

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN**

BAYER HEALTHCARE, LLC,

**Plaintiff-
Counterclaim Defendant,**

v.

**Case No. 08-C-953
(consolidated w/Case No. 09-C-108)**

**NORBROOK LABORATORIES, LTD.,
and NORBROOK, INC. USA,**

**Defendants-
Counterclaimants.**

DECISION AND ORDER

This patent action is before the Court on the Civil Local Rule 7(h) expedited non-dispositive motion¹ of Bayer Healthcare LLC (“Bayer”) to strike the expert reports of Stephen R. Byrn (“Byrn”) and Laurel J. Gershwin (“Gershwin”) and the amended interrogatory responses of Norbrook Laboratories, Ltd., and Norbrook, Inc. USA (collectively “Norbrook”). Bayer asserts that this Court should preclude Norbrook from asserting defenses that Norbrook expressly abandoned and had not identified prior to the close of fact discovery.

Norbrook contends that Bayer is effectively seeking summary judgment on Norbrook’s invalidity defense; Bayer had fair notice of Norbrook’s invalidity defenses; those

¹The Court has corrected Bayer’s reference to the local rule under which its expedited motion is brought – Civil Local Rule 7(h). The Local Rules of this District were amended effective February 1, 2010. Bayer’s motion refers to the prior rule, Civil Local Rule 7.4, that is no longer in effect.

defenses and Norbrook's related expert reports were necessarily dependant on fact discovery that Bayer only recently received; and there is no prejudice to Norbrook.

The motion involves two aspects of Norbrook's defenses and counterclaims – invalidity for obviousness under § 103(a) and a 35 U.S.C. § 112 enablement theory. The Court will review some factual background that is essential to the resolution of the motion.

Factual Background

In its first amended answer and counterclaim, Norbrook alleged that “the claims of the ‘506 patent were invalid for failure to comply with the conditions for patentability as specified in 35 U.S.C. § 1 *et seq.*” No facts were alleged. (Fisher Decl. ¶ 3, Ex. A (Dkt. 12, ¶ 59).) Bayer filed a motion to strike/dismiss under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) contending that Norbrook's pleading was inadequate because of the hundreds of patentability requirements of Title 35 of the United States Code. (Fisher Decl. ¶ 4, Ex. B (Dkt. 15, 16).)

In an attempt to resolve the motion without a Court ruling, Norbrook sent to Bayer a draft second amended answer that “add[s] some specificity to our invalidity defense and counterclaim and an inequitable conduct defense and counterclaim.” (Fisher Decl. ¶ 5, Ex. C (Jan. 19, 2009 Kim email).) Norbrook's draft specifically identified challenges under 35 U.S.C. §§ 102 and 103 (prior art and obviousness) and § 112 (enablement and written description). No facts supporting the § 112 defense were included. (Fisher Decl. ¶ 6, Ex. D, ¶¶ 37, 60.)

Bayer responded to Norbrook that it was only asserting two claims of the patent (claims 4-5), and requested that Norbrook “supplement[] [its] 112 arguments as to those claims.” (Fisher Decl. ¶ 7, Ex. E (Jan. 26, 2009, Maurer email).) In response, Norbrook sent to Bayer a subsequent draft of the second amended answer with no § 112 defense pleaded. In its accompanying email, Norbrook wrote: “As you will see in the attached draft, we have removed the 112 invalidity defense and counterclaim in this draft as a result of your representation that only claims 4 and 5 of the ‘506 patent survive the disclaimer.” (Kim Decl. ¶¶ 7-8, Exs. E (Jan. 29, 2009, Kim email), F (revised draft).) Thereafter, Bayer “agree[d] to the filing of the Second Amended Answer and [withdrew] its Twombly motion.” (Kim. Decl. ¶ 7, Ex. E (Jan. 26, 2009, Maurer email).)

Paragraphs 39 and 60 of Norbrook’s Second Amended Answer and Counterclaims, which are identical, allege:

The claims of the ‘506 patent are invalid for failure to comply with one or more of the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.* More specifically, the claims of the ‘506 patent are invalid under at least 35 U.S.C. §§ 102 and/or 103. The following are examples of prior-art references which, individually or in combination, render the claims of the ‘506 patent invalid: Graham C. Dick, *Use of Enrofloxacin*, The Veterinary Record, p. 616 (June 12, 1993), Ana Cabanas, et al., *Pharmacokinetics of Enrofloxacin After Intravenous and Intramuscular Injection in Rabbits*, 53 Am. J. Vet. Res. 11, p. 2090 (November 1992), and S. Pyorala, et al., *Single-dose Pharmacokinetics of Enrofloxacin in Horses*, 6th EAVPT Congress, P18, p. 45 (August 1994).

(Dkt. 25, ¶¶ 39 & 60.)

During discovery, Bayer served interrogatories seeking Norbrook's invalidity contentions. Norbrook's responses mirrored its answer and contained no § 112 defense. (Fisher Decl. ¶ 9, Ex. G (June 15, 2009, Resp. to Interrogs. Nos. 12-13).) Specifically, Bayer's interrogatory number 12 stated:

State in detail all the bases for Defendants' contentions, on a claim-by-claim, element-by element basis (by way of claim charts), that the claims of the '506 patent are invalid for failure to satisfy 35 U.S.C. §§ 1 *et seq.* (and specifically §§ 102 and/or 103), and identify all documents, witnesses and other information Defendants will rely on to support those contentions, including but not limited to Defendants' contention that the following publications (either separately or in combination with one another) render the '506 patent invalid:

(1) Graham C. Dick, *Use of Enrofloxacin*, The Veterinary Record, p. 616 (June 12, 1993);

(2) Ana Cabanas, et al., *Pharmacokinetics of Enrofloxacin After Intravenous and Intramuscular Injection in Rabbits*, 53 Am. J. Vet. Res. 11, p. 2090 (November 1992);

(3) S. Pyorala, et al., *Single Dose Pharmacokinetics of Enrofloxacin in Horses*, 6th EAVPT Congress, P18, p. 45 (August 1994).

Norbrook responded:

Norbrook objects to this Interrogatory to the extent that it purports to be a single interrogatory. Norbrook further objects to this Interrogatory to the extent that it seeks information protected from disclosure by the attorney-client privilege and/or attorney work product doctrine. Norbrook further objects to this Interrogatory as premature, as discovery is at a very preliminary stage and Bayer has not come forward with any infringement contentions. Subject to and without waiving any general or specific objections, Norbrook responds that its investigation is still ongoing and Norbrook will subsequently supplement its response as required.

Bayer also propounded interrogatory number 13 which stated:

State in detail the basis of Defendants' contention that the claims of the '506 patent are unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO"), and in particular, the identities of any individuals who Defendants allege violated a duty of disclosure to the PTO, the basis for Defendants' contention that Graham C. Dick, *Use of Enrofloxacin*, The Veterinary Record, p. 616 (June 12, 1993) was material to prosecution of the application leading to the '506 patent and the basis for Defendants' contention that "Bayer, the patentees, and/or Bayer's counsel intentionally misled the PTO and failed to disclose the Dick referenced [sic]." See Second Amended Answer & Counterclaims ¶ 38.

Norbrook responded:

Norbrook objects to this Interrogatory on the grounds that it is vague, overly broad, unduly burdensome, and requests information that is neither relevant to any issue presented in this action nor reasonably calculated to lead to the discovery of admissible evidence. Norbrook further objects to this Interrogatory to the extent that it purports to be a single interrogatory. Norbrook further objects to this Interrogatory to the extent that it seeks information protected from disclosure by the attorney-client privilege and/or attorney work-product doctrine. Norbrook further objects to this Interrogatory as premature, as discovery is at a very preliminary stage and Bayer has not yet provided any discovery to Norbrook on this or any other issue. Subject to and without waiving any general or specific objections, Norbrook responds that the claims of the '506 patent are unenforceable due, at least, to the patentees' inequitable conduct before the United States Patent and Trademark Office ("PTO"). In the June 12, 1993 issue of The Veterinary Record, p. 616, Graham C. Dick from Bayer plc, Veterinary Business Group, Eastern Way, Bury St. Edmunds, Suffolk IP32 7A11, wrote that "a single daily dose of 5 mg/kg" of enrofloxacin "has been shown to be effective, thereby easing the problem of owner compliance during protracted periods of medication." On information and belief, in violation of Bayer's duty of candor to the PTO under 37 C.F.R. § 1.56, Bayer, the patentees, and/or Bayer's counsel intentionally misled the PTO and failed to disclose the Dick

reference, which was material to prosecution, during prosecution of patent application no. 863,384, the application that led to the issuance of the '506 patent. On information and belief, Bayer, the patentees, and/or Bayer's counsel did so with the intent to deceive the PTO concerning the patentability of the application, and therefore committed inequitable conduct rendering the '506 patent unenforceable.

The deadline to amend pleadings passed on November 20, 2009, and fact discovery closed on August 13, 2010. (Dkt. 34, 128.)

Discovery proceeded on the basis of the invalidity defense pleaded, the §§ 102-103 defense regarding three specifically identified pieces of prior art.

On September 17, 2010, Norbrook served two expert reports and amended interrogatory responses. In those reports and the amended interrogatory responses, Norbrook advanced the § 112 defense that it had previously removed and introduced three new § 102 prior art references, while withdrawing its prior bases of invalidity. (Fisher Decl. ¶¶ 10-12, Exs. H-J.)

Analysis

Norbrook contends that Bayer's statement that it forfeited its § 112 defense is false. Norbrook asserts that it initially stated one § 112 defense based on the improper dependency of patent claims 2 and 3 on claim 1. However, Norbrook relies on its original amended answer and counterclaims which simply stated that the claims of the '506 patent were invalid for failure to comply with the conditions for patentability as specified in 35 U.S.C.

§ 1 *et seq.*” and the ‘506 patent. Neither citation bears out Norbrook’s contention. Norbrook has not provided information that establishes what its specific defense was under § 112 originally.²

Moreover, the text of Norbrook’s January 26, 2009, email indicates that it was removing that defense based on Bayer’s representation that only claims 4 and 5 of the ‘506 patent survive the disclaimer. The reasonable interpretation of the email is that the Norbrook was withdrawing the § 112 defense in reliance on Bayer’s representation. Objectively, viewed the parties had agreed that, as long as only claims 5 and 6 would be at issue in this litigation,

²Section 112 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.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

An enablement defense or counterclaim is based on paragraph one of § 112. *See Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1336 (Fed. Cir. 2005).

Norbrook would not be relying on § 112 as a basis for a defense or counterclaim. Norbrook's interrogatory answers were consistent with that agreement until it provided Bayer with its supplemental interrogatory responses on September 17, 2010.

While the parties did not stipulate in open court, the principles underlying the enforcement of the parties' agreement are similar to those cited in *Nichia Corp. v. Seoul Semiconductor Co., Ltd.*, No. C 06-0162 MMC, 2007 WL 2533729, at * 2 (N.D. Cal. Aug. 31, 2007) (stating that "[b]ecause stipulations serve both judicial economy and convenience of the parties, courts will enforce them absent indications of involuntary or uninformed consent," citing *CDN Inc. v. Kapes*, 197 F.3d 1256, 1258 (9th Cir. 1999)). Norbrook does not contend that its agreement was involuntary or uninformed. Norbrook also knew that it had not engaged in extensive discovery. While Norbrook represents that its § 112 defense stems in large part from the deposition testimony of the '506 patent inventors which occurred in the last two months (Kim Decl. ¶ 8, Ex. 6), it took the risk when it agreed to withdraw the defense that it might later learn new or additional facts that would be relevant to a defense under § 112. Agreements between counsel must be honored. Therefore, the Court concludes that Norbrook agreed to forego any § 112 defense and counterclaim and to that extent will grant Bayer's motion to strike the expert reports and amended interrogatory answers.

However, the Court will deny the motion to strike as to Norbrook's reliance on different prior art than that previously relied on and to its change in theory from obviousness to anticipation. The situation presented is analogous to that of *DataQuill, Ltd. v. Handspring*, No. 01 C 4653, 2003 WL 25696445, at *1 (N.D. Ill. Dec. 19, 2003), where the court denied

a motion to exclude an expert's report that relied upon several prior art references that had not been identified in the party's contention interrogatory responses.

In this action, Norbrook's second amended answer and counterclaims cited three pieces of prior art as examples. Norbrook also retained the right to supplement its interrogatories, and did so once it learned of three prior art references that it asserts provide a basis for an anticipation defense. Bayer will also have sufficient time to take discovery on these matters. Rebuttal reports are due on October 15, 2010, and expert discovery does not close until December 17, 2010. (Dkt. 128.) As such, Bayer's motion to strike is denied as to the new prior art and anticipation defense(s) and counterclaim(s).

**NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY
ORDERED THAT:**

Bayer's Civil Local Rule 7(h) to strike the expert reports of Byrn and Gershwin and the amended interrogatory responses of Norbrook (Docket No. 129) is **GRANTED** to the extent those materials relate to § 112 defense(s) and counterclaim(s) and **DENIED** to the extent that those reports and amended interrogatory responses relate to the new prior art and anticipation defense(s) and counterclaim(s).

Dated at Milwaukee, Wisconsin this 14th day of October, 2010.

BY THE COURT

s/ Rudolph T. Randa

Hon. Rudolph T. Randa
U.S. District Judge