

United States District Court,
E.D. Pennsylvania.

ORASURE TECHNOLOGIES, INC.,

v.

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.

July 6, 2005.

Craig R. Tractenberg, Frank W. Ryan, Renee F. Bergmann, Nixon Peabody LLP, New York, NY, David L. May, Jeffrey A. Lindeman, Robert P. Fletcher, Nixon Peabody LLP, Washington, DC, for Orasure Technologies, Inc.

Danielle Anne Phillip, Lewis Clayton, Steven C. Herzog, Theodore V. Wells, Paul Weiss Rifkind Wharton & Garrison LLP, Theodore K. Cheng, Proskauer Rose LLP, New York, NY, James D. Cashel, Richard L. Scheff, Montgomery McCracken Walker & Rhoads, LLP, Philadelphia, PA, for Schering-Plough Healthcare Products, Inc.

MEMORANDUM AND ORDER

NORMA L. SHAPIRO, Senior District Judge.

Plaintiff, OraSure Tehnologies, Inc. ("OraSure"), filed an action for patent infringement against defendant, Schering-Plough Healthcare Products, Inc. ("Schering"). OraSure markets cryosurgical assemblies under the Histofreezer(R) and Freeze Off(TM) trade names. Cryosurgery, freezing of skin and other tissue, is used to remove warts, skin tags, and other benign skin lesions; the body sloughs the frozen tissue and the skin lesion is removed. The Food and Drug Administration ("FDA") approved OraSure's Compound W(R) Freeze Off(TM) device in March, 2003, and it became available to consumers in August, 2003. Schering's competing product, Dr. Scholl's(R) Freeze Away(TM), went on the market in March, 2004. OraSure alleges Dr. Scholl's(R) Freeze Away(TM) infringes three of its patents: (1) U.S. Patent No. 5,738,682 (the " '682 patent"), entitled "Apparatus for Cooling Surface"; (2) U.S. Patent No. 6,092,527 (the " '527 patent"), entitled "Method for Cooling Surfaces"; and (3) U.S. Patent No. 4,865,028 (the " '028 patent"), entitled "Device for Carrying Out a Therapeutic Treatment by Means of a Refrigerant." This court held a Markman hearing to consider the meaning of the disputed patent terms. *See* 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).

Principles of Claim Construction

Patent infringement allegations are litigated in two stages. In "claim construction," the court determines the scope and meaning of the patent claims. The judge or jury then compares the judicially defined claims with the allegedly infringing device. *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc); *Markman*, 52 F.3d 967.

Two types of evidence are relevant to claim construction: "intrinsic" and "extrinsic." Intrinsic evidence consists of the patent's claims, specification, FN1 and, if in evidence, the prosecution history. FN2 *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). Extrinsic evidence consists primarily of expert testimony, inventor testimony, and scientific publications. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1373 (Fed.Cir.2001).

FN1. The specification of a patent should describe the invention in clear terms so that a person skilled in the relevant art may make and use the invention. 35 U.S.C. s. 112. It usually includes the background of the invention, a summary of the invention, drawings, and a detailed description of the invention's preferred embodiment.

FN2. The prosecution history is the public record of a patentee's submissions to the Patent and Trademark Office regarding the particular patent. *See Tulip Computers, Internazionali B.V. v. Dell Computer Corp.*, 236 F.Supp.2d 364, 371 (D.Del.2002).

A court begins claim construction by examining intrinsic evidence because the language of a patent generally resolves how a court should define a patent's disputed terms. *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001). Where possible, the intrinsic evidence alone should determine the meaning of a claim term. *Optical Disc Corp. v. Del Mar Avionics*. 208 F.3d 1324, 1334 (Fed.Cir.2000).

The court "look[s] first to the claim language itself to define the scope of the patented invention." *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed.Cir.2001). The words of a claim are generally given their ordinary and customary meaning, *Vitronics Corp.*, 90 F.3d at 1582, and dictionaries may be used to determine a term's ordinary meaning. *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed.Cir.2003); *see also*, *Teleflex Inc. v. Filosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed.Cir.2002) (dictionaries and treatises are no longer considered extrinsic evidence). When the language of the claim is clear on its face, the court gives the disputed term its "ordinary and accustomed meaning" as understood by one of ordinary skill in the art at the time of invention. *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 965 (Fed.Cir.2000) (quoting *Renishaw PLC v. Marposs Societa Per Azioni*, 158 F.3d 1243, at 1248 n. 2 (Fed.Cir.1998)).

If a term has more than one plausible ordinary meaning, the court must consult the intrinsic record to identify which of the possible meanings is "most consistent with the use of the words by the inventor." *Texas Digital Systems v. Telegenix, Inc.*, 308 F.3d 1193, 1203 (Fed.Cir.2002). After the claim language, the court considers the remaining intrinsic evidence, *Interactive Gift*, 256 F.3d at 1331; but the court "does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves." *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1552 (Fed.Cir.1997), *overruled* on other grounds by *Cybor Corp.*, 138 F.3d at 1452-55.

The court's consideration of the specification and prosecution history is restricted to determining whether either of the two conflicts with the ordinary and accustomed meaning of the claim language. *Interactive Gift*, 256 F.3d at 1331. Although there are limitations on the degree to which a court can rely on the specification and prosecution history in construing a claim term, "the intrinsic record ... must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted." *Id.* at

FN3. In a limited number of circumstances, a court may reject the ordinary and accustomed meaning of a claim term. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed.Cir.2002).

A court may refer to extrinsic evidence only if the disputed term's ordinary and accustomed meaning cannot be discerned from the intrinsic evidence. *Vitronics*, 90 F.3d at 1584. Although extrinsic evidence "may not be used to vary or contradict the claim language," *id.*, extrinsic materials "may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." *Markman*, 52 F.3d at 980. The court first considers the claim language; then the remaining intrinsic evidence; and finally, the extrinsic evidence in limited circumstances. *See, e.g., Interactive Gift*, 231 F.3d at 865-66.

I. Construction of the Disputed Terms in the '682 Patent: "Apparatus for Cooling Surface"

OraSure contends defendant infringes claim 1 of its '682 patent. The patent covers an apparatus for cooling surfaces. With disputed terminology highlighted, claim 1 of the '682 patent reads:

An assembly for dispensing a refrigerant, said assembly comprising

(1) a container which

(a) includes a valve having an inlet, and an outlet, and

(b) is sealed except for the valve;

(2) a liquid refrigerant which

(a) is contained under pressure within the container and

(b) has a boiling point at atmospheric pressure of less than 0 (deg.)C;

(3) a **feed tube** which has

(a) a first end **within the refrigerant**, and

(b) a second end which communicates with the inlet of the valve;

(4) an outlet tube which has

(a) a first end which communicates with the outlet of the valve, and

(b) a discharge end; and

(5) a dispensing head which

(a) comprises a shaped member composed of an **open celled foam**, and

(b) is **secured to** the discharge end of the outlet tube so that, when the valve is open, the refrigerant is **dispensed through** the **open celled foam**.

1. "*Feed Tube*" and "*Within the Refrigerant*"

The '682 patent does not define the term "feed tube." OraSure claims the "feed tube" is "a hollow cylinder used for the conveyance of fluids"; Schering contends it is "the tubular structure that functions as the pathway by which the refrigerant moves from within the container to the inlet of the valve." OraSure defines "feed tube" as a "hollow cylinder." Schering defines it tautologically: a "tubular structure."

Webster's defines "tube" as "a hollow cylinder or pipe of metal, glass, rubber, etc." *Webster's New World Dictionary, Third College Edition* (3d. ed. 1986) ("Webster's"). "Feed tube" will be construed according to its common and ordinary meaning; it means "a hollow cylinder."

The '682 patent states the feed tube "has a first end *within the refrigerant* and a second end which communicates with the inlet of the valve." OraSure claims that "in the context of the claimed device, the 'feed tube' is immersed in the refrigerant when the device is in operation." Schering agrees that "within the refrigerant" refers to the location of the intake end of the feed tube, which is submerged in the liquid phase of the refrigerant.

Although the parties agree that the feed tube is either "immersed" or "submerged" "within the refrigerant," OraSure asks the court to construe "within the refrigerant" as "in contact with the refrigerant." Schering proposes "the location of the intake end of the feed tube, which lies submerged in the liquid phase of the refrigerant."

The patent application diagrams show that, as the refrigerant is depleted, the feed tube will extend above the refrigerant water line. Therefore, the feed tube is neither "immersed" nor "submerged" within the refrigerant because, according to Webster's, the words mean "to cover completely" or "to cover over." The feed tube is only partly "immersed" or "submerged" while the device remains operable. The term "within the refrigerant" shall mean that the feed tube is "partly immersed when the device is in operation."

2. "*Open Celled Foam*"

"Open celled foam" refers to the composition of the applicator tip of the patented product. The patent specifications state "[o]pen celled foam materials are well known and those of ordinary skill will have no difficulty, after consideration of the disclosure in this specification, in selecting open celled foams which are suitable for use in this invention." ('682 patent, col.2, ll. 25-28).

Although "open celled foam" is not defined in the '682 patent, the patent describes its preferred embodiments: "open celled foam is preferably composed of a foamed synthetic organic polymer which does not react chemically with the refrigerant and which has suitable physical properties throughout the range of temperatures to which it is exposed in the method" ('682 patent, col. 2, ll. 29-30), "when there is space between the foam member and the discharge tube and that space contains a permeable and absorbent material, the foams which can be used include the so-called reticulated foams." ('682 patent, col. 2, ll. 59-63).

OraSure defines "open celled foam" as "[a] cellular plastic composed of the membranes, walls, or a network of polymer separating small cavities or cells where at least some of the cells are interconnecting and having sufficient porosity to allow a fluid to flow through." OraSure cites a standard from ASTM International (formerly the American Society for Testing and Materials) in support of its definition. ASTM D 2856-94 (published May 1994): Std. Test Method for Open-Cell Content of Rigid Cellular Plastics by the Air Pycnometer.

Schering offers the definition of open celled foam found in the McGraw-Hill Dictionary of Scientific and Technical Terms (5th ed.1994): "a foamed material, natural or synthetic, rigid or flexible, organic or metallic, in which there is interconnection between the cells."

There are a number of reasons to adopt Schering's construction. It is logical that "open celled foam" describes "a foamed material," and the patent specification repeatedly describes the embodiment of "open celled foam" as "the foam" or the "shaped foam." Schering's definition conforms to the language of the '682 patent.

Schering's construction is taken directly from the McGraw-Hill Dictionary of Scientific and Technical Terms; there is a presumption in favor of a dictionary definition if the patentee has not clearly set forth an explicit definition of the term different from its ordinary meaning. Although Orasure's definition appears in quotation marks, it is not a direct quotation of an ASTM International standard.FN4 OraSure cites a section of ASTM International entitled "Standard Test Method for Open-Cell Content of Rigid Cellular Plastics by the Air Pycnometer," where the term "open celled foam" never appears.

FN4. OraSure attached 11 pages from ASTM International Standard D2856-94 as Exhibit "E" to its brief. The term "open cell" is defined in these attached pages, but there is no definition for the term "open celled foam." ASTM International defines "open cell" as "a cell not totally enclosed by its walls and hence interconnecting with other cells."

OraSure's "quote" from ASTM International is a paraphrase of section 1.1 (p.143), where the ASTM standard distinguishes between open and closed cell variations of cellular plastics: "Cellular plastics are composed of the membranes or walls of polymer separating small cavities or cells. These cells may be interconnecting (open cell), non-connecting (closed cell), or any combination of these types." The term "open celled foam," means "a foamed material, natural or synthetic, rigid or flexible, organic or metallic, in which there is interconnection between the cells."

3. "*Secured to*"

OraSure asks the court to construe "secured to" according to the dictionary definition: "made firm, fast, or tight." Webster's. Schering uses a different dictionary to arrive at the same definition: "[t]o make firm or tight; fasten." The American Heritage Dictionary of the English Language (4th ed.2000). The term "secured to" in the '682 patent shall mean "made firm, fast, or tight."

4. "*Dispensed Through*"

The '682 patent states when the valve is open, "the refrigerant is *dispensed through* the open celled foam." Although the parties agree "dispensed through" is contested, they define only the word "through." The court will therefore define only the word "through."

OraSure argues "through" is properly construed as "flows into and out of." Schering, offering the example of a person walking "through the door," proposes the court adopt the American Heritage Dictionary definition of "through" as "in one side and out the opposite or another side of."

Schering's directional sense of the word "through" is overly restrictive and not in accord with how the patent describes the refrigerant being "dispensed through" the open celled foam. A walk "through" the park does not require a person walk "in one side and out the opposite or another side of" the park. The expression "got soaked *through* in the rain" is analogous with the operation of OraSure's apparatus; a person's apparel will be saturated much as the refrigerant saturates the applicator tip. The word "through" as it appears in the '682 patent shall mean "flows into and out of."

II. Construction of the '527 Patent "Methods for Cooling Surfaces"

The '527 patent is directed to methods for cooling surfaces. The '527 patent is a divisional of the '682 patent. FN5 OraSure alleges claims 21 and 22 of the '527 patent are being infringed. The disputed terms are highlighted. Claim 21 of the '527 patent reads:

FN5. Because the '527 patent is a divisional of the '682 application, the specification and drawings of the two patents are identical and they will be construed consistently. *See* Abtox, Inc. v. Exitron Corp., 131 F.3d 1009, 1010 (Fed.Cir.1997) ("Although these claims have since issued in separate patents, it would be improper to construe this term differently in one patent than another, given their common ancestry.").

A method of using a container including a pressurized liquid refrigerant and a dispensing head **secured to** a tube to cool the skin of a living mammal, the dispensing head including a shaped member composed of an **open celled foam**, the method comprising the steps of:

(1) supplying the liquid refrigerant to the dispensing head; and

(2) placing the open celled foam of the dispensing head **adjacent to the skin** so that the liquid refrigerant **passes through the open celled foam** and **evaporates adjacent to the skin**.

The court has already defined the terms "open celled foam," and "secured to." Open celled foam means "a foamed material, natural or synthetic, rigid or flexible, organic or metallic, in which there is interconnection between the cells." "Secured to" means made firm, fast or tight." The parties disputed only the word "through" in the term "passes through" as used in the '527 patent. The word "through" in the '527 patent shall be given the same definition that the word was given in the construction of the '682 patent because the two patents use the word to identify the same process and both parties proffered a single definition for the terms "passes through" and "dispensed through" as they appear in the '527 and '682 patents respectively. The word "through" means "flows into and out of."

OraSure claims both "adjacent to the skin" and "evaporates adjacent to the skin" are to be construed, but it defines only "adjacent to the skin" as "near or close to, with or without touching, the skin." Schering states "evaporates adjacent to the skin means "the cooling mechanism must be evaporation adjacent to the skin, not evaporation from a cooling tip before the tip is placed on the skin."

The words requiring construction in the disputed term "evaporates adjacent to the skin" are "evaporates" and

"adjacent." Neither party defines "evaporates." The court will construe "evaporates" and "adjacent" according to their common and ordinary meanings as found in Webster's. "Evaporates" means "to change (a liquid or solid) into vapor"; "adjacent" means "near or close to."

III. Construction of the '028 Patent: "Device for Carrying Out a Therapeutic Treatment By Means of a Refrigerant"

The '028 patent covers a device for therapeutically treating a portion of the skin.FN6 The '028 patent has 4 claims; only claim 1 is independent. OraSure contends Claims 1 and 4 of the '028 patent are being infringed.FN7

FN6. The '028 patent is written in "Jepson format." In a Jepson claim the prior art is recounted first in a preamble; a transition is then typically announced by the words "the improvement consisting" or "the improvement wherein"; then, the rest of the claim sets forth the improvement added by the invention. *See Dow*, 257 F.3d at 1368. When a Jepson claim is made, the preamble is impliedly admitted to be prior art; the claimed invention consists of the preamble in combination with the improvement asserted. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed.Cir.1985).

FN7. In their briefs, the parties construed different terms from the '028 patent. However, during the Markman hearing, both sides agreed the following terms need to be defined: "cotton wool"; "encompassing"; "surrounds"; "permeable"; and "exposed outer surface of cotton wool." Although neither party asked the court to define the term "application of the refrigerant thereto," when they demonstrated how their devices operate, the parties disputed how the refrigerant was being applied. The parties also construed the term "application of the refrigerant thereto" in their briefs. Therefore, the court will construe the term "application of the refrigerant thereto."

In device for the therapeutic treatment of a portion of the skin of a human or animal by the freezing of said portion of said skin by **application of a refrigerant thereto**, said device comprising a spray can containing a liquid refrigerant that boils within the temperature range of 0 (deg.)C. To -50 (deg.)C., and a supply tube having a supply end positioned within said spray can and a discharge end having an outlet for said refrigerant, the improvement wherein said device further comprises a **cotton wool bud encompassing** said discharge end of said supply tube and which cotton wool bud **surrounds** said outlet of said supply tube and is **permeable** by said liquid refrigerant and has an **exposed outer surface of cotton wool**.

1. "Application of a Refrigerant Thereto"

The language "application of a refrigerant thereto" is not defined in the specification or the '028 patent prosecution history. OraSure defines "application of a refrigerant thereto" as "putting the cotton wool bud containing and cooled by the refrigerant on." Schering claims the word "application" means "[t]he act of applying," and "apply" means "[t]o bring into nearness or contact with something; to put on, upon, or to." Because the refrigerant is the thing that is being applied, Schering concludes the phrase should be construed as "placing the refrigerant in contact with the skin, rather than freezing the skin by merely using a cooled tip."

"Application" shall be defined by the common and accustomed meaning of its root word "apply" as found in Webster's: "to put on or spread on." "Application of the refrigerant thereto" means "to put on or spread on the refrigerant."

2. "Cotton Wool Bud"

The '028 patent claims a "cotton wool bud" as its applicator tip. OraSure states "cotton wool bud" is "a small piece of absorbent natural fiber material." Schering argues the term is "limited to cotton in its natural or raw state shaped in the form of a bud." The dispute is whether "cotton wool bud" encompasses materials other than cotton.

"Subject matter disclosed [in the specification] but not claimed in a patent application is dedicated to the public." *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106-1107 (Fed.Cir.1996); *see also*, *Miller v. Brass Co.*, 104 U.S. 350, 352, 26 L.Ed. 783 (1881) ("[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed."); *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed.Cir.2002) (en banc). ("When a patent drafter discloses but declines to claim subject matter ... this action dedicates that unclaimed subject matter to the public.")

The specification of the '028 patent discloses the use of a "cotton wool bud or similar plug of absorbent material." ('028 Patent at col. 1, l. 9). However, every claim of the '028 Patent requires that the discharge end of the device is a "cotton wool bud." "Cotton wool bud" therefore shall be defined as "cotton in its natural or raw state shaped in the form of a bud."

3. "Cotton Wool Bud Encompassing" and "Cotton Wool Bud Surrounds"

OraSure contends "encompassing" and "surrounds" are defined as "encircling." During oral argument counsel for Schering informed the court defendant would agree that these terms are defined as encircling. The terms "encompassing" and "surrounds" are defined as "encircling."

4. "Is Permeable"

OraSure defines the term "permeable" as "open to passage by fluids." Schering claims "the refrigerant must physically be able to spread or flow throughout the cotton wool bud, and not just a portion of the bud, thereby soaking the bud." This is not a definition. The term "is permeable" is defined as "open to passage by fluids."

5. "Exposed outer surface of cotton wool"

OraSure defines "exposed outer surface of cotton wool" as "a surface of exposed fibers." Schering claims "the discharge end must have an exposed surface composed of cotton in its natural or raw state, or cotton wool." This court has already determined that "cotton wool bud" is defined as "cotton in its natural or raw state shaped in the form of a bud." During the hearing the parties agreed that "exposed means exposed." The court adopts the common and ordinary definition as found in Webster's: "to make accessible or subject (to an influence or action)."

CONCLUSION

The discussion and analysis presented above represents this Court's construction of the disputed terms.

ORDER

AND NOW, this *6th* day of July, 2005, upon consideration of the parties' Memorandums of Law on Claim Construction, and after a *Markman* hearing held on November 19, 2005, at which both parties were heard, it is **ORDERED** that the meaning and scope of the patent claims asserted to be infringed and presented by the parties for construction are determined as set forth in the forgoing Memorandum.

E.D.Pa.,2005.

Orasure Technologies, Inc. v. Schering-Plough Healthcare Products, Inc.

Produced by Sans Paper, LLC.