay was not the only reason for the court’s denial. In *Optivus*, claim construction was already complete and the motion cut-off date had already passed when the defendant filed its motion for leave to amend. *Id.* at *2. Furthermore, the court found the proposed amendment futile and that “Defendant has failed to substantiate its allegations that patentees withheld a material prior art reference from the patent examiner during prosecution.” *Id.* at *4.

Defendants’ motion for leave to file an amended answer including an inequitable conduct claim is granted. The parties can engage in any necessary discovery during the recently extended discovery period.

IV. Conclusion

For the reasons set forth above, Defendants’ motion for leave to amend their Amended Answer, Affirmative Defenses and Counterclaims is granted.

ENTER:

/s/

JOAN B. GOTTSCHALL
United States District Judge

DATED: April 16, 2009