Ex. 2003

Pozen Inc. v. Par Pharm., Inc.,
719 F.Supp.2d 718 (E.D. Tex. 2011)

gram Administrator and the plaintiff has sued both Regions and Lot under the same contract—the 6697 Loan. Accordingly, the plaintiff's actions have bound her to arbitrate with Lot. *See Grigson v. Creative Artists Agency, LLC,* 210 F.3d at 528–29 (estoppel binding non-signatory through claim on common instrument with signatory); *Washington Mutual Finance Group, LLC v. Bailey,* 364 F.3d 260, 266 (5th Cir.2004) (same); and *Terminix Int'l, Inc. v. Rice,* 904 So.2d 1051, 1058 (Miss.2004) (even though only the wife was the only signatory to the extermination contract at issue, because the husband's claims related to the contract, he was also required to arbitrate even though he was a non-signatory).

[7] Once the court finds that the parties agreed to arbitrate, it must then determine whether any legal constraints external to the parties' agreement foreclose the arbitration of the claims involved. The court can find no legal constraint which prevents this case from being submitted to arbitration. In fact, the plaintiff has stated that she "does not claim that external legal constraints have foreclosed arbitration in this case." *See* Doc.[7] at 1–2.

Once the court determines that a valid arbitration agreement exists and that the claims presented are arbitrable thereunder, the court has to make a decision as to the course of the litigation before it. The FAA contemplates that parties that are aggrieved by another party's failure to arbitrate under a written agreement, may file a motion to stay the trial of an action until such arbitration has been had in accordance with the terms of the agreement. *See,* 9 U.S.C. § 3. After arbitration, the parties can then file a request with the court to enforce the results of the arbitration. However, this court follows the practice of dismissing the present litigation without prejudice subject to the refiling of an enforcement action at the conclusion of arbitration, if such is necessary.

IT IS THEREFORE ORDERED AND ADJUDGED that the defendants' Motion to Compel Arbitration **[# 4]** is Granted and the parties are ordered to submit the matter to binding arbitration as per the agreement between the parties.

IT IS FURTHER ORDERED AND ADJUDGED that this matter is dismissed without prejudice subject to a refiling of a future separate action to enforce any arbitration award and that any other pending motions herein are denied as moot.

POZEN INC., Plaintiff,

v.

PAR PHARMACEUTICAL, INC., Alphapharm Pty. Ltd., Teva Pharmaceuticals USA Inc., Dr. Reddy's Laboratories, Inc., Defendants.

Civil Action Nos. 6:08cv437–LED–JDL, 6:09cv003, 6:09cv182.

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

June 18, 2010.

Background: Patentee brought action against competitors, alleging infringement of patents describing pharmaceutical formulation and corresponding methods for treating migraine headaches.

Holdings: Following a *Markman* hearing, the District Court, John D. Love, United States Magistrate Judge, held that:

(1) term "administering" meant to mete out, and

(2) term "multilayer pharmaceutical tablet" meant a pharmaceutical tablet with at least two separate, distinct layers.

Ordered accordingly.

1. Patents ⚿165(2)

The claims of a patent define the invention to which the patentee is entitled the right to exclude.

2. Patents ⚿314(5)

Courts construe the scope and meaning of disputed patent claims as a matter of law.

3. Patents ⚿165(1), 167(1), 168(2.1)

In patent claim construction, courts examine the patent's intrinsic evidence to define the patented invention's scope; intrinsic evidence includes the claims themselves, the specification, and the prosecution history.

4. Patents ⚿157(1), 161

Courts give patent claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent.

5. Patents ⚿162

A patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope.

6. Patents ⚿167(1)

A specification may resolve ambiguous patent claim terms where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.

7. Patents ⚿167(1.1)

Although a specification may aid the court in interpreting the meaning of disputed patent claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.

8. Patents ⚿101(2, 11)

Term "administering" in patents describing pharmaceutical formulation and corresponding methods for treating migraine headaches meant to mete out; term would be given its ordinary and customary meaning.

9. Patents ⚿101(2, 11)

Term "concomitant administration" in patents describing pharmaceutical formulation and corresponding methods for treating migraine headaches meant simultaneous administration or administration of second drug for migraine relief while first drug was present in a therapeutically effective amount.

10. Patents ⚿101(2, 11)

Term "long-acting, nonsteroidal, anti-inflammatory drug" in patents describing pharmaceutical formulation and corresponding methods for treating migraine headaches meant an NSAID with a pharmacokinetic half-life of at least about 4-6 hours and preferably about 8-14 hours and a duration of action equal to or exceeding about 6-8 hours.

11. Patents ⚿101(2, 11)

Term "multilayer pharmaceutical tablet" in patents describing pharmaceutical formulation and corresponding methods for treating migraine headaches meant a pharmaceutical tablet with at least two separate, distinct layers.

Patents ⚿328(2)

6,060,499, 6,586,458, 7,332,183. Construed.

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MEMORANDUM OPINION AND ORDER

JOHN D. LOVE, United States Magistrate Judge.

This Memorandum Opinion and Order sets forth the Court's constructions for the disputed claim terms in the patents asserted by Plaintiff Pozen Inc. ("Pozen"). Pozen asserts U.S. Patent Nos. 6,060,499 ("the '499 patent"), 6,586,458 ("the '458 patent"), and 7,332,183 ("the '183 patent") and has filed an Opening Claim Construction Brief (Doc. No. 164) ("Opening"), as well as a Reply in support of Pozen's proposed constructions (Doc. No. 176) ("Reply"). Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Defendants") [1] have filed a Responsive Claim Construction Brief (Doc. No. 170) ("Response"). A *Markman* hearing was held on February 25, 2010 (Doc. No. 184), where thirteen disputed claim terms were submitted to the Court for construction. (Doc. No. 159–2) ("Joint Claim Chart").[2] The Court entered a Provisional Claim Construction Order (Doc. No. 189) on March 26, 2010, 2010 WL 2231989. For the reasons stated herein, the Court adopts the constructions set forth below.

BACKGROUND

This case is a patent infringement suit arising out of the Hatch–Waxman Act, 21 U.S.C. § 355. All three patents-in-suit cover a pharmaceutical formulation and corresponding methods for treating migraine headaches. The disclosed inventions relate to migraine treatment through the combination of two established drugs. The '499 and '458 patents disclose a treatment model that provides relief for migraine headaches through the simultaneous administration of two therapeutic agents in a single tablet: (1) sumatriptan [3] and (2) long-acting, non-steroidal anti-inflammatory agent ("LA–NSAID") naproxen.[4] The sumatriptan is targeted at reduc-

1. Defendant Teva Pharmaceuticals USA, Inc. originally joined in this briefing but later entered into a stipulation with Pozen on April 14, 2010 to stay the case as to Teva based on a settlement reached by these two parties.

2. The parties also provided the Court with a Joint Claim Construction Chart pursuant to P.R. 4–5(d).

3. Sumatriptan is the preferred species in the ''triptan'' family of drugs, also known as 5–HT agonists, which are a subtype of cell surface receptor proteins.

4. Naproxen, or naproxen sodium, is the preferred species of a class of non-steroidal anti-inflammatory drugs (''NSAIDs''), which binds in a highly selective way to 5–HT agonists (e.g. sumatriptan).

ing already-existing inflammation and the naproxen is targeted at reducing residual inflammation. OPENING at 4. The combination of these drugs produces "longer lasting efficacy" than the administration of either drug alone. '458 patent at 2:18–22.

This treatment model is currently sold in a single tablet as an FDA-approved pharmaceutical known as Treximet®. Defendants have each submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic bioequivalent of the Pozen product. These applications challenge the patents-in-suit by asserting that they are invalid or not infringed by Defendants' proposed products. RESPONSE at 2. After Defendants filed ANDAs, Pozen filed three separate lawsuits,[5] alleging infringement of the asserted claims. Claim 1 of the '458 patent is set forth below as a representative claim, with disputed claim terms set forth in bold.

1. A method of treating a patient for migraine headache, comprising:

a) **administering** a 5–HT agonist to said patient, wherein said 5–HT agonist is a triptan; and

b) **administering** a **long-acting, non-steroidal, anti-inflammatory drug (LA–NSAID)** to said patient, wherein said LA–NSAID has a pharmokinetic half-life of at least 4 hours and a duration of action of at least 6 hours;

wherein:

i) said 5–HT agonist and said LA–NSAID are **concomitantly administered** in unit dosage form; and

(ii) the respective amounts of said 5–HT agonist and said LA–NSAID administered to said patient are sufficient to produce longer lasting efficacy compared to the administration of said 5–HT agonist in the absence of said LANSAID or the administration of said LANSAID in the absence of said agonist.

'458 patent at 12:6–25 (claim 1).

The '183 patent discloses a unique tablet architecture to orally administer the combination of therapeutic agents. In this delivery model, sumatriptan and naproxen are "segregated into separate layers" that dissolve in the stomach substantially independent of one another. '183 patent at 1:56–57. The specific oral dosage and the segregation of the therapeutic agents is intended to provide superior dissolution and absorption in the body. *Id.* at 1:60–62 ("The dosage forms of the invention have been found to have substantial advantages over others in terms of release properties, stability, and? pharmacokinetic profile."). The Treximet® product contains the tablet architecture claimed by the '183 patent for the delivery of sumatriptan and naproxen. OPENING at 5. Claim 1 of the '183 patent is set forth below as a representative claim with disputed claim terms set forth in bold.

1. A **multilayer pharmaceutical tablet** comprising naproxen and a triptan and, wherein

a) **substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer;** and

b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan.

'183 patent at 18:30–37 (claim 1).

The parties present thirteen disputed claim terms for construction. The fol-

5. The separate lawsuits were consolidated into a single action in February 2009 (Doc. No. 30).

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