IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SALIX PHARMACEUTICALS, INC. and
DR. FALK PHARMA GmbH,

Plaintiffs/Counter-Defendants,

v. **CIVIL ACTION NO. 1:15CV109**
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC. and
MYLAN, INC.,

Defendants/Counter-Claimants.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves four United States patents issued to the plaintiff, Dr. Falk Pharma GmbH, and licensed by the plaintiff, Salix Pharmaceuticals, Inc. (collectively, "Salix"). These include: Patent No. 6,551,620 ("the '620 Patent"); Patent No. 8,337,886 ("the '886 Patent"); Patent No. 8,496,965 ("the '965 Patent"); and 8,865,688 ("the '688 Patent"). The '620, '886, and '965 Patents, collectively referred to as the Otterbeck patents,[1] contain two disputed claim terms, while the parties dispute one claim term in the '688 Patent.

The Otterbeck patents cover a controlled release pellet formulation containing mesalamine for the treatment of the intestinal tract, and associated method of treatment claims. The '688 Patent covers methods of maintaining remission of ulcerative

[1] The Otterbeck patents, which claim priority to a German patent application, share a common specification.

colitis for at least six months with certain dosing and target limitations. Salix uses the formulations and methods described in these patents in a commercial product known as Apriso®.

I. BACKGROUND

In a letter dated May 14, 2015, the defendants, Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively, "Mylan"), notified Salix that they had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a 375 mg mesalamine oral extended release capsule ("generic capsule"). Mylan also filed a certification with the FDA alleging that certain claims of the patents-in-suit are invalid, unenforceable, and not infringed by Mylan's manufacture or sale of its generic capsule. Salix responded to Mylan's ANDA by filing this patent infringement action pursuant to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

In its complaint, Salix contends that the generic capsule described in Mylan's ANDA infringes claims in the patents-in-suit. The parties have identified three terms from those patents in need of construction for which they have proposed competing claim constructions. They also have submitted 12 agreed claim

constructions. Following a claim construction hearing and full briefing of the issues, for the reasons that follow, the Court adopts the following constructions.

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, the specifications, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). According to a fundamental principle of claim construction, the invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the

invention. Id.

Claim terms should be construed according to 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." Claim construction therefore requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. at 1314. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910

(Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a technical term.'" Id. at 1315 (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In

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