United States District Court,
N.D. Illinois, Eastern Division.

MEDEVA PHARMACEUTICALS MANUFACTURING, INC., et al,
Plaintiffs.
v.
MORTON GROVE PHARMACEUTICALS, INC,
Defendant.

Aug. 8, 2001.

Assignee of patent for steroid formulation sued competitor for infringement. Construing claim language, the District Court, Shadur, Senior District Judge, held that "suitable for oral administration" meant only that solution had only to be nonharmful to humans.

Claim construed.

4,448,774. Cited.

David C. Van Dyke, Cassiday, Schade & Gloor, Chicago, IL, Ronald J. Brown, Steven J. Wells, Dorsey & Whitney LLP, Thomas E. Popovich, Popovich & Wiles, PA, Minneapolis, MN, for Plaintiffs.

James F. Hurst, John E. Mahoney, Lynn C. MacDonald, Winston & Strawn, Chicago, IL, for Defendant.

MEMORANDUM ORDER

SHADUR**, Senior District Judge.**

Medeva Pharmaceuticals Manufacturing, Inc., Medeva Pharmaceuticals, Inc. and Fisons Investments Inc. (collectively "Fisons," treated after this sentence as a singular noun), the assignees of United States Patent No. 4,448,774 ("Patent '774") FN1 covering a "Steroid Formulation," brought this infringement action against Morton Grove Pharmaceuticals, Inc. ("Morton Grove"). Morton Grove then counterclaimed for declaratory and other relief on grounds of non-infringement and patent invalidity. In pursuit of its Counterclaim Morton Grove has moved for a *Markman* FN2 ruling construing the phrase "suitable for oral administration," which appears in claim 1 of Patent '774. Both sides have submitted claim construction memoranda, enabling this Court to address the disputed claim as a matter of law.FN3

FN1. All other patents referred to hereafter were also issued by the United States Patent Office.

FN2. Under Markman v. Westview Instruments, Inc., 517 U.S. 370, 384-91, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) this Court is required to construe the scope and meaning of a patent's claims as a matter of law before the factual application of those claims to the accused product.

FN3. This opinion will refer to Morton Grove's initial memorandum as "M. Mem.-," to Fisons' response memorandum as "F. Mem.-" and to Morton Grove's reply memorandum as "M. R. Mem.-." Citations to the

parties' exhibits will also use the "M." and "F." designations.

Steroid Formulation

Steroids are used to treat a variety of ailments from bronchial asthma to organ transplantation shock. They can be administered in a number of ways, including topically through lotions or creams, intravenously or orally (M.Ex. A).

Patent '774 describes an aqueous solution for oral administration containing any of four well-known steroids: prednisolone, prenisolone sodium phosphate, prednisone and methyl prednisolone (*id*.). Previous oral steroid formulations were either in the form of (1) tablets or (2) suspensions FN4 in a liquid vehicle or (3) aqueous alcoholic solutions (*id*.).

FN4. Suspensions are "a class of pharmacopeial preparations of finely divided, undissolved drugs...dispersed in liquid vehicles for oral or parenteral use" (*Stedman's Medical Dictionary* 1374 (5th lawyers' ed.1982)). In contrast, a "solution" is the "incorporation of a solid, a liquid, or a gas in a liquid or noncrystalline solid resulting in a homogeneous single phase" (*id*. at 1300).

According to Patent '774, its formulation solves many of the problems inherent in those earlier oral formulations. First, because it is in liquid rather than tablet form, it can more easily be administered in a variety of doses (id.). Second, suspensions tend to "settle out," creating variable doses at different levels in the same container, while solutions are more stable (id.). Third, because Patent '774's formulation does not contain alcohol, it is more appropriate for treating children and people with adverse reactions to alcohol (id.). Finally, Patent '774 teaches that the solution can contain sweeteners, making it more palatable and thus leading to greater patient compliance.

All claims in Fisons' initial application were rejected as obvious based on the combination of Patent Nos. 4,302,452 ("Pittman Patent"), 3,980,778 ("Ayer Patent") and 4,344,940 ("Chow Patent") (M. Ex. B 55-56). In that regard the Examiner stated (id .):

The references disclose the use of prednisolone type compounds in aqueous solutions as well as other anti-inflammatory, compounds used in conjunction, methyl hydroxy benzoate, EDTA (4,344,940), sugar (3,980,778) as well as other buffer materials (4,302,452). From a totality of the disclosures of the cited prior art it is submitted that the claimed compositions as well as their method of use would be very obvious to one of ordinary skill in the steroid art.

In other words, the application was rejected as an obvious combination of the Chow Patent's use of a chelating agent, the Pittman Patent's use of buffer materials and the Ayer Patent's use of sugar.

In response to that rejection, the applicants made several amendments to their application, including supplementing claim 1 to include the requirement that the formulation be a pharmaceutical solution "suitable for oral administration" (M. Ex. B 47). That revised application also pointed to differences between the applicants' invention and the Pittman, Ayer and Chow Patents and argued that the combination was not obvious (id. 50-51). After the amendments, all claims were allowed and Patent '774 issued on May 15, 1984 (F. Ex. A FH61).

Claim Construction

[1] Our American patent system serves two equally important goals: to secure the patentee's rights (the definitional goal) and to put others on notice of what the patentee has removed from the public domain for

the life of the patent (the notice goal) (Markman, 517 U.S. at 373, 116 S.Ct. 1384, quoting McClain v. Ortmayer, 141 U.S. 419, 424, 12 S.Ct. 76, 35 L.Ed. 800 (1891)). Hence cases such as Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340 (Fed.Cir.1999) instruct that the language in the documents constituting the public record-the claims, the specification and the prosecution history-should be principally involved in construing patent claims. Extrinsic evidence, such as expert testimony, should be relied on only if analysis of the intrinsic evidence fails to resolve an ambiguity in the disputed claim term (Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir.1996)).

[2] [3] That being said, a court may nonetheless rely on dictionary definitions when construing (though not in contradicting) claim terms, even though such dictionary evidence is extrinsic (id. at 1584 n. 6). As Vitronics, 90 F.3d at 1582, 1584 explains, because claim terms are given the ordinary and customary meaning ascribed to them by persons experienced in the field of the invention, dictionaries may often be useful to that end. But reliance on dictionary definitions is improper where a patentee has chosen "to be his own lexicographer" and has clearly stated in the patent specification or file history that a term has been given a special definition (id. at 1582). In such a case the special definition controls over the ordinary and customary meaning.

[4] Moreover, while the specification "is the single best guide to the meaning of a disputed term" (*id.*), claim language may be broader than any limitations set forth in the specifications. As Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1362 (Fed.Cir.2000) (quoting Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1348 (Fed.Cir.1998), with emphasis in original and quotation marks omitted) cautions:

This court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification which is improper.

"***Suitable for Oral Administration***"

Claim 1, with the language now at issue underlined, reads in full:

An aqueous pharmaceutical solution *suitable for oral administration* comprising as an active ingredient a steroid selected from the group consisting of prednisolone sodium phosphate, prednisone and methyl prenisolone, the steroid being present at a concentration of at least 0.3 mg/ml, the pH of the formulation being between 5 and 8 and the formulation containing a pharmaceutically acceptable preservative, a pharmaceutically acceptable chelating agent, and being substantially free of ethanol.

Because both parties agree that Patent '774 does not contain a special definition of "suitable for oral administration," the ordinary and customary meaning of that phrase controls.

[5] Morton Grove argues that the ordinary meaning of the phrase is simply that "animals and/or humans can ingest the solution orally" (M.Mem.5). According to Morton Grove, a solution would not be "suitable" for oral administration only "if it would lead to certain death or debilitating harm or, perhaps, contained ingredients humans are incapable of digesting and eliminating" (id.).FN5 Fisons, on the other hand, contends that "suitable for oral administration" contemplates much more, including "patient acceptance, stability, toxicity and efficacy" (F.Mem.12).

FN5. Although at first glance that characterization may seem somewhat stark, it really captures the essence of the term "suitable"-a view that is fortified when, as the ensuing discussion demonstrates, Morton Grove's suggested locution is contrasted with the insupportable contentions advanced by Fisons.

That broad brush reading by Fisons clearly attempts to put more weight onto the phrase "suitable for oral administration" than it can possibly carry. What Fisons urges is a type of hindsight revaluation of what its patent counsel should perhaps have said if the intention were indeed to convey the multiple considerations it now seeks to advance. It cannot be gainsaid that "suitable for oral administration" is too cryptic and too inartful a phrase to prescribe to the relevant reading public-persons skilled in the art-or, indeed, to any objective reader the congeries of meanings now sought to be attributed to that phrase.

As Morton Grove points out, drugs are routinely administered orally despite their being unstable, horrid-tasting, highly toxic and without therapeutic activity (M.Mem.2). For example, solutions made extemporaneously by pharmacists and used in a very short period of time need not be stable, yet they may be "suitable for oral administration" (M.Ex. F). Similarly, Morton Grove has pointed to various drugs that are administered orally yet are horrid tasting, such as dicloxacillin and potassium chloride (M. Ex. C 69; M. Ex. G 243-46). As admitted by Fisons' lead inventor on the '774 Patent, Dr. Emmet Clemente,FN6 such a drug is "suitable for oral administration"-it just might not be a successful product (M. Ex. G 244-46).

FN6. This opinion gives credit where credit is due by initially attaching the appellation "Doctor" to the holder of a Ph.D. degree in any field. But this Court then follows its customary practice of limiting any later usage of the title "Dr. X" to anyone who is a medical doctor, using simply "X" to refer to the possessor of any different doctorate. After all, apart from Germanic ("Herr Doktor-") and similar usage, lawyers don't refer to any of our fellow possessors of J.D. degrees as "Doctor-."

Fisons relies on the report of its claimed expert Dr. Joel Zatz ("Zatz") in arguing that toxicity is relevant to determining whether a solution is "suitable for oral administration" (F. Ex. F 5):

To be suitable for oral administration, pharmaceutical solutions must satisfy the requirements of oral preparations generally, as well as those related specifically to solutions. Ingredients must be non-toxic when ingested. This requirement excludes certain ingredients that may be commonly used for other delivery routes. For example, ophthalmic and other topical products may contain as a preservative benzalkonium chloride, a substance not generally used orally.

But as M. Mem. 12 points out, "virtually *all* drugs are 'toxic' to some degree, but nevertheless are 'suitable for oral administration.' "

While the concerns expressed in Zatz's report are obviously relevant to developing solutions for oral use, the phrase "suitable for oral administration" really does not raise those issues, let alone convey what toxins or toxicity levels are acceptable so that others are put on notice of what is and what is not within Patent '774's limited monopoly. Indeed, the very fact that Fisons found it necessary to resort to assertedly expert testimony-rather than relying solely on the phrase's admittedly unambiguouslanguage FN7-to explain what toxicity considerations it believes fall within the phrase demonstrates with devastating force that the phrase itself does not capture those considerations (see Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997), noting that purported "expert" testimony cannot be used to change claim terms' unambiguous meaning). This Court is constrained to add that Zatz's standing as a claimed expert was drastically undercut by his testimony in which, whenever he was pressed during cross-examination to support his stated standards, he retreated to a "no opinion" position (see, e.g., Zatz Dep. 42-43, 86-88). It surely does not require a full-fledged *Daubert* analysis to find Zatz's asserted "expert" underpinning totally wanting.

FN7. Fisons points to language in Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298 (Fed.Cir.1999) to suggest that it is relying on Zatz's testimony not to give the phrase a meaning other than its ordinary and customary meaning, but rather to demonstrate the ordinary and customary meaning in the pharmaceutical field. In that regard Pitney Bowes, id. at 1309 states:

Thus, under *Vitronics,* it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.

But this Court finds that Zatz's opinion does not reflect "clearly expressed, plainly apposite, and widely held understandings" in the pharmaceutical field. As the discussion above demonstrates, Zatz's construction of the disputed phrase rather operates to create ambiguity where it would not otherwise exist.
Fisons' claim that "suitable for oral administration" contemplates a certain level of efficacy fails for the same reason. Once more Fisons is forced to rely on Zatz's expert report (F. Ex. F 5):

Another requirement for a pharmaceutical solution suitable for oral administration is that it be therapeutically active and efficacious. For example, a drug may be efficacious when injected intravenously but, because of breakdown in the gut by enzymes, lose its activity when administered orally. In addition, certain drugs are absorbed poorly or not at all from the gut.

Again M. Mem. 14 identifies the flaw in such reliance: It points out accurately that "drugs are routinely administered orally despite a lack of *any* efficacy." More importantly, "suitable" does not at all convey what level of efficacy is necessary.

Alternatively Fisons argues that Patent '774's written description demonstrates that "suitable for oral administration" implies palatability, stability, toxicity and efficacy. That is simply not the case. While the patentees clearly contemplated that their solution would have greater stability than previously developed oral formulations and, in its preferred embodiment, would be sweetened so as to be more palatable, those limitations cannot be read into the broader language in claim 1 (see Kemco Sales, 208 F.3d at 1362). As for toxicity and efficacy, the written description is virtually silent on those issues in any event.

Next Fisons argues that Patent '774's prosecution history demonstrates that "suitable for oral administration" implies those requirements. Fisons contends that it was able to distinguish the Pittman, Chow and Ayer Patents by adding the phrase "suitable for oral administration" to Patent '774's claim 1. Because the formulations set forth in those patents would not cause certain death or debilitating harm if taken orally, Fisons suggests that the Examiner recognized that "suitable for oral administration" means more than that and allowed Patent '774 to issue on that ground.FN8

FN8. No court is of course bound by what an Examiner may have found persuasive, else no patent could ever be held invalid.

It is true that the amended application pointed out that the Pittman Patent teaches formulations for intravenous use and the Chow Patent teaches formulations "directed very largely" to topical use (M. Ex. B 50). But Fisons also pointed to a variety of other purported differences between its proposed patent and the prior art. Regarding the Pittman Patent, Fisons noted not only that it is for a different use but also that it suggests an alcoholic solution of a different steroid (id. at 51). Regarding the Ayer Patent, Fisons noted that its compounds "mainly intended for topical application rather than oral administration" concern steroids structurally different from prednisone and that its compounds intended for oral administration are suspensions containing ethanol and no sequestering agent (id. at 50). As for the Chow Patent, Fisons noted that its formulations use different steroid compounds (id.).

Fisons did not argue that the Pittman, Ayer and Chow formulations are unsuitable for oral administration or argue that its patent is distinguishable from the prior art on that basis alone. Thus Patent '774's prosecution history does not reveal that the phrase "suitable for oral administration" in this context means something other than its ordinary meaning-that is, that the formulation can be ingested.FN9

FN9. Moreover, the language of claim 1 does not invite reference to either the written description or the prosecution history. Thus it would be inappropriate to narrow the meaning of the claim terms in light of those sources in any event (Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989-90 (Fed.Cir.1999)).

Accordingly, this Court finds that Morton Grove's construction of "suitable for oral administration" accurately reflects the phrase's ordinary and customary usage. It does not carry the extra baggage sought to be loaded onto the phrase by Fisons.

Conclusion

This opinion has construed the disputed portion of claim 1 as a matter of law. Morton Grove has put the matter both succinctly and well at the very outset of its presentation (M.Mem.1):

A solution must be merely "suitable," not optimal, for ingestion.

It now becomes necessary to determine the next steps needed to move the case forward for ultimate disposition, and a status hearing is accordingly set for 9 a.m. August 16, 2001.

N.D.Ill.,2001.
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