United States District Court,
D. Delaware.

CEPHALON, INC. and University Of Utah Research Foundation,
Plaintiffs.
v.
BARR LABORATORIES, INC,
Defendant.

No. CIV.A. 05-29 JJF

Oct. 6, 2005.

Background: Owner of patent for method of producing drug-containing lollipops sued competitor for infringement.

Holding: Construing claims, the District Court, Farnan, J., held that patented process did not include use of free liquid.

Claims construed.

4,863,737. Construed.

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MEMORANDUM OPINION

FARNAN**, District Judge.**

Cephalon, Inc. and the University of Utah Research Foundation (collectively "Cephalon") brought this patent infringement action against Barr Laboratories, Inc. ("Barr"). Cephalon alleges that a product that Barr intends to produce and sell will infringe U.S. Patent No. 4,863,737 ("the '737 patent"). Presently before the

Court is the claim construction dispute of the parties. The parties briefed their respective positions, and the Court held a *Markman* hearing on September 14, 2005. This Memorandum Opinion provides the Court's interpretation of the claim phrases disputed by the parties.

BACKGROUND

The patent at issue in this lawsuit relates to drug-containing lollipops and their methods of manufacture. These lollipops can be used to deliver medications through the mucosal tissues of a patient's mouth, pharynx, and esophagus. The '737 patent is assigned to the University of Utah Research Foundation, and Cephalon is the exclusive licensee. In December, 2004, Barr informed Cephalon that Barr intends to market a generic version of Cephalon's ACTIQ(R) product, a lollipop used to deliver a pain-relieving medication. Cephalon then brought the instant lawsuit, alleging that the product Barr intends to market would infringe the '737 patent if it were made or sold in the United States.

DISCUSSION

I. Legal Principles Of Claim Construction

[1] [2] [3] Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In interpreting a claim, a court should look first to the intrinsic evidence, i.e. the patent itself, including the claims and the rest of the specification, and, if in evidence, the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Although it is within the sound discretion of a court to use extrinsic evidence as an aid in construing a claim, extrinsic evidence is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Phillips v. AWH Corp., 415 F.3d 1303, 1319 (Fed.Cir.2005) (en banc).

[4] [5] [6] A claim term should be construed to mean "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." Markman, 52 F.3d at 986. However, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. Thus, the specification is usually "dispositive; it is the single best guide to the meaning of a disputed term." Id. at 1315 (quoting Vitronics, 90 F.3d at 1582). In other words, a claim term can be given its correct construction only within the context of "what the inventors actually invented and intended to envelop with the claim." Phillips, 415 F.3d at 1316.

II. Construction Of The Disputed Phrases

The parties dispute the construction of four phrases: "substantially powdered form," "mixing the drug and the carbohydrate material," "solid integral mass," and "drug-containing matrix." The four disputed phrases appear in independent Claims 1, 6, 18, and 37 of the '737 patent. Claims 1 and 18 are method claims and Claims 6 and 37 are article of manufacture claims. The language of Claims 1 and 6 are representative of the disputed phrases. In full, Claim 1 provides (emphasis added):

1. A method for producing a drug-containing lollipop for use in transmucosal delivery of the drug to a patient, the method comprising the steps of:

(a) obtaining a pharmacologically effective dose of the drug in a *substantially powdered form,* the drug

being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus;

(b) obtaining a soluble carbohydrate material capable of forming a compressible confectionary matrix and capable of dissolving in the mouth of the patient;

(c) *mixing the drug and the carbohydrate material* at a temperature below the melting points of the drug and the carbohydrate material to form a *drug-containing matrix* such that the drug is dispersed substantially throughout the matrix, the *drug-containing matrix* being capable of releasing the drug for absorption through the mucosal tissues upon dissolution of the matrix in the mouth of the patient;

(d) compressing the *drug-containing matrix* in a mold to form an integral mass such that, when the integral mass dissolves in the mouth of the patient, the drug is released for absorption through the mucosal tissues; and

(e) incorporating a holder as part of the integral mass in order to form the drug-containing lollipop.

('737 patent, col. 26, ll. 35-60).

In full, Claim 6 provides (emphasis added):

6. A drug-containing lollipop for use in transmucosal delivery of the drug to a patient comprising:

a soluble, compressible carbohydrate material;

a pharmacologically effective dose of a drug in a *substantially powdered form,* the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus and being dispersed substantially uniformly throughout the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material and compressed with the carbohydrate material into a *solid integral mass* which is capable of dissolving in the mouth of the patient so that the drug is released for absorption through mucosal tissues of the mouth, pharynx, and esophagus upon dissolution of the integral mass in the mouth of the patient;

holder means secured to the integral mass so as to form a drug-containing lollipop, the holder means being configured so as to permit convenient insertion and removal of the drug-containing integral mass into and out of the mouth of a patient.

('737 patent, col. 27, ll. 12-33).

The essence of the dispute with regard to all four disputed phrases is whether they should be construed to require the absence of "free liquid." "Free liquid" is defined by Barr as "any liquid that is not incorporated chemically into the fine particles, beyond that which may be sorbed naturally." (D.I. 41 at 15 n. 8.) Cephalon takes no position with regard to whether Barr's definition of "free liquid" is correct. (D.I. 50 at 7 n. 17.) The Court construes "free liquid" in accordance with Barr's definition.

Cephalon contends that the disputed claim phrases should not be limited by requiring the absence of free liquid, first, because the plain and ordinary meaning of the phrases does not require it, and second, because neither the specification nor the prosecution history shows any clear disclaimer of the use or presence of

free liquid. In response, Barr contends that statements in the specification that describe the "present invention" limit the scope of the claims to preclude free liquid. Barr further contends that the prosecution history shows an effective disclaimer of the use of free liquid in the methods and articles of manufacture claimed by the '737 patent.

The Federal Circuit's recent decision in *Phillips v. AWH Corp.* clarified the approach that a court should take in construing disputed terms of a patent claim. 415 F.3d 1303 (Fed.Cir.2005). Rather than beginning with a broad, dictionary definition and then limiting it in accordance with the specification and the prosecution history, the preferred approach is to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history ...." Id. at 1321. Here, both the specification and the prosecution history demonstrate that the inventions actually described and claimed by the '737 patent are a method of producing drug-containing lollipops using the compression of dry, powdered ingredients, and the products resulting from the use of that method. Nowhere in the claims, the specification, or the prosecution history do the inventors ever discuss the possibility of using a liquid as part of their invention. In addition, and more significant, many of their statements indicate that the inventors viewed their invention as enveloping only the dry mixing and compression of powders to form the drug-containing lollipops.

The following are illustrative examples. In the Summary of the Invention section, the '737 patent states that "[t]he present invention teaches the combination of dry powdered ingredients by geometric dilution," ('737 patent, col. 5, ll. 43-45); and "flavorings, drugs, and other components (which may be insoluble in liquid form) are easily mixed when they exist as a dry powder," (Id. at col. 6, ll. 6-8). In the General Discussion of the Preferred Embodiments section, the '737 patent states that "the present invention teaches the mixing of solid powders at room temperature, as opposed to liquid components at elevated temperatures," (Id. at col. 7, ll. 62-65); and "because solid powders are combined together, constituents which may be chemically incompatible when in a heated solution or suspension can be mixed," (Id. at col. 8, ll. 3-6). In the Methods of Manufacture of the Preferred Embodiments section, the '737 patent states that "[e]ach of the components is mixed with the other components in dry form to produce the compositions of the present invention." (Id. at col. 11, ll. 47-49).

[7] [8] Cephalon argues that these examples do not amount to a clear disclaimer of the use of liquid in the claimed manufacturing method (D.I. 50 at 12-13), but that argument is misplaced. Whether or not there was an explicit disclaimer, the consistent use of a claim term by the inventor in the specification may serve to limit the scope of a claim. Nystrom v. Trex Co., Inc., 424 F.3d 1136, 1144-45, 2005 WL 2218632, *6-7 (Fed.Cir.2005).

"What *Phillips* now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to ... those of ordinary skill in the art ... that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

Id. at 1145, 2005 WL 2218632, *7 (citing Phillips, 415 F.3d at 1321). Here, the inventors consistently referred to the "present invention" as teaching the formation of drug-containing lollipops through the compression of "dry" or "solid" powders. There is nothing in the written description or the prosecution history to suggest that they intended the disputed phrases to cover methods or articles using free liquid. Therefore, it would be improper for this Court to broaden the inventors' use of the disputed phrases and construe them to encompass the use of free liquid.

This result is not, as Cephalon argues (D.I. 50 at 12-13), the improper importation of limitations from the specification into a claim. This is a case where "the specification read as a whole suggests that the very character of the invention requires the limitations to be a part of every embodiment." Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1369 (Fed.Cir.2003).

For the reasons discussed above, the Court construes the disputed claim phrases as follows:

A. "**Substantially powdered form**" means "largely in the form of fine particles absent the presence of free liquid."

B. "**Mixing the drug and the carbohydrate material**" means "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids."

C. "**Solid integral mass**" means "a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous."

D. "**Drug-containing matrix**" means "drug-containing powder matrix."

CONCLUSION

An Order consistent with this Memorandum Opinion will be entered setting forth the meaning of the disputed phrases in the patents-in-suit.

ORDER

At Wilmington, this 6 day of October 2005, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that for the purposes of United States Patent No. 4,863,737, the following phrases are construed as follows:

1. The phrase "**substantially powdered form**," as used in Claims 1, 6, 18, and 37 means "largely in the form of fine particles absent the presence of free liquid;"

2. The phrase "**mixing the drug and the carbohydrate material**," as used in Claims 1 and 18 means "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids;"

3. The phrase "**solid integral mass**," as used in Claims 6 and 37 means "a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous;"

4. The phrase "**drug-containing matrix**," as used in Claims 1 and 18 means "drug-containing powder matrix."

D.Del.,2005.
Cephalon, Inc. v. Barr Laboratories, Inc.

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