IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,	§	
	§	
v.	§	**CIVIL ACTION NO. 2:09-cv-97**
	§	
SANDOZ INC.,	§	
ALLERGAN, INC.,	§	
	§	
v.	§	**CIVIL ACTION NO. 2:09-cv-182**
	§	
HI-TECH PHARMACAL CO., INC.,	§	
ALLERGAN, INC.,	§	
	§	
v.	§	**CIVIL ACTION NO. 2:09-cv-348**
	§	
ALCON LABORATORIES, INC., et al.,	§	
ALLERGAN, INC.,	§	
	§	
v.	§	**CIVIL ACTION NO. 2:10-cv-200**
	§	
APOTEX INC. and APOTEX CORP.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is Defendants Sandoz Inc.'s ("Sandoz"); Alcon Laboratories, Inc.'s, Alcon Research Ltd.'s, Alcon Research, Inc.'s, and Falcon Pharmaceuticals, Ltd.'s ("Alcon"); Apotex Inc.'s and Apotex Corp.'s ("Apotex"); and Watson Laboratories, Inc.'s ("Watson") (collectively, "Defendants") motion for summary judgment of non-infringement of claims 1-3 of Allergan Inc.'s ("Allergan") U.S. Patent No. 7,030,149 ("the '149 patent"). (D.I. 196.) Defendants contend the Court should decide as a matter of law that Allergan cannot assert infringement of claims 1-3 of the '149 Patent under 35 U.S.C. § 271(e)(2); and/or there is no evidence that each of the Defendants infringe claims 1-3 of the '149 patent. Having carefully considered the parties' arguments, the court GRANTS Defendants' motion for summary

judgment that none of the Defendants are seeking FDA approval for the uses claimed in claims 1-3 of the '149 patent and that the uses claimed in claims 1-3 of the '149 patent are not FDA approved. In addition, Plaintiff's request for reconsideration of the Court's claim construction is DENIED.

I. Factual Background

Allergan is the holder of a New Drug Application ("NDA") for a 0.2% brimonidine tartrate/0.5% timolol fixed combination ophthalmic drug called Combigan®. *See, e.g.,* D.I. 1 at ¶ 12. Under the Hatch-Waxman Act, Allergan is required to disclose to the United States Food and Drug Administration ("FDA") the patent numbers and expiration dates of those patents that Allergan believes claim the "drug" for which its NDA is submitted, or patents covering a "method of using such drug." *See* 21 U.S.C. §§ 355(b)(1) and (c)(2). Pursuant to 21 U.S.C. § 355(b)(1)(G), Allergan caused the FDA to publish the '149 patent, along with U.S. Patent Nos. 7,320,976; 7,323,463; and 7,642,258, in the FDA "Orange Book" in connection with its NDA for Combigan®. *See, e.g.,* D.I. 1 at ¶ 13.

Each of Sandoz, Alcon, Apotex and Watson submitted an ANDA to the FDA seeking approval to manufacture and market a 0.2% brimonidine tartrate/0.5% timolol fixed combination ophthalmic drug. *See, e.g.,* D.I. 1 at ¶ 15. Each of the Defendants included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that the '149, '976, '463 and '258 patents are invalid and/or will not be infringed by the manufacture, importation, use or sale of the drug product described in their ANDAs. *See, e.g.,* D.I. 1 at ¶¶ 16-17. Furthermore, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, each of the Defendants sent a Confidential Notice Letter to Allergan informing Allergan of the filing of their ANDA and providing the detailed basis for their Paragraph IV certifications. Allergan filed

lawsuits against each of the Defendants, alleging that each of their ANDA products infringe the '149, '976, '463 and '258 patents ("patents-in-suit"). *See, e.g.*, D.I. 1.

Allergan served its infringement contentions on Sandoz and Alcon on March 22, 2010, Apotex on August 16, 2010, and Watson on March 7, 2011. *See, e.g.*, Exh. F. Sandoz and Alcon served their invalidity contentions on Allergan on May 24, 2010, while Apotex and Watson served their invalidity contentions on Allergan on September 15, 2010 and March 21, 2011, respectively. The Court conducted a Markman hearing on January 28, 2011 and issued a Memorandum Opinion and Order on claim construction on April 27, 2011. D.I. 151. Fact discovery closed on May 2, 2011. On May 11, 2011, Defendants submitted a letter brief requesting permission to file for summary judgment of noninfringement of claims 1-3 of the '149 patent. D.I. 160. Allergan submitted its responsive brief on May 25, 2011 and Defendants submitted their reply brief on June 3, 2011. D.I. 169 and 177.

Allergan served its opening expert report on infringement of the patents-in-suit to each of the Defendants on May 27, 2011. Each of the Defendants submitted their opening expert reports on invalidity of the claims of the patents-in-suit on May 27, 2011. Defendants and Allergan served rebuttal reports on June 17, 2011. Allergan amended its infringement contentions on May 27, 2011 and Defendants amended their invalidity contentions on June 15, 2011. The Court granted Defendants' request to file for summary judgment of non-infringement of claims 1-3 of the '149 patent on June 23, 2011. D.I. 186.

II. Legal Standard

Summary judgment is proper if the pleadings and evidence show that "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Anderson v. Liberty*

Lobby, Inc., 477 U.S. 242, 248-55 (1986). "Summary judgment is as appropriate in a patent case as it is in any other case." *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 672 (Fed. Cir. 1990). When the summary judgment movants demonstrate the absence of a genuine dispute over any material fact, the burden shifts to the non-movant to show there is a genuine factual issue for trial. *Celotex*, 477 U.S. at 323-24. The court must draw all reasonable inferences in favor of the non-moving party. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007).

An infringement analysis requires comparison of the construed patent claims to the accused devices. *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1577 (Fed. Cir. 1993). This determination of infringement is a question of fact. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). In the absence of a genuine dispute regarding the structure or function of the accused product, the question of infringement may collapse into one of claim construction and thus is well suited for summary judgment. *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1381 (Fed. Cir. 1999); *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1461-62 (Fed. Cir. 1998). Literal infringement requires the accused device to contain each claim limitation exactly. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001); *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998). As a matter of law, the absence of a single claim limitation from the accused product precludes literal infringement. *Wolverine World Wide Inc. v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994). A dependent claim cannot be infringed unless the claim from which it depends is infringed. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

III. The Court's Claim Construction Ruling

In its April 27, 2011 Memorandum Opinion and Order, the Court construed several terms that are present in claim 1 of the '149 patent. *See* D.I. 151. Claim 1 of the '149 patent is as follows:

> A method of **treating glaucoma or ocular hypertension** by topical administration of about 0.2% brimonidine by weight to an eye of a person in need thereof, said improvement comprising topically administering to said eye, in a single composition, about 0.2% brimonidine by weight and about 0.5% timolol by weight twice a day; as the sole active agents; wherein said method is **as effective as** administration of 0.5% timolol twice a day and 0.2% brimonidine three times a day to said eye, wherein the two compounds are **administered in separate compositions**.

'149 patent 9:14-10:4. The Court construed the bolded terms above of claim 1 of the '149 patent as follows:

Claim Phrase in Claim 1 of the '149 patent	Court's Construction
"treating glaucoma or ocular hypertension"	"treating glaucoma or ocular hypertension"
"as effective as"	"equal or greater at lowering intraocular pressure (IOP)"
"administered in separate compositions"	"serially administered to the eye in separate compositions as brimonidine three times a day and timolol twice a day"

See D.I. 151 at 14-18, 20-24, and 27-30. Based on this construction, claim 1 can be summarized as a method of treating glaucoma or ocular hypertension of about 0.2% brimonidine and about 0.5% timolol in a single composition dosed twice a day that is equal or greater at lowering intraocular pressure as compared to a serial administration to the eye in separate compositions of brimonidine three times a day and timolol twice a day.

IV. Discussion and Analysis

In the context of Hatch-Waxman cases, the Federal Circuit has held that a party cannot assert infringement for uses not approved by the FDA. *Allergan, Inc. v. Alcon Labs., Inc*., 324

F.3d 1322, 1332-1333 (Fed. Cir. 2003). Defendants contend that they are not seeking FDA approval for the uses claimed in claims 1-3 of the '149 patent because the proposed products included in Defendants' ANDA are not equal or greater at lowering intraocular pressure as compared to a serial administration of the active agents. Instead, Defendants argue that their proposed ANDA products state that the lowering of intraocular pressure by their ANDA products is slightly less (not "equal or greater") than a concomitant regimen of brimonidine tartrate dosed three times a day and timolol dosed twice a day. Additionally, Defendants contend that the FDA approved use stated in Allergan's Combigan® label is not the same use claimed in claim 1 of the '149 patent.

Allergan responds that Defendants have each identified the indication of their products in their ANDAs, and that none of the ANDAs identify the indications as being anything other than the lowering of IOP. Accordingly, Allergan argues that Defendants' "off-label" arguments are contrary to their ANDAs, and should be rejected. Allergan argues that the FDA approved use is simply a method of lowering IOP. That is, Allergan contends that the language that Defendants rely on—that the IOP lowering of the fixed combination formulation is "slightly less" than that of serial administration of brimonidine TID and timolol BID—is not part of the approved indication. Allergan argues that while this information may be relevant to the ultimate infringement inquiry, it does not transform everything on the label into the "approved indication" for purposes of whether a Hatch-Waxman suit is "off-label" under Section 271(e)(2). Allergan concludes that the approved use for Combigan®, and for Defendants' products, is "the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunction or replacement therapy due to inadequately controlled IOP."

The Court disagrees with Allergan and finds that its "'hypothetical [infringement

analysis] is properly grounded in the ANDA application and the extensive materials typically submitted in its support.' Therefore, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-1249 (Fed. Cir. 2000) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

The Court concludes that Defendants are not seeking FDA approval for the uses claimed in claims 1-3 of the '149 patent because Defendants' ANDA products are not equal or greater at lowering intraocular pressure as compared to a serial administration of the active agents. *See* '149 patent 9:14-10:4; D.I. 151 at 20-24; 27-30; D.I. 196-3, Sandoz draft label at SAN-BRI-000079; D.I. 196-4, Alcon's draft label at ALCON(BRIM) 003254; D.I. 196-5, Apotex's draft label at ANDA0000018; D.I. 196-6, Watson's draft label at WAT0000093. Like Allergan, Defendants' proposed ANDA products state that the lowering of intraocular pressure by their ANDA products is slightly less (not "equal or greater") than a concomitant regimen of brimonidine tartrate dosed three times a day and timolol dosed twice a day. *Id.* and D.I. 196-7, Combigan® Prescribing Information at AGN_COMBI0080429, AGN_COMBI0080430 and AGN-COMBI0080437. Additionally, the FDA approved use stated in Allergan's Combigan® label is not the same use claimed in claim 1 of the '149 patent.

In *Allergan*, the Federal Circuit precluded Allergan from suing Alcon and B & L under section 271(e)(2) for inducing infringement of two patents, because Alcon and B & L were not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patent were not FDA-approved. 324 F.3d at 1332-1333; *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003) ("[I]t is not an act of infringement to submit an ANDA for

approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA."). In its May 25, 2011 responsive letter brief, Allergan's attempt to distinguish these cases on the basis that the methods in dispute in those cases are more distinct than the methods in this case. The Court disagrees and finds that the Federal Circuit's reasoning in *Allergan* and *Warner-Lambert* did not apply a level of distinctness between the methods claimed and the methods approved by the FDA. Moreover, as discussed above, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder when conducting an infringement analysis under § 271(e)(2)(A). Thus, Allergan's attempt to distinguish these cases is misguided.

The uses for which Defendants are seeking FDA approval here are stated in each of the labels of their ANDA products. The "Indications and Usage" section of each of Defendants' proposed labels contain the following language:

> [T]he IOP-lowering of brimonidine tartrate and timolol maleate ophthalmic solution dosed twice a day was slightly less than that seen with the concomitant administration of 0.5% timolol maleate ophthalmic solution dosed twice a day and 0.2% brimonidine tartrate ophthalmic solution dosed three times a day.

See D.I. 196-3, Sandoz draft label at SAN-BRI-000079; D.I. 196-4, Alcon's draft label at ALCON(BRIM) 003254; D.I. 196-5, Apotex's draft label at ANDA0000018; D.I. 196-6, Watson's draft label at WAT0000093. As the excerpted labels demonstrate, Defendants are not seeking FDA approval for a method of treating glaucoma or ocular hypertension of about 0.2% brimonidine and about 0.5% timolol in a single composition dosed twice a day *that is equal or greater at lowering intraocular pressure as compared to a serial administration to the eye in separate compositions of brimonidine three times a day and timolol twice a day*, the use claimed

in claim 1 of the '149 patent. Additionally, as admitted in its label, Allergan's Combigan® product has less intraocular pressure lowering than a concomitant administration of 0.2% brimonidine tartrate dosed three times a day and 0.5% timolol dosed twice a day:

> [T]he IOP-lowering of COMBIGAN® dosed twice a day was slightly less than that seen with the concomitant administration of timolol maleate ophthalmic solution, 0.5% dosed twice a day and brimonidine tartrate ophthalmic solution, 0.2% dosed three times per day.
>
> * * *
>
> However, the IOP lowering of COMBIGANTM BID was less (approximately 1-2 mm Hg) than that seen with the concomitant administration of 0.5% timolol BID and 0.2% brimonidine tartrate TID.

See D.I. 196-7 at AGN_COMBI0080429, AGN_COMBI0080430 and AGN-COMBI0080437 (emphasis added). Thus, the FDA approved use stated in Allergan's Combigan® label is not the same use claimed in claim 1 of the '149 patent.

In its May 25, 2011 responsive letter brief, Allergan asks the Court to rely on the first section of the "Indications and Usage" section of the FDA-approved Combigan® label and ignore the last two-thirds of this section entirely. However, the last two-thirds of the "Indications and Usage" section is not merely superfluous or irrelevant information. Rather, the FDA specifically required Allergan to include this material in its label because it defines the indications and use of Combigan® in its entirety. Indeed, Allergan gives the Court no basis for ignoring the "Indications and Usage" section of the Combigan® label in its entirety. In addition, the FDA's Summary Review for NDA Application No. 21-398 for Combigan® states "[t]he combination is *slightly inferior* to brimonidine and timolol being given concomitantly (approximately 0.19-1.69 mmHg)." *See* D.I. 196-27, FDA Summary Review at AGN_COMBI0673031 (emphasis added). For these reasons, the Federal Circuit's reasoning in *Allergan* is equally applicable here and the Court finds that none of the Defendants are seeking

FDA approval for the uses claimed in claims 1-3 of the '149 patent and that the uses claimed in claims 1-3 of the '149 patent are not FDA approved.

VII. Conclusion

For the foregoing reasons, the Court GRANTS Defendant's motion for summary judgment that none of the Defendants are seeking FDA approval for the uses claimed in claims 1-3 of the '149 patent and that the uses claimed in claims 1-3 of the '149 patent are not FDA approved.

It is so ORDERED.

SIGNED this 25th day of August, 2011.

T. John Ward

T. JOHN WARD
UNITED STATES DISTRICT JUDGE