United States District Court,
C.D. California.

AMERICAN BIOSCIENCE, INC,
Plaintiff.
v.
BAKER NORTON PHARMACEUTICALS, INC., Zenith Goldline Pharmaceuticals, Inc., IVAX Corporation and Does 1-10, inclusive,
Defendants.

No. CV 00-09589-MRP (AJWx)

Aug. 31, 2001.

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ORDER RE: PARTIAL CLAIM CONSTRUCTION

MARIANA R. PFAELZER**, District Judge.**

Pursuant to the Court's earlier Claim Construction Scheduling Order, each of the parties has submitted papers in support of its proposed constructions and in opposition to those proffered by the other. In these papers, the parties have identified five disputed limitations appearing in three claims of U.S. Patent No. 6,096,331 ("the '331 patent"). The action came before the Court on August 13, 2001 under Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995).

INTRODUCTION

This case involves a cancer treatment drug known generically as "paclitaxel." Paclitaxel is the active ingredient in Taxol (R), a cancer treatment drug currently marketed by Bristol-Myers Squibb Company ("Bristol"). Plaintiff American Bioscience, Inc. ("ABI") obtained the '331 patent, which issued on August 1, 2000. The '331 patent is directed to pharmaceutical formulations that contain the anti-cancer agent paclitaxel.

On September 7, 2000, ABI brought this action against defendants Baker Norton Pharmaceuticals, Inc., Zenith Goldline Pharmaceuticals, Inc. and IVAX Corporation (collectively "IVAX") for infringement of the

'331 patent. IVAX markets a pharmaceutical formulation containing paclitaxel that is the generic version of Taxol(R). IVAX filed counterclaims seeking, *inter alia,* a declaratory judgment that the '331 patent is invalid, unenforceable and not infringed. After IVAX filed its motion for partial summary judgment, this Court entered its May 22, 2001 order for claim construction proceedings.

ANALYSIS

"*Sufficient Quantity of Taxane*"

It appears that the claim limitation "sufficient quantity of taxane" (as well as its corollary limitation, "quantity of taxane is sufficient") is no longer the subject of any significant dispute. For this reason, the Court finds no need to construe this limitation.

"*Wherein Said Formulation is Useful for the Reduction of Serum* Testosterone *Levels in a Subject*"

Defendants argue that this term does not constitute a substantive limitation on Claim 39, but is at best a statement of advantage or intended use. With only one relevant exception, FN1 however, defendants only cite cases in which the courts refused to read clauses from the preamble into the claims. The limitation in this case, however, is not in the preamble.

FN1. In addition to *Texas Instruments,* the other case cited by defendants that did not deal with reading in limitations from the preamble is Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co ., 732 F.2d 903, 906-7 (Fed.Cir.1984). This case is inapposite, however, as it did not concern claim construction at all, but rather a district court's basis for a determination of obviousness.

The only case appearing to be even obliquely on point is Texas Instr., Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165 (Fed.Cir.1993), in which the Court of Appeals for the Federal Circuit held that clauses such as "whereby" and "to preclude" simply describe the result of arranging claim components, and do not add anything to patentability or the substance of the claims. Further, the contextual meaning of the word "wherein" prevents the Court from reading this limitation out of the claim.

"Whereby," as used in the context of the patent-in-suit in *Texas Instruments* is descriptive; it describes the result of the steps it modifies, basically meaning the same as "from which." "Wherein," as used in the context of the claim at issue in this case (claim 39), is restrictive; it limits the set of claimed formulations to those "in which" serum testosterone is reduced. Because it is plain that the patentee clearly intended to claim that subset of formulations in which the serum testosterone is actually reduced, the Court holds this clause to constitute a substantive limitation on claim 39. FN2

FN2. Even if the drafter had chosen to place this clause in the preamble of claim 39, the Court would still have no choice but to read it in as a substantive claim limitation. The term "wherein" is simply too restrictive for the Court to ignore its effect on the scope of that which is claimed.

To the extent that defendants allude to issues of invalidity with respect to the Court's construction for claim 39, their arguments and the alleged facts supporting them are incomplete and, in any event, inappropriate at this stage of the litigation. While the Court recognizes that one of the varying and conflicting "canons of claim construction" encourages courts to construe claims so as to maintain their validity, this Court will

construe the claim based on its clear meaning in relation to the intrinsic evidence; defendants may always, if appropriate, bring an invalidity challenge at a later time.

"*Vessel*"

The Court finds that the term "vessel" is neither ambiguous nor a term of art. In the context of the specification and claims of the patent, "vessel" simply takes its ordinary meaning: a "vessel" is a "container."

In the '331 specification, the words "container," "vessel," and "vial" are used interchangeably. *See, e.g.,* '331 patent at col. 20, ln. 63-col. 21, ln. 8; col 13, ln. 57; col. 14, ln. 19. The specification makes no mention of a need for such "vessels" to be in any special form or to have any special characteristics.

While the plaintiff's experts opine that a suitable "vessel" for producing a *marketable* and *FDA acceptable manufactured* product should have certain features, including sterility, freedom from pyrogens, and storage stability, these additional limitations are not mandated by the claim language of the patent. The patent does not require the claimed invention be manufactured, marketable, or FDA acceptable. An accused infringer need not be a large pharmaceutical company, as the "vessel" of plaintiff's claim would read as much on a burlap sack as it would on a sealed, pyrogen-free, glass vial.

"*Pharmaceutically Acceptable*"

Plaintiff again proposes a severely limited construction for this element. Without intrinsic support, ABI suggests that the "pharmaceutically acceptable" formulation claimed in the patent must be "sterile," "pyrogen-free," "produced by a pharmaceutical manufacturer under conditions that satisfy FDA's cGMP [current Good Manufacturing Practice] regulations," "stable following its manufacture" and "appropriately labeled." This position is untenable.

As with "vessel," the Court finds that this element is neither ambiguous nor a special term of art. According to the Oxford English Dictionary (Second Edition), the plain meaning of "pharmaceutically" is "related to pharmacy"; the plain meaning of "pharmacy" is "the use or administration of drugs or medicine." Thus, a "pharmaceutically acceptable" formulation is one "acceptable for administration." While experts may debate what would make a particular formulation *ideal* for administration, their observations have no place in the interpretation of this unambiguous term. FN3

FN3. ABI's experts may properly testify to what might be "pharmaceutically acceptable" in the context of FDA approved cGMP parenteral drug manufacture, but their opinions are not proper in the context of claim construction.

"*Unit Dosage Form*"

Claims 31 and 41 are directed to a "unit dosage form." The meaning of this claim term must be determined from the perspective of one of ordinary skill in the art of the "use and preparations of compositions (formulations) of drugs", as stated in the '331 patent itself. Col. 1, ln. 21-23. Though ABI would have this Court read a limitation into these claims that would enable only a manufacturer to qualify as one skilled in the art, the patent itself contains no such limitation on the claims.

ABI argues that the term "unit dosage form" refers to an article of manufacture as it is produced by a manufacturer in accordance with the current Good Manufacturing Practice ("cGMP") regulations of the Food and Drug Administration. Thus, ABI contends, the unit dosage form must be effective, sterile, pyrogen-free, storage stable, and bear a manufacturer's label indicating the identity and strength of the drug substance, the manufacturer's name, its lot number, and an expiration date. ABI does not seek support in the claims, the specification or the prosecution history. Instead, ABI "confirms" its construction by referring to the manner in which Taxol (R) is prepared and dispensed. This simply is not relevant. ABI has provided no significant reason for its highly specific construction of the term "unit dosage form."

IVAX argues that the term "unit dosage form" is not capable of interpretation as it is fatally indefinite. Through examination of intrinsic and extrinsic evidence, IVAX attempts to demonstrate that the term "unit dosage form" can be interpreted as a desired dosage for a particular patient or as a standard dose for all patients (such as one aspirin tablet). In the end, the extrinsic evidence demonstrates only that "unit dosage form" is subject to a wide range of possible definitions.

The only independent claim at issue, however, clearly defines what a "unit dosage form" is. Claim 31 defines a "unit dosage form" as "a vessel containing a sufficient quantity of taxane to allow systemic administration at a dose in [the ranges specified in Claims 31 and 41 respectively] over an administration period of less than 3 hours." The term "unit dosage form" is also present in Claim 41, which is dependent on Claim 31, and incorporates the definition of "unit dosage form" used in Claim 31.

In the '331 patent, there is no mention of whether the systemic administration pertains to one or many patients, whether the formulation needs to be prepared in accordance with cGMP, or even the exact quantity of taxane that should be used. As such, this Court will not craft a definition for the term "unit dosage form" which has no basis in the patent itself.

In addition, the term "unit dosage form" is mentioned in two other places in the specification. The first describes an embodiment of the invention and the preparation of the "unit dosage form." Col. 13, ln. 39-48. This section mirrors the definition present in Claim 31. The other reference is in the title of Example 12:

***Unit Dosage Forms* for Capxol**

Capxol is prepared as a lyophilized [*i.e.*, freeze-dried] powder in vials of suitable size. Thus, a desired dosage can be filled in a suitable container [and] lyophilized to obtain a powder containing essentially albumin and paclitaxel in the desired quantity. Such containers are then reconstituted with sterile normal saline or aqueous diluent to the appropriate volume at the point of use to obtain a homogeneous suspension of paclitaxel in the diluent. This reconstituted solution can be directly administered to a patient either by injection or infusion with standard i.v. infusion sets. (Emphasis added)
Col. 20, ln. 65-col. 21, ln. 8. Despite its title, this section fails to provide a definition of the term "unit dosage form." The term "unit dosage form" does not appear anywhere, nor specifically refer to anything, in the body of the example.
Therefore, the Court's construction can be determined solely from the claims. There is no need to look outside the patent. A "unit dosage form" is "a vessel containing a sufficient quantity of taxane to allow systemic administration at a dose in the ranges specified in claims 31 and 41 respectively over an administration period of less than 3 hours."

Indeed, "unit dosage form" is nothing more than a label for what is claimed. A claim's preamble is of no

significance in claim construction if the claim's body fully and intrinsically sets forth the complete invention, including all of its limitations. *See* Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999). As used here, "unit dosage form" adds nothing to the language in claims 31 and 41, which require a vessel containing a sufficient quantity of taxane to allow systemic administration at a dose within the ranges and time frame prescribed. There is nothing in the patent itself to indicate that "unit dosage form" means anything else.

Defendants' lengthy exhibition of inconsistent usage in the extrinsic evidence, while providing a context for the proposed constructions, fails to offer any insight regarding the usage in the patent itself. Since the patentee has provided a clear explanation of the manner in which he used the term, he may be his own lexicographer. *See, e.g.,* Hoechst Celanese Corp. v. BP Chemical Ltd., 78 F.3d 1575 (Fed.Cir.1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning."). The claims clearly demonstrate how the term "unit dosage form" should be defined. The Court need not rely on extrinsic evidence.

CONCLUSION

Having thoroughly considered the papers filed in support of and in opposition to the parties' respective proposals, the other pleadings and papers on file, as well as the evidence presented and the arguments of counsel at the *Markman* hearing, the Court holds the following:

-> The term "sufficient quantity of taxane" needs no construction.

-> The clause "wherein said formulation is useful for the reduction of serum testosterone levels in a subject" is a substantive limitation.

-> The term "vessel" means "container."

-> The term "pharmaceutically acceptable" means "acceptable for administration."

-> The term "unit dosage form" means "a vessel containing a sufficient quantity of taxane to allow systemic administration at a dose in the ranges specified in claims 31 and 41 respectively over an administration period of less than 3 hours."

IT IS SO ORDERED.

C.D.Cal.,2001.
American Bioscience, Inc. v. Baker Norton Pharmaceuticals, Inc.