NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., et al.,	:	CIVIL ACTION NO. 11-3962 (MLC)
Plaintiffs,	:	**MEMORANDUM OPINION**
v.	:	
DR. REDDY'S LABORATORIES, LTD., et al.,	:	
Defendants.	:	

Cooper, District Judge

OUTLINE

PRELIMINARY STATEMENT

This is a consolidated action involving four patents listed as covering plaintiffs' marketed pharmaceutical product Aloxi®. Defendants have filed Abbreviated New Drug Applications ("ANDAs") with the Federal Food and Drug Administration ("FDA"),

seeking to market generic versions of the product and challenging those patents as invalid or unenforceable, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). This Court has jurisdiction under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), and 28 U.S.C. §§ 1331 and 1338(a). (See, e.g., dkt. 1.)[1]

Aloxi® contains the active pharmaceutical ingredient palonosetron hydrochloride, and is FDA-approved to treat chemotherapy-induced nausea and vomiting and postoperative nausea and vomiting. (Dkt. 178-2 at 3.) The four related patents-in-suit are United States Patents No. 7,947,724 ("'724 patent"), No. 7,947,725 ("'725 patent"), No. 7,960,424 ("'424 patent"), and No. 8,598,219 ("'219 patent"). (Dkt. 174 at 2.) Those are all composition patents. There are other patents in the same patent family history, including method patents.[2] Only the four composition patents listed above, however, are

[1] The Court will cite to the documents filed in the Electronic Case Filing System ("ECF") by referring only to their docket entry numbers by the designation of "dkt." All of those references are to the consolidated docket in the lead case, Civil Action No. 11-3962, unless another docket is specified. The two later-filed actions that have been consolidated into this lead case are Civil Actions No. 11-5579 and No. 13-5815. Copies of the four patents-in-suit are attached as exhibits to those respective complaints, and also to various Markman filings throughout the docket. We will simply cite to the patents by page or column and line number. The plaintiffs in this consolidated action are Helsinn Healthcare S.A. and Roche Palo Alto LLC. The originally-named defendants are Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Sandoz Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. For purposes of this claim construction opinion, we will refer to each side collectively as "plaintiffs" and "defendants."

[2] The parties supplied, upon request by the Court, a Diagram of the Patent Family History of the Patents-in-Suit, which we have had filed on the docket in this action. (Dkt. 289.) It is very helpful in showing all applications, and approved patents, stemming from an original Provisional Application No. 60/444,351, filed on January 30, 2003. That date is the critical date for all of the ensuing patents, and the patents-in-suit are subject to terminal disclaimers tied to the first-issued of those patents, the '724 patent.

asserted in this particular consolidated action.[3]

This opinion addresses certain language that appears in the preamble portion of the two independent claims of the '219 patent, including asserted claim 1. The entire preamble of claim 1 reads: "A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, [comprising....]." See n.7, infra (quoting '219 patent). Language in the body of claim 1 refers to "said formulation." Id.

The parties agree that all of the words of that preamble up to and including "formulation" constitute claim limitations, because those words provide antecedent basis for the "said formulation" language that follows in the claim body. However, the parties dispute whether the balance of the preamble text, consisting of the phrases "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting," should be read as claim limitations. Plaintiffs argue that

[3] The parties have filed a Stipulation, narrowing and specifying the patents and claims at issue in this consolidated action. Those are as follows: '724 patent, claims 2 and 9; '725 patent, claim 2; '424 patent, claim 6; and '219 patent, claims 1, 2, 6, and 7. (Dkt. 174 at 2.) Here in the District of New Jersey, other patent cases involving this family of patents (those asserted here and a later-issued patent) are docketed as Civil Actions No. 12-2867, No. 14-4274, No. 14-6341, No. 15-1228, No. 15-2077, and No. 15-2078. Some of those are consolidated with each other, and others are not currently consolidated. There is also pending litigation in the District of Delaware involving the same patent family. See, e.g., Helsinn Healthcare S.A., et al. v. Cipla Ltd., et al., D. Del. Civil Action No. 13-688 (consol.).

the language is limiting, and defendants argue to the contrary. (Dkt. 175 at 6–9 (joint claim construction chart).)[4]

The Court has considered the written submissions of the parties and conducted oral argument on this issue. The evidence presented by the parties as relevant to this claim construction was all intrinsic evidence. That evidence included the claims, specification, and prosecution history of the '219 patent and related patents in the same family history, as well as some of the prior art references cited in those United States Patent and Trademark Office ("USPTO") filings. Based on the intrinsic evidence and the arguments of the parties presented in these claim construction proceedings, this Court concludes that the disputed preamble language in claim 1 of the '219 patent does constitute claim limitations of the patent.[5]

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[4] In addition to the Joint Claim Construction & Prehearing Statement (dkt. 175), the submissions on this claim construction issue are as follows: dkt. 176, Defs.' Opening Br.; dkt. 176-1 to 176-4, Barker I Decl.; dkt. 177, Pls.' Opening Br.; dkt. 178 to 178-4, Ni I Decl.; dkt. 182, Defs.' Responsive Br.; dkt. 182-1 to 182-17, Barker II Decl.; dkt. 181, Pls.' Responsive Br.; dkt. 181-1, Ni II Decl.; and dkt. 220, Markman Oral Arg. Tr. The attorney declarations contain numerous exhibits, which we will cite simply by reference to ECF page numbers. Following oral argument, the Court requested and received from the parties the complete '219 patent prosecution history file from the United States Patent and Trademark Office (three volumes, not docketed).

[5] Defendants have provided discovery and contentions relating to their invalidity arguments in alternative form, depending on whether the Court would find the disputed preamble language to be limiting. Those arguments include written description contentions. (Dkt. 182 at 17 n.12.)

I. BACKGROUND

A. Legal standard

Courts define the meaning and scope of patent claims by the process of claim construction. Markman v. Westview Instruments, 52 F.3d 967, 976, 978, 1026 (Fed.Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). A court first looks to the intrinsic evidence to construe claims. See Interactive Gift Express v. Compuserve, 256 F.3d 1323, 1331 (Fed.Cir. 2001) (en banc reh'g denied). Here, the parties have argued their positions primarily with reference to the intrinsic evidence and did not request an evidentiary hearing. (See dkt. 175.) Although some extrinsic evidence was identified in the parties Joint Claim Construction Statement (id.), the Court finds the briefing and the oral argument to be sufficient to resolve this issue without resort to extrinsic evidence.

The intrinsic record, which includes the claims, specification, and complete prosecution history, is the most significant source for the legally operative meaning of disputed claim language. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir. 1996). A patent's prosecution history consists of the record of proceedings before the USPTO and the prior art cited during the patent's examination. Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed.Cir. 2005) (en banc).

It is well settled that "[t]he determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim." Manual of Patent Examining

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