United States District Court,
E.D. Pennsylvania.

BIOVAIL LABORATORIES, INC,
Plaintiff.
v.
TORPHARM, INC,
Defendant.

July 13, 2004.

Background: Holder of patent for drug used to treat hypertension and angina brought patent infringement action against generic drug manufacturer.

Holdings: The District Court, Anita B. Brody, J., held that:
(1) language of patent claims asking reader to "select" a wetting agent "from the group consisting of" several chemicals did not define term "wetting agent," and
(2) term "wetting agent" would be construed as its ordinary and customary meaning.

Ordered accordingly.

5,288,505, 5,529,791. Construed.

Charles R. Krikorian, Eric C. Cohen, James P. White, Robert B. Breisblatt, Welsh & Katz, Ltd., Chicago, IL, Michelle T. Wirtner, Grant & Eisenhofer, P.A., Wilmington, DE, Robert S. Tintner, Fox, Rothschild, O'Brien & Frankel LL, Philadelphia, PA, for Plaintiff.

Manny D. Pokotilow, Michael J. Berkowitz, William J. Castillo, Robert S. Silver, Caesar, Rivise, Bernstein, Cohen & Pokotilow, Philadelphia, PA, for Defendant.

MEMORANDUM AND ORDER

ANITA B. BRODY**, District Judge.**

INTRODUCTION

On September 3, 2002, plaintiff Biovail Laboratories, Inc. ["Biovail"] filed a complaint for patent infringement against defendant Torpharm, Inc. ["Torpharm"]. In its complaint, Biovail alleged that Torpharm infringed two of its patents: U.S. Patent No. 5,529,791 [hereinafter "the '791 patent"] and U.S. Patent No. 5,288,505 [hereinafter "the '505 patent"] when Torpharm filed an Abbreviated New Drug

Application ("ANDA") FN1 for Diltiazem HC1 Capsules Type TZ (Diltiazem Hydrochloride Extended-Release Capsules USP) 120mg, 180mg, 240mg, 300mg and 360mg. The patents-in-suit involve extended release forms of Diltiazem, a drug used to treat hypertension and angina.

FN1. These applications to market new drugs are filed with the Federal Food and Drug Administration ("FDA") pursuant to 21 U.S.C. s. 355. They may be challenged in a lawsuit for infringement.

On November 27, 2002, Torpharm moved for summary judgment, arguing that its proposed ANDA product does not contain a "wetting agent" as required by the claims of the patents-in-suit. (Def.Mot.Sum. J. 1.) Biovail responded to the motion for summary judgment on March 18, 2003, alleging that Torpharm's proposed ANDA product does contain a "wetting agent" as defined by Biovail's patent, thereby making Torpharm's proposed ANDA product an infringement of Biovail's patent. On June 9, 2004 a hearing was held pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The parties presented the court with a tutorial on their patents and proposed constructions of the term "wetting agent."

RELEVANT LANGUAGE IN THE PATENTS-IN-SUIT

Claim 1 of '505 Patent**:**

An extended-release galenical composition of Diltiazem or one or more pharmaceutically-acceptable salts thereof, which comprises beads, said beads consisting essentially of in admixture together: a) an effective amount of Diltiazem or said one or more salts thereof as an active ingredient, and b) an effective amount of a wetting agent, wherein said wetting agent is selected from the group consisting of a sugar, a C12-C20 fatty acid ester of sucrose or xylose, a glyceride of sucrose, a fatty acid ester of polyoxyethylene, an ether of fatty alcohols and polyoxyethylene, an ester of sorbitan, an ester of polyoxyethylene sorbitan, a glyceride-polyglycide, an alcohol-polyglycide ester, lecithins and a combination thereof,FN2

FN2. This group of chemicals is known as a "Markush group." "A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." Abbott Labs. v. Baxter Pharm. Prods. Inc., 334 F.3d 1274, 1280 (Fed.Cir.2003.)

-'505 Patent, Col. 9, Lines 5-13.

Claim 1 of '791 Patent**:**

An extended-release galenical composition of Diltiazem or one or more pharmaceutically-acceptable salts of Diltiazem which comprises beads containing an effective amount of one or more of said Diltiazem salts as the active ingredient, each bead containing one or more of the Diltiazem salts and an effective amount of a wetting agent in admixture with the one or more Diltiazem salts to maintain the solubility of the Diltiazem in each bead ... wherein the wetting agent is selected from the group consisting of sugars, C12-C20 fatty acid esters of sucrose or xylose, glycerides of sucrose or xylose, glycerides of sucrose, fatty acid esters of polyoxyethylene, ethers of fatty alcohols and polyoxyethylene, esters of sorbitan, esters of polyoxyethylene sorbitan, alcohol-polyglycide esters, glyceride-polyglycides, lecithins and a combination thereof.

-'791 Patent, Col. 9, lines 7-13.

PRINCIPLES OF CLAIM CONSTRUCTION

[1] There are two stages in the litigation of patent infringement cases. First, the court must determine the scope and meaning of those patent claims disputed by the parties. Searfoss v. Pioneer Consol. Corp., 2004 WL 1486822 (Fed.Cir.2004). Second, the claims as construed by the court are compared limitation by limitation to the features of the allegedly infringing device. *Id*. The first step, often referred to as "claim construction," typically occurs after a court conducts a" *Markman* hearing," wherein the parties present arguments for why the court should construe a claim a certain way. The second step occurs at trial, after the court has issued its decision on how the claims should be construed.

[2] [3] The "claim construction inquiry begins and ends in all cases with the actual words of the claim." *Searfoss* (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002).) "Absent an express intent to impart a novel meaning to a claim term, the words take on the ordinary and customary meaning attributed to them by those of ordinary skill in the art." TI Group Auto. Sys. v. VDO N. Am., LLC, 375 F.3d 1126, 1133 (Fed.Cir.2004). "To determine the ordinary and customary meaning of a claim term, we may review sources including the claims themselves, dictionaries and treatises, and the written description, drawings, and prosecution history." *Id*.

I will follow the sequence of analysis I adopted in Illinois Tool Works, Inc. v. Ion Sys., Inc., 250 F.Supp.2d 477, 483 (E.D.Pa.2003). In that case, I adopted the sequence proposed by Magistrate Judge Mary Pat Thynge of the Delaware district court in Tulip Computers, Internationali B.V. v. Dell Computer Corp., 236 F.Supp.2d 364, 373 (D.Del.2002), which recommended that the court first "determine the ordinary and accustomed meaningsof disputed claim words through an examination of the relevant dictionaries, encyclopedias, or treatises," in order to "reveal the broadest definition of those terms as understood by one of skill in the art." 236 F.Supp.2d at 373. Next, the court "examine[s] the written description and prosecution history to determine whether the full scope of the definition of a disputed term is covered by the invention or whether that scope has necessarily been limited as a result of the patentee clearly setting forth an inconsistent definition of the disputed term or otherwise disavowing or disclaiming the full scope of the term's meaning." *Id*. This is done because, "[a]lthough words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, *as long as the special definition is clearly stated in the patent specification or file history*." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996) (emphasis added.) By using this procedure, the court "may avoid improperly importing claim limitations to a single embodiment described in the specification as might occur if the court begins its analysis with an examination of the written description and prosecution history." Tulip Computers, 236 F.Supp.2d at 373.

CONSTRUCTION OF THE DISPUTED TERM

The parties have requested claim construction of the term "wetting agent." FN3 Pursuant to the structure laid out above, I will first examine the definitions of "wetting agent" as supplied by dictionaries and treatises, of which Torpharm has submitted three in evidence. The definitions are as follows:

FN3. Although the District Court for the Southern District of Florida previously construed this term in Biovail Corp. Int'l v. Andrx Pharmaceuticals, Inc., 158 F.Supp.2d 1318 (S.D.Fla.2000), I have already informed the parties, via a written Notice issued on February 25, 2004, that there is no issue preclusion. That district court found that "wetting agent" is defined as "any of a group of surface active agents which, when

added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface." 158 F.Supp.2d 1318 at para. 55.

Wetting Agent: any of a group of surface-active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface.
-WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 1616 (2d ed.1980).

Wetting Agents are surface active substances that are used to reduce the contact angle and therefore improve wetting.

-LEON LACHMAN ET AL., THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY 120 (Lea & Fibiger 1970).

A Wetting Agent is a surfactant which, when dissolved in water, lowers the advancing contact angle and aids in displacing an air phase at the surface and replacing it with a liquid phase.

-ALFRED N. MARTIN ET AL., PHYSICAL PHARMACY 437 (2d ed.1969).

Torpharm advocates that I adopt one of these dictionary definitions as the definition of "wetting agent." On the other hand, Biovail proposes that "wetting agent" be defined as "a group consisting of a sugar, a C12-C20 fatty acid ester of sucrose or xylose, a glyceride of sucrose, a fatty acid ester of polyoxyethylene, an ether of fatty alcohols and polyoxyethylene, an ester of sorbitan, an ester of polyoxyethylene sorbitan, a glyceride-polyglycide, an alcohol-polyglycide ester, lecithins and a combination thereof." In other words, Biovail reads the Markush group in the patents as *defining* wetting agents.

[4] [5] Although these dictionary sources provide clear definitions of "wetting agent," "the presumption in favor of a dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning." Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002). The "language of the claim defines the boundary of its scope." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002). I therefore turn to the language of the patents to determine whether it provides an explicit definition of "wetting agent."

[6] The language of the claims asks the reader to "select" a wetting agent "from the group consisting of" several chemicals. The language thus instructs the reader of the patent to do two things: (1) select a wetting agent, and (2) do so from the list provided. The reader should not understand the patent's language to mean either that a wetting agent should simply be selected, or, as Biovail would have the court read the language, that one of the items in the Markush group should be selected irregardless of whether it is a wetting agent. Both steps are necessary. Thus, asking the reader to select a wetting agent from a list of chemicals is not the same as *defining* the term wetting agent. Rather, it is qualifying the term; to treat this usage as a definition would be to severely alter the term's meaning.FN4

FN4. My rejection of Biovail's construction might also be illustrated by a simple example. Suppose one were to read the instructions: "Select a woman from the group consisting of an American, a Canadian, and a Mexican." Obviously this instruction does not define all Americans as women, though by Biovail's logic it would. By the same reasoning, not all sugars need be defined as wetting agents.

Biovail misinterprets the significance of a Markush group. In support of its argument, Biovail cites to the MANUAL OF PATENT EXAMINING PROCEDURE, s. 2173.05(h), which, under the heading "Markush Groups," provides that, "Alternative expressions [within claims] are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims." One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." This statement goes no further than the already established description of a Markush group in establishing whether listing a group of chemicals as a Markush group is equivalent to providing a definition.

[7] [8] The patents' prosecution histories FN5 do nothing to alter my conclusion that Biovail's patent does not define "wetting agent." I consider the prosecution histories "to determine whether the patentee intended to deviate from a term's ordinary and customary meaning or that the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms." Nystrom v. Trex Co., Inc., 374 F.3d 1105 (Fed.Cir.2004). Biovail calls attention to three aspects of the patents' prosecution histories:

FN5. Prosecution histories, as "undisputed public record[s] of proceedings in the Patent and Trademark Office," are considered to be of "primary significance in understanding the claims." Markman, 52 F.3d at 980. The reason behind this deference is that the "construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his half [sic], when his application for the original patent was pending ... When a patent bears on its face a particular construction, inasmuch as the specification and claim are in the words of the patentee, ... such a construction may be confirmed by what the patentee said when he was making his application." *Id*. (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L.Ed. 149 (1880).)

(1) The original applications for the '505 and '791 patents included the language about selecting a wetting agent from "the group consisting of sugars/a sugar." (Prosecution History of Patent No. 5,288,505 at 505-036; Prosecution History of Patent No. 5,529,791 at 791-040.)
(2) In the written description of the '505 patent invention, under the heading "DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS," the '505 patent states: "Among the wetting agents associated with the Diltiazem or salt thereof in the beads, the following compounds may more particularly be exemplified: FN6 sugars, for example, saccharose, mannitol, soribitol, and lactose ... In addition to at least one of the above named wetting agents the beads may contain excipients or carriers." (Prosecution History of Patent No. 5,288,505 at 505-009.)

FN6. Exemplify: to show or illustrate by example. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 434 (1984).

(3) In the '505 patent prosecution history, the patentee explained that "wetting agents claimed in the present invention are substances which are believed to modify the solubility of Diltiazem inside the coated beads when they are placed in a dissolution medium or when they are ingested by a mammal." (Prosecution History of Patent No. 5,288,505 at 505-081.)
[9] The patent histories are consistent with the patents' language and go beyond the patents' language in describing the role of the wetting agent in the compound. However, Biovail has not provided any evidence

that the histories go farther than the plain language of the patents in *defining* "wetting agent."

[10] Because I find that the language of the patents does not "limit," "disavow," or "disclaim" the understood meaning of the term "wetting agent," I will construe the claim as its "ordinary and customary meaning." Illinois Tool, 250 F.Supp.2d at 484. "[D]ictionary definitions may establish a claim term's ordinary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). "If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital, 308 F.3d at 1203. The parties do not contend that the three proffered definitions taken from dictionaries and treatises conflict with one another, and I see no reason not to encompass all three definitions in my construction. I therefore construe the term "wetting agent" as: "any of a group of surface-active agents which, when added to a liquid, reduce the contact angle and cause the liquid to spread more easily over, or penetrate into, a solid surface."

CONCLUSION

The discussion and analysis presented above represents this court's construction of the parties' disputed term.

ORDER

AND NOW, this 13th day of July 2004, upon consideration of the briefs, exhibits, and oral argument presented by the parties in conjunction with the *Markman* hearing in which they all participated, it is hereby **ORDERED** that the meaning and scope of the patent claim asserted to be infringed and presented by the parties for construction is determined as set forth in the foregoing Memorandum.

E.D.Pa.,2004.
Biovail Laboratories, Inc. v. Torpharm, Inc.

Produced by Sans Paper, LLC.