United States District Court,
D. New Jersey.

AVENTIS PHARMACEUTICALS, INC., Merrell Pharmaceuticals, Inc., and Carderm Capital L.P,
Plaintiffs.
v.
BARR LABORATORIES, INC,
Defendant.
Impax Laboratories, Inc,
Defendant.
Teva Pharmaceuticals, USA, Inc,
Defendant.
Mylan Pharmaceuticals, Inc,
Defendant.
Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc,
Defendants.

Nos. CIV.A. 01-3627(JAG), CIV.A. 02-1322(JAG), CIV.A. 03-487(JAG), CIV.A. 03-1179(JAG), CIV.A. 03-1180(JAG)

Oct. 22, 2004.

Background: Patentee brought infringement action against manufacturers of generic versions of its patented drug.

Holding: The District Court, Greenway, J., held that claims in drug patent did not impart a product limitation of a disintegrant incorporated into granules in resulting product.

Ordered accordingly.

5,738,872. Construed.

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OPINION

GREENAWAY**, District Judge.**

This is a patent infringement suit in which Aventis Pharmaceuticals, Inc., Merrell Pharmaceuticals Inc., and Carderm Capital L.P. (collectively "Plaintiffs" or "Aventis") have sued generic drug manufacturers, Barr Laboratories, Inc. ("Barr"), Impax Laboratories, Inc. ("Impax"), Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals, Inc. ("Mylan"), Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. ("Reddy") (collectively "Defendants") for infringement of U.S. Patent Nos. 5,738,872 ("the '872 patent"), 6,113,942 ("the "2 patent"), 5,855,912 ("the '912 patent"), 5,932,247 ("the '247 patent"), and 6,039,974 ("the '974 patent") which disclose solid unit dosage fexofenadine formulations sold in the United States under the tradenames ALLEGRA(R) and ALLEGRA-D(R). Defendants filed a motion for summary judgment on their claim that the '872 patent is invalid as anticipated, and that the '872, '912, "2, and '247 patents are not infringed. In an opinion dated June 30, 2004, FN1 this Court ruled that Defendants' products do not infringe the '912, "2, and '247 patents. A ruling on the validity of the '872 patent was reservedpending the Court's construction of claims 1 and 2 of the patent. Aventis submitted the expert report of Dr. Chowhan, and Defendants submitted the expert report of Dr. Peck, on the issue of construction of the claims, and presented these experts' testimony at a Markman hearing held on September 9th, 21st, 24th, and 28th. The Court's construction of claims 1 and 2 of the '872 patent is set forth below.

FN1. *See* Aventis Pharmaceuticals, Inc. v. Barr Laboratories Inc., 335 F.Supp.2d 558 (D.N.J.2004).

BACKGROUND

Defendants assert that claims 1 and 2 of the '872 patent are anticipated by prior art references U.S. Patent Nos. 4,929,605 ("the '605 patent"), 4,996,061("the '061 patent"), 6,037,353 ("the '353 patent"), 5,375,693 ("the '693 patent"), and 4,254,129 ("the '129 patent") and, are thus, invalid under 35 U.S.C. s. 102(b). FN2 Plaintiffs argue that the '872 patent is valid because the prior art references do not disclose each limitation of claims 1 and 2 of the '872 patent, as they must to anticipate. This Court has disposed of all but one argument pertaining to anticipation of the '872 patent. The principle issue that remains to be resolved is whether the language "diluent and a disintegrant are mixed with a solution of a binding agent; the wet granulation is screened, the wet granulation is dried, and the dry granulation is screened" imparts a product limitation of a disintegrant incorporated into the granules in the resulting product (i.e., separate intragranular disintegrant).

FN2. "A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. s. 102(b).
[1] [2] The '872 patent involves product-by-process claims. Product-by-process claims are not limited to the product prepared by the process set forth in the claims; however, process steps may establish product characteristics which are claim limitations. In an infringement or validity analysis, characteristics or product properties imparted by process steps recited in product-by-process claims are only relevant to the extent that the resulting characteristics are claimed. Claims cannot be "saved" from invalidity by reading extraneous limitations not present in the claims. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988); *see also* SmithKline Beecham Corp. v. Geneva Pharms., Inc., 2002 WL 32350031, 2002 U.S. Dist. LEXIS 25275 (E.D.Pa.2002).

Claim 1 of the '872 patent states:

Claim 1: A pharmaceutical composition prepared by a wet granulation process comprising, preparing the wet granulation wherein a compound of [fexofenadine hydrochloride]; wherein X is a number ranging from about zero to 5, and the individual optical isomers thereof, a diluent and a disintegrant are mixed with a solution of a binding agent; the wet granulation is screened, the wet granulation is dried, and the dry granulation is screened.

('872 patent, col. 33, lines 9-34.)

Claim 2 is identical to Claim 1, except instead of reciting that "the dry granulation is screened," it recites that "the dry granulation is combined with a lubricant." (Id., col. 33, lines 35-60.)

The following outlines the major points of each of the expert reports submitted to this Court for consideration.

Dr. Chowhan's FN3 ***Expert Report (Submitted by Aventis)***

FN3. Zak T. Chowhan, Ph.D., is an independent pharmaceutical development consultant. He received his Ph.D. in pharmaceutical chemistry from the University of Michigan. He has over 30 years of experience in the pharmaceutical industry and has published over 100 scientific papers. (Chowhan Expert Report at 1-2.)

Dr. Chowhan asserts that one of ordinary skill in the art would understand that the language of claims 1 and 2 of the '872 patent requires granules which have a separate disintegrant incorporated in the granules. In particular, Dr. Chowhan states that the recited process steps in the claims, namely mixing the active ingredient with a diluent and a disintegrant and a solution of a binding agent, result in granules having a structure comprising the active ingredient, a diluent, a disintegrant, and a binding agent. (Chowhan Expert Report at 2-3.) As the disintegrant is incorporated in the granules, the disintegrant is an "intragranular" disintegrant. Because the disintegrant is "mixed with" the binding agent, the intragranular disintegrant is a separate ingredient from the binding agent. (Id. at 2-3,7.)

According to Dr. Chowhan, a composition in which the disintegrant is not included in the wet granulation, but is only added after the granules are formed and dried, has an "extragranular disintegrant" and is a different product with a different structure than a product containing an intragranular disintegrant. (Id. at 6-7.) Tablets in which a disintegrant is added both before and after the drying and screening processes have both intragranular and extragranular disintegrants. Id. From a functional perspective, disintegrants facilitate the break-up of tablets and/or granules to administer the active ingredient to the patient. Id. Extragranular disintegrants help break apart the tablet into the component granules from which it was compressed. (Id. at 7.) Intragranular disintegrants help break apart the component granules into the original powdered ingredients used in the wet granulation process. Id. Intragranular disintegrants have been shown to improve the dissolution and reduce the friability of tablets. Dr. Chowhan refers to research articles FN4, patents, and treatises that purportedly demonstrate or note the structural and functional differences between intragranular and extragranular disintegrants. (Id. at 10-15.)

FN4. Dr. Chowhan co-authored several of the referenced articles.

Dr. Peck's FN5 ***Expert Report (Submitted by Defendants)***

FN5. Garnet E. Peck, Ph.D., is Professor Emeritus of the Department of Industrial and Physical Pharmacy at Purdue University. Dr. Peck has taught in the field of pharmacy for over 37 years, and has published more than 120 publications in the area of pharmaceutical sciences. (Peck Expert Report at 1-2).

Dr. Peck asserts that the product (i.e., pharmaceutical composition) made by the process set forth in claims 1 and 2 would not necessarily contain an intragranular disintegrant. Claims 1 and 2 both recite a pharmaceutical composition. According to Dr. Peck, these claims encompass pharmaceutical compositions in the form of tablets and capsules. (Peck Expert Report at 5.) Dr. Peck's primary contention is that a number of variables in the processing steps required to form tablets or capsules could occur such that granules would form, but then cease to exist during the subsequent stages that form the pharmaceutical composition, that is the product of the claims. (Id. at 9.) Consequently, a person of ordinary skill in the art would understand that an intragranular disintegrant would not be a necessary product of claims 1 and 2 of the '872 patent.

Dr. Peck describes several scenarios in which he asserts that the product created by claims 1 and 2 would not contain an intragranular disintegrant. Dr. Peck claims that if insufficient water or binding agent are added to the granulation mixture, soft granules will form, which will break down during subsequent processing steps such as lubrication, transport to a tablet press, or tablet compression. (Id. at 10-11.) Even if excipient amounts were used such that optimal granules were formed, the tablet compression process may exert such pressure on the tablet material that the granules may no longer exist as granules at the conclusion of the formulation process. (Id. at 12-14.) Dr. Peck refers to scientific literature which purportedly notes this phenomena. (Id. at 12-13).

Dr. Peck concludes that because of the possibility that any or all of these scenarios could occur while producing the product claimed in claims 1 and 2, one of ordinary skill in the art would understand that an intragranular disintegrant would not be a necessary product of claims 1 and 2 in the '872 patent.

LEGAL STANDARD

[3] [4] [5] In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. However, it is well-settled that the Court should first look to to the claim language, the patent specification, and the prosecution history on record, which together constitute the "intrinsic evidence." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Id*. If possible, claims should be construed so as to sustain their validity. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 (Fed.Cir.1984). Moreover, claims should be read in a way that avoids ensnaring prior art if it is possible to do so. Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1153 (Fed.Cir.1997).

[6] This Court must look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention. The specification acts as a dictionary "when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1577. The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. 35 U.S.C. s. 112. Thus, 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." Vitronics, 90 F.3d at 1582.

[7] The prosecution history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. *Id*. The prosecution history limits the interpretation that was disclaimed during prosecution. Included within an analysis of the file history may be an examination of the prior art cited therein. Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995).

[8] Although extrinsic evidence may be considered, if needed, to assist in determining the meaning or scope of technical terms in the claims, where extrinsic evidence is inconsistent with the specification and file history, it should be accorded no weight. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed.Cir.2001).

DISCUSSION

[9] As an initial matter, Dr. Peck, Defendants' expert, concedes that granules containing a separate intragranular disintegrant will be formed by practicing the steps in the claims. (*See* 9/9/04 Tr. at 47-49.) FN6 The key dispute between the parties is whether the claims can be read to require that intact granules (with separate intragranular disintegrant) remain in the resulting formulation (or final product) of the claims.

FN6. Although Dr. Peck stated in testimony and in his expert report that the lubrication step recited in the claims could break down the granules if insufficient moisture or binding agent were added to the mixture, (9/9/04 Tr. at 29; Peck Report para. 25), he later testified that the granules would not be expected to break down during lubrication. (9/9/04 Tr. at 45.) In any event, this Court finds that one of ordinary skill in the art would use the amount of moisture and/or binding agent appropriate to obtain optimal granulation.

Defendants argue that claims 1 and 2 encompass solid unit dosage formulations, namely tablets and powders FN7, which do not contain granules in their structures. Aventis contends that the claims do not encompass these formulations, and even if they did, contrary to Defendants' assertions, the processes that one of ordinary skill in the art would use to prepare these formulations would not destroy the granules.

FN7. The issue of whether granules exist in powder formulations was not addressed by Dr. Peck in his expert report, and was raised by Defendants for the first time at the *Markman* hearing.

[10] The starting point for claim construction is the plain language of the claims. Quickie Mfg. Corp. v. Libman Co., 180 F.Supp.2d 636, 643 (D.N.J.2002) (citing CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co., 224 F.3d 1308, 1316 (Fed.Cir.2000); Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1334 (Fed.Cir.2000)). To resolve the parties' competing contentions, this Court evaluates which formulation results from practicing the steps recited in the claims.FN8 If the claims merely consisted of the steps recited therein, based on the evidence provided, this Court would conclude that the claims were directed to a granulation formulation. The claims, however, state, "[a] pharmaceutical composition prepared by a wet granulation process *comprising,* preparing ...." (872 patent, col. 33, lines 9-10, 37-38) (emphasis added). Therefore, this Court may consider additional, unrecited elements in making its claim construction determination.

FN8. "The transitional phrases 'comprising', 'consisting essentially of' and 'consisting of' define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim." MANUAL OF PATENT EXAMINING PROCEDURE s. 2111.03.

[11] "The term 'comprising' is a term of art used in claim language and means the named elements are essential, but other elements may be added and still fall within the scope of the claim." Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 301 F.Supp.2d 970, 991 (S.D.Iowa 2004) (citations omitted). *See also* Vivid Technologies, Inc. v. American Science and Engineering, Inc., 200 F.3d 795, 811 (Fed.Cir.1999) ("comprising [is] generally understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited."). Absent specific limiting language in the claims, this Court would be compelled to conclude that claims 1 and 2 would encompass additional process steps which could result in the formulations asserted by Defendants.

[12] [13] In light of this analysis, the term "pharmaceutical composition", contained in the preamble FN9 of claims 1 and 2, takes on special significance. Although the parties have not presented extensive evidence relating to the specific meaning of that term, both parties appear to agree that as a general matter FN10, pharmaceutical compositions can take the form of the solid unit dosage forms listed in the '872 patent specification (namely, tablets, coated tablets, powders, dragees, and hard or soft gelatin capsules, etc.).FN11

FN9. "A patent claim typically has three parts: 1) the preamble; 2) the transition; and 3) the body." E.I. DuPont De Nemours v. Monsanto Co., 903 F.Supp. 680, 693 (D.Del.1995) (citing 2 DONALD S. CHISUM, PATENTS s. 806[1][b] (1994)). In this case, the portion of the claims' language that is before the word "comprising" is the preamble. "Generally, the preamble will be construed to be a claim limitation if it is necessary to give 'life, meaning, and vitality to the claim,' or if it 'recites essential structure.' " Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002). "Where a patentee uses the claim preamble to recite *structural limitations* of his claimed invention, the PTO and courts give effect to that usage." Rowe v. Dror, 112 F.3d 473, 478 (Fed.Cir.1997) (emphasis added).

FN10. *See* Tr. 9/24/04 at 8 -10, Testimony of Dr. Chowhan.

FN11. The patent specification states, "The pharmaceutical composition of the present invention is administered orally in the form of a solid unit dosage form. Examples of solid unit dosage forms are tablets, coated tablets, powders, dragees, and hard or soft gelatin capsules and the like." ('872 Patent, col. 7, lines 62-66.)

Notwithstanding the language in the patent specification, Aventis argues that "pharmaceutical composition" as set forth in claims 1 and 2 does not encompass pharmaceutical compositions in solid unit dosage form. In support of this theory Aventis points out that claims 1 and 2 are the only claims that use the precise language "pharmaceutical composition." Every other claim of the patent calls for a pharmaceutical composition in "solid unit dosage form" (claims 3-17), or "solid form" (claim 18). Aventis also refers this Court to the "Background of the Invention" portion of the patent which states, "[t]he present invention relates to pharmaceutical compositions and pharmaceutical compositions in solid unit dosage form ...." ('872 patent, col. 1, lines 47-49.)

[14] Aventis claims that ignoring the distinction between "pharmaceutical composition" and "pharmaceutical composition in solid [unit dosage] form" would render the claim language "solid [unit dosage] form" superfluous. To be sure, "no claim language may be interpreted as mere surplusage." British Telecommunications PLC v. Prodigy Communications Corp., 189 F.Supp.2d 101, 113 (S.D.N.Y.2002) (citing Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed.Cir.1993)). This maxim, however, does not mandate the conclusion that the '872 claim term "pharmaceutical composition" in the absence of the terms "in solid [unit dosage] form" therefore describes only pharmaceutical compositions that are *not* in solid unit dosage form.

This Court finds the more plausible construction to be that "pharmaceutical composition", in the absence of other stated limitations, encompasses pharmaceutical compositions in all forms. The terms "pharmaceutical compositions in solid [unit dosage] form" encompasses the subset of pharmaceutical compositions which are in solid unit dosage form. Such a construction avoids the surplusage issue raised by Aventis.

Aventis attempts to argue that the steps encompassed by the comprising language of the claims should not be construed as limitations on the claims.

Mr. Katcoff: That's what comprising means. You could do anything. You could add additional steps, but the fact that you can do anything doesn't mean that anything becomes a claim interpretation which can be interpreted in claim limitation.

(9/28/04 Tr. at 63-64.)

[15] This Court disagrees with this proposition. A claim that employs the term "comprise" is more broad than a claim that employs the phrase "consists of" because a comprising claim does not exclude additional steps or elements. For example, in a comprising claim, the mere inclusion of additional steps or elements will not negate infringement. *See* Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1380 (Fed.Cir.2001) ("an accused method 'does not avoid literally infringing a method claim ... simply because it employs *additional* steps.' ") (citation omitted). Aventis cannot be permitted to argue that its claims are broad enough to encompass accused products which contain additional process steps, but for invalidity

purposes, argue that its claims are not so limited. "[C]laims must be construed the same way for validity and for infringement." Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed.Cir.1991).

The final and ultimate issue for this Court is to determine whether the solid unit dosage formulations asserted by Defendants contain intact granules. The Court has heard voluminous testimony by both parties at the *Markman* hearing, and been presented with a number of articles and studies which bear on the question of whether the compaction process used in forming tablets from a granulation destroys the granules. Because Aventis' expert has conceded that the solid unit dosage form of powders does not contain granules, the Court need not resolve whether granules remain intact in the tableting process. The Court relies on two significant admissions by Dr. Chowhan for its conclusion that powders do not contain granules, and thus, do not contain separate intragranular disintegrants. First, Dr. Chowhan conceded on cross-examination that powders would not contain granules.

Mr. Pfadenhauer: You would not expect to find any granules in the powder?

Dr. Chowhan: Probably not.

[. . . . .]

Mr. Pfadenhauer: So if the pharmaceutical composition in Claims One and Two of the '872 patent is a powder, then it wouldn't have intragranular disintegrants, would it?

Dr. Chowhan: If you don't have granules, you don't have intragranular disintegrants.

(9/24/04 Tr. at 92.)

Dr. Chowhan also provided a reason that one of ordinary skill in the art might choose to use the process steps described in claims 1 and 2 to create a powder formulation.

Mr. Pfadenhauer: Doctor, you told me that there are reasons to use a granulation no matter what the final dosage form is to get a better distribution of your active amongst the other particles, and you would get a better distribution of a very small amount of active by making granulation, making granules, and milling that than you would as compared to dry blending, wouldn't you?

Dr. Chowhan: That is a special case when you have low dose and you want to administer the drug in micrograms, or even up to few milligrams.

Mr. Pfadenhauer: And the '872 patent says that the pharmaceutical compositions of the patent include powders, right?

[. . . . .]

Dr. Chowhan: Yes, it includes, in general terms, powders.

(9/24/04 Tr. at 93-94.)

Given these admissions,FN12 this Court must conclude that one can practice the steps recited in claims 1 or 2, create a granulation, mill the granulation into powder form, and still be within the scope of the claims. Because powders do not contain granules, powders will not contain separate intragranular disintegrants. Consequently, the Court finds that the language of claims 1 and 2 does not impart a product limitation of a disintegrant incorporated into granules.

FN12. Dr. Chowhan also testified that no one in their "right senses" would start with powders, create granules, and grind the formulation back into powders. (9/24/04 Tr. at 93.) However, this testimony is contradicted by the immediately preceding testimony provided by Dr. Chowhan that is noted above.

CONCLUSION

For the forgoing reasons, this Court construes the language of claims 1 and 2 of the '872 patent as set forth above.

D.N.J.,2004.
Aventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.