IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 14-1451-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP., Defendants.	Civil Action No. 14-1573-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT INC., Defendants.	Civil Action No. 14-1574-RGA

MEMORANDUM OPINION

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June 29, 2016

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,906, 277 ("the '277 patent"), 8,900,497 ("the '497 patent"), 8,603,514 ("the '514 patent"), 8,475,832 ("the '832 patent"), and 8,017,150 ("the '150 patent). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 108).[1] The Court heard oral argument on March 31, 2016. (D.I. 174).

I. BACKGROUND

The present claim construction dispute arises from Hatch-Waxman litigation involving Suboxone® sublingual film, Plaintiffs' pharmaceutical film product for the treatment of opioid dependence. The parties divide the five patents at issue into two groupings: the process patents and the Orange Book patents. The process patents, which include the '277 and '497 patents, claim processes for manufacturing pharmaceutical films. The process patents are asserted against the Defendants in all three of the present actions.

The Orange Book patents, which include the '150, '832, and '514 patents, claim various pharmaceutical film compositions. Plaintiffs' actions for infringement of the Orange Book patents against Defendants Watson and Par have already gone to trial and I have issued a final decision on the merits. (C.A. No. 13-1674-RGA, D.I. 446). Accordingly, the proposed claim constructions offered here for the '514, '832, and '150 patents only involve Civil Action No. 14-1451-RGA, Plaintiffs' action against Defendant Teva.

II. LEGAL STANDARD

"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

[1] Unless otherwise specifically noted, all references to the docket refer to Civil Action No. 14-1451-RGA.

(Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all

evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The '277 and '497 Patents (the Process Patents)

The '277 and '497 patents both claim processes for making pharmaceutical films that contain substantially uniform amounts of the active ingredient. The two patents contain nearly identical specifications. Claim 1 of the '497 patent is representative and reads as follows:

> 1. A process for making a film having a substantially uniform distribution of components, comprising the steps of:
>
> (a) forming a flowable polymer matrix comprising an edible polymer, a solvent and a desired amount of at least one active, said matrix having a substantially uniform distribution of said at least one active;
>
> (b) casting said flowable polymer matrix;
>
> (c) rapidly evaporating at least a portion of said solvent upon initiation of drying to form a visco-elastic film within about the first 4.0 minutes to maintain said substantially uniform distribution of said at least one active by locking-in or substantially preventing migration of said at least one active within said visco-elastic film;

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