UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. DR. REDDY'S LABORATORIES INC., et al., Defendants.	Civil Action No. 11-2317 (JAP) (lead case) 11-4275 (JAP) 11-6348 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E, Inc. and Pozen, Inc. ("Astra" or "Plaintiffs") bring these Hatch-Waxman patent infringement actions against Defendants Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories Ltd (together, "Dr. Reddy's"), Lupin Ltd., Lupin Pharmaceuticals Inc. (together, "Lupin"), Anchen Pharmaceuticals, Inc. ("Anchen") alleging infringement of U.S. Patent No. 6,926,907 (the " '907 patent"), No. 6,369,085 (the " '085 patent"), No. 7,411,070 (the " '070 patent"), No. 7,745,466 (the " '466 patent"), No. 5,714,504 (the " '504 patent") and 6,875,872 (the " '872 patent"). Presently before the Court is the parties' request for claim construction. The Court has held a *Markman* hearing and construes the disputed claim terms as set forth below.

I. BACKGROUND

Astra's pharmaceutical product Vimovo is a combination drug that contains the active ingredients naproxen, which is a non-steroidal anti-inflammatory drug ("NSAID"), and

esomeprazole magnesium trihydrate, which is a proton pump inhibitor ("PPI"). Vimovo is used to treat the symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. The esomeprazole magnesium trihydrate in Vimovo is the same active ingredient in Astra's drug product Nexium, an acid inhibitor used to treat gastrointestinal disorders. With the combination of these two drug products, patients taking Vimovo have a decreased risk of developing NSAID-associated gastric ulcers.

There are six patents-in-suit. The '085 patent, the '070 patent and the '466 patent relate to esomeprazole magnesium trihydrate. The relevant claims of the '907 patent relate to a unit dosage form which contains a combination of an NSAID and an acid inhibitor. The '504 and '872 patents relate to optically pure compositions of certain omeprazole salts. Four of the patents, specifically, the'504 patent, '872 patent, '085 patent and '070 patent, have been the subject of other actions before this court involving the drug Nexium and, consequently, the Court has previously considered and ruled upon the meaning of certain of claim terms at issue in this case. *See AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 05-5553 (JAP) (the "Nexium action"). In addition to the claim terms being addressed by this Court for the first time in the instant actions, Defendants have asked the Court to reconsider some of its earlier rulings with regard to some of the disputed claim terms.

II. LEGAL STANDARD

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal

quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves ... to define the scope of the patented invention"). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), therefore, it is "[t]he duty of the trial judge ... to determine the meaning of the claims at issue," *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312–13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of "the words of the claims

themselves, the remainder of the specification, [and] the prosecution history," *id.* at 1314, and extrinsic evidence "concerning relevant scientific principles, the meaning of technical terms, and the state of the art," *id.*

When considering the intrinsic evidence, the court's focus must begin and remain on the language of the claims, "for it is that language that the patentee chose to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. § 112, ¶ 2). The specification is often the best guide to the meaning of a disputed term. *Honeywell Int'l v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). It is improper, however, to import limitations from the specification into the claims. *Seachange Int'l v. C–COR Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may also consider as intrinsic evidence a patent's prosecution history, which is evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the

court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322–23.

III. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

The '907 Patent

The '907 patent is

> directed to a drug dosage forms that release an agent that raises the pH of a patent's gastrointestinal tract, followed by a non-steroidal anti-inflammatory drug. The dosage form is designed so that the NSAID is not released until the intragastric pH has been raised to a safe level. The invention also encompasses methods of treating patients by administering this coordinated release, gastroprotective, antiarthritic/analgesic combination unit dosage form to achieve pain and symptom relief with a reduced risk of developing gastrointestional damage such as ulcers, erosions and hemorrhages.

'907 Patent, Abstract. All of the disputed terms of the '907 patent are found in claim 1. This claim is set forth below, and discussion of the disputed claim language follows.

Claim 1 of the '907 patent reads:

> A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:
>
> (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
>
> (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms; and wherein said unit dosage form provides for coordinated release such that:
>
> i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;

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