reserved the authority to make final claims determination regarding *pre-service* and *post service* claims[.]" *Id.* at 2, 86–87 (emphasis added). Thus, Ingenix's discretion as Claims Administrator is limited to "urgent care claims." See *id.* at 61. While the nature of Quintana's insurance claims are not expressly clear from the pleadings or motions, they appear to be "urgent care claims" over which Ingenix exercises discretion and responsibility to determine eligibility and amount. *Id.* at 2. Consequently, for purposes of this case, Ingenix may very well be an ERISA fiduciary. See, *e.g.*, *Reich*, 55 F.3d at 1049. Because the court has determined that Quintana's claim is outside the scope of § 502, however, such a finding is immaterial. See, *e.g.*, *Memorial Hospital*, 904 F.2d at 245.

III. *CONCLUSION*

For the above state reasons, the plaintiff's motion to remand the case to the state court from which it was previously removed is **GRANTED.** This case is **REMANDED** to the **193rd Judicial District Court of Dallas County, Texas.** The clerk shall mail a certified copy of this memorandum opinion and order to the district clerk of Dallas County, Texas. 28 U.S.C. § 1447(c).

SO ORDERED.

ALLERGAN, INC., Plaintiff,

v.

SANDOZ INC., Defendant.

Allergan, Inc., Plaintiff,

v.

Alcon Laboratories, Inc., Alcon Research, Ltd., Alcon, Inc. and Falcon Pharmaceuticals, Ltd., Defendants.

Allergan, Inc., Plaintiff,

v.

Apotex Inc. and Apotex Corp., Defendants.

Allergan, Inc., Plaintiff,

v.

Watson Laboratories, Inc., Defendant.

Civil Action Nos. 2:09–cv–97, 2:09–cv–348 TJW, 2:10–cv–200 TJW, 2:10–cv–344 TJW.

United States District Court,
E.D. Texas,
Marshall Division.

Aug. 22, 2011.

Background: Patentee brought action against competitors, alleging infringement of patents for a drug used to treat glaucoma and ocular hypertension.

Holdings: The District Court, T. John Ward, J., held that:

(1) patents were not invalid as anticipated by prior art reference, and

(2) patents were not invalid for obviousness.

Ordered accordingly.

1. Patents ⇐312(4), 314(5)

Patent infringement is a question of fact and must be proven by a preponder-

ance of the evidence. 35 U.S.C.A. § 271(e)(2).

2. Patents ⇐72(1)

A patent is invalid as anticipated if a single prior art reference discloses each element of the claimed invention. 35 U.S.C.A. § 102.

3. Patents ⇐65

A prior art reference may anticipate a patent claim, and, thus, render it invalid, when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. 35 U.S.C.A. § 102.

4. Patents ⇐58

If a claim limitation is not explicitly disclosed in an allegedly anticipating prior art reference, the party alleging patent invalidity bears the burden of showing that the limitation is inherently disclosed by the reference. 35 U.S.C.A. § 102.

5. Patents ⇐65

To establish that a claim limitation is inherent in an allegedly anticipating prior art reference, the anticipatory feature or result must be consistent, necessary, and inevitable, not simply possible or probable, and it should be clear that it would be so recognized by persons of ordinary skill. 35 U.S.C.A. § 102.

6. Patents ⇐65

In order to establish patent invalidity, an anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence was recognized by persons of ordinary skill in the field of the invention. 35 U.S.C.A. § 102.

7. Patents ⇐65

Anticipation of a patent, rendering it invalid, requires enablement, whereby the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation. 35 U.S.C.A. § 102.

8. Patents ⇐62(2)

Generally, testimony concerning patent anticipation must be testimony from one skilled in the art and must identify each claim element, state the witness' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference; testimony is insufficient if it is merely conclusory. 35 U.S.C.A. § 102.

9. Patents ⇐62(1)

Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to the analysis of whether a patent in invalid as anticipated. 35 U.S.C.A. § 102.

10. Patents ⇐66(1.12)

Patents for a drug used to treat glaucoma and ocular hypertension were not invalid as anticipated by a prior art reference describing pharmaceutically acceptable compounds for controlling intraocular pressure in patients with glaucoma and ocular hypertension; prior art reference failed to describe a fixed combination of brimonidine and timolol or a method of treating glaucoma using such a combination. 35 U.S.C.A. § 102.

11. Patents ⇐16(2, 3), 16.13, 36.1(1)

A determination of obviousness is a legal determination based on four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the patent claims and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations of non-obviousness. 35 U.S.C.A. § 103.

12. Patents ⇐16.5(1)

When the patented invention is a combination of known elements, in evaluating a claim of invalidity for obviousness, the court must determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue by considering the teach-

ings of multiple references, the effects of demands known to the design community or present in the marketplace, and the background knowledge possessed by a person having ordinary skill in the art. 35 U.S.C.A. § 103.

13. Patents ⇨36.1(1), 36.2(1)

Secondary considerations that provide evidence of the non-obviousness of a patent include copying, commercial success, failure of others, long-felt need, general skepticism of those in the art, and unexpected results. 35 U.S.C.A. § 103.

14. Patents ⇨36.2(7)

A presumption arises that the patented invention is commercially successful, as evidence that it is not invalid for obviousness, when a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent. 35 U.S.C.A. § 103.

15. Patents ⇨16.5(4)

If there is no proof that there were a finite number of identified and predictable solutions in the prior art at the time of the patented invention, this cuts against a finding of invalidity for obviousness. 35 U.S.C.A. § 103.

16. Patents ⇨16(3, 4)

Patent obviousness is analyzed from the perspective of one of skill in the art at the time of the invention, and the use of hindsight is not permitted. 35 U.S.C.A. § 103.

17. Patents ⇨16.25

Patents for a drug used to treat glaucoma and ocular hypertension were not rendered invalid for obviousness by a prior art reference describing pharmaceutically acceptable compounds for controlling intraocular pressure in patients with glaucoma and ocular hypertension; person of ordinary skill in art would not have had reason, after reading prior art reference, to develop claimed combination of brimonidine and timolol given unpredictable nature of field, patentee's clinical studies of drug demonstrated unexpected results, and there was a long felt need for a fixed combination product to treat glaucoma at time of patented invention. 35 U.S.C.A. § 103.

Patents ⇨328(2)

5,502,052. Cited as Prior Art.

Patents ⇨328(2)

7,030,149, 7,320,976, 7,323,463, 7,642,258. Valid and Infringed.

W. Chad Shear, Fish & Richardson, Dallas, TX, A. Martina Tyreus Hufnal, Fish & Richardson, Wilmington, DE, Aine M. Skow, Deanna J. Reichel, Elizabeth M. Flanagan, Jonathan E. Singer, Susan M. Coletti, Fish & Richardson, Minneapolis, MN, Gregory Phillip Love, Todd Y. Brandt, Stevens Love Hill & Holt PLLC, Longview, TX, Juanita R. Brooks, Fish & Richardson, San Diego, CA, Otis W Carroll, Jr., Ireland Carroll & Kelley, Tyler, TX, for Plaintiffs.

Barry P. Golob, Kerry B. McTigue, William Blake Coblentz, Duane Morris LLP, Washington, DC, Ian Scott, Duane Morris LLP, New York, NY, Joseph M. Bennett-Paris, Duane Morris, Atlanta, GA, Richard T. Ruzich, Robert M. Gould, Duane Morris LLP, Chicago, IL, William Ellsworth Davis, III, The Davis Firm, PC, Longview, TX, for Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

T. JOHN WARD, District Judge.

I. INTRODUCTION

This is a consolidation of four patent infringement suits brought by Plaintiff Al-

lergan, Inc.'s ("Allergan") pursuant to the Hatch–Waxman Act.[1] *See* Drug Price Competition and Patent Term Restoration Act, which is commonly referred to as the Hatch–Waxman Act, in 1984. Pub. L. No. 98–417, 98 Stat. 1585. Defendants Sandoz, Inc. ("Sandoz"); Alcon Laboratories, Inc., Alcon Research, Ltd., Alcon, Inc., and Falcon Pharmaceuticals, Ltd. ("Alcon"); Apotex, Inc. and Apotex Corp. ("Apotex"); and Watson Laboratories, Inc. ("Watson") (collectively "Defendants") are each seeking approval from the Food and Drug Administration ("FDA") to market generic copies of Allergan's Combigan® product, used for the treatment of glaucoma and ocular hypertension.[2] In this consolidated action, Allergan alleges that Defendants' proposed generic pharmaceutical products infringe the asserted claims of United States Patent Nos. 7,030,149 ("the '149 patent"); 7,320,976 ("the '976 patent"); 7,323,463 ("the '463 patent"); and 7,642,258 ("the '258 patent") (collectively, the "patents-in-suit"). The Court held a four-day bench trial in the case on August 2, 2011 through August 5, 2011.

Pursuant to Fed.R.Civ.P. 52, and after having considered the entire record in this case and the applicable law, the Court concludes that: (1) each of the Defendants infringe claim 4 of the '149 Patent, claim 1 of the '976 patent, claims 1–6 of the '463 Patent, and claims 1–9 of the '258 Patent; and (2) the patents-in-suit are not invalid. These findings of fact and conclusion of law are set forth in further detail below. The Court's findings of fact are based on the admissible evidence. Any finding of fact that is actually a conclusion of law should be treated as such. Any conclusion of law that is actually a finding of fact should be treated as such.

II. FINDINGS OF FACT

A. The Parties

1. Allergan, Inc. is a Delaware corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 92612.

2. Sandoz Inc. is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

3. Alcon Laboratories, Inc. is a Delaware corporation, with a place of business in Texas.

4. Alcon Research, Ltd. is a Delaware corporation, with a place of business in Texas.

5. Alcon, Inc. no longer exists, based on a merger with Novartis AG.

6. Falcon Pharmaceuticals, Ltd. is a Texas corporation, with a place of business in Texas.

7. Apotex, Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

8. Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

9. Watson Laboratories, Inc. is a Nevada corporation with a place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

1. A fifth action, *Allergan, Inc. v. Hi–Tech Pharmacal Co., Inc.*, C.A. No. 2:09–cv–182 (TJW) was also consolidated with these four actions. However, Allergan and Hi–Tech resolved the dispute and filed a stipulation of dismissal (D.I. 168), which was ordered by this court on May 31, 2011. (D.I. 175.)

2. Specifically, these consolidated suits relate to the filing of Abbreviated New Drug Application ("ANDA") No. 91–087 by Sandoz, ANDA No. 91–574 by Alcon, ANDA No. 91–442 by Apotex, and ANDA No. 201949 by Watson with the FDA, pursuant to the Federal Food, Drug, and Cosmetic Act.

B. Glaucoma and Ocular Hypertension

10. Glaucoma is an incurable disease of the eye that causes gradual damage to the optic nerve resulting in vision loss that, ultimately, can lead to blindness. (D.I. 238, Trial Tr. Day 1(AM) at 51:24–52:2; 52:21–53:7 (Whitcup).)[3] About 2 million people in the United States are diagnosed with glaucoma every year. (*Id.* at 52:7–10 (Whitcup).)

11. While incurable, glaucoma can be managed by pharmaceutical and surgical treatment options that slow the progression of the disease. (D.I. 242, Trial Tr. Day 3(AM) at 71:4–9 (Noecker).) One such treatment option is to use medication to lower the intraocular pressure ("IOP") in the eye. (*Id.* at 72:20–73:7 (Noecker).) Scientists and medical professionals believe that the elevated IOP found in glaucoma patients contributes to the gradual retinal deterioration and loss of vision that are characteristics of the disease. (D.I. 238, Trial Tr. Day 1(AM) at 53:15–21; 54:10–21 (Whitcup); D.I. 242, Trial Tr. Day 3(AM) at 66:3–15 (Noecker).) Intraocular pressure is measured in millimeters of mercury ("mm Hg"). (D.I. 242, Trial Tr. Day 3(AM) at 66:3–8 (Noecker).) For each millimeter of mercury IOP is lowered, patients are 10% less likely to suffer visual field loss. (*Id.* at 67:14–18 (Noecker).)

12. Patients suffering from ocular hypertension ("OHT") also have elevated IOP and, although not diagnosed with glaucoma, must be observed closely for its onset. (D.I. 242, Trial Tr. Day 3(AM) at 66:21–67:25 (Noecker).) These patients can utilize the same pharmaceutical and surgical options used by glaucoma patients to attempt to reduce IOP. (*Id.* at 71:4–9 (Noecker).)

C. Treatment of Glaucoma and Ocular Hypertension with Brimonidine and Timolol

13. One treatment method for patients with glaucoma or ocular hypertension is the use of eye drops. This form of treatment is the most convenient and acceptable to patients. (D.I. 242, Trial Tr. Day 3(AM) at 71:4–9; 81:20–84:25 (Noecker).)

14. There are at least 20 different glaucoma drugs on the market today that can be used in such treatments. (D.I. 238, Trial Tr. Day 1(AM) at 54:22–55:5 (Whitcup).) Those that are commonly used in clinical practice fall into several different classes of medication, and have different mechanisms of action. (D.I. 240, Trial Tr. Day 2(AM) at 50:10–18; (Tanna); D.I. 242, Trial Tr. Day 3(AM) at 72:6–78:8 (Noecker).) Most relevant here are two classes of medication, alpha$_2$ adrenergic agonists and so-called "beta blockers."

15. Brimonidine tartrate 0.2% was marketed by Allergan as Alphagan®, and was first developed by Allergan as a new glaucoma medication in the late 1980s and early 1990s. (D.I. 239, Trial Tr. Day 1(PM) at 75:8–10 (Batoosingh).) Brimonidine is an alpha$_2$ adrenergic agonist that lowers IOP in glaucoma patients by reducing fluid production in the eye while also increasing outflow of that fluid from the eye. (D.I. 238, Trial Tr. Day 1(AM) at 59:22–60:7 (Whitcup); D.I. 239, Trial Tr. Day 1(PM) at 74:14–75:7 (Batoosingh).) The FDA approved Alphagan® in 1996. (D.I. 239, Trial Tr. Day 1(PM) at 75:8–10 (Batoosingh).)

3. As used herein, "DTX," "PTX," and "JTX" refer to Defendants' exhibit, Plaintiffs exhibit, and Joint Exhibit respectively, and will be followed by the exhibit number. "Trial Tr. Day" refers to the trial transcript and will be followed by the day, page number, and line numbers. For example, "Trial Tr. Day 1(AM) at 53:15–21" refers to the morning trial transcript, day 1, page 53, lines 15–21.

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