United States District Court,
W.D. New York.

FOREST LABORATORIES, INC. and Ony, Inc,
Plaintiffs.
v.
ABBOTT LABORATORIES and Tokyo Tanabe Company, Ltd,
Defendants.

No. 96-CV-159A

Aug. 3, 1998.

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DECISION AND ORDER

RICHARD J. ARCARA**, District Judge.**

INTRODUCTION

Prior to trial in this patent case, the parties raised various issues regarding claim construction. A *Markman* hearing was held on these claim construction issues on June 9 through June 11, 1998. On June 12, 1998, the Court issued a Decision and Order, summarily construing the disputed claims. FN1 The instant Decision and Order provides the reasoning, explanation and support for the Court's claim constructions.

FN1. The parties also filed several motions *in limine* prior to trial. The Court's June 12, 1998 Decision and Order addressed those motions in summary fashion as well. The Court will issue a separate Decision and Order regarding its rulings on those motions.

BACKGROUND

This case involves two patents owned by defendant Tokyo Tanabe Company, Ltd. ("Tokyo Tanabe"). U.S. Patent No. 4,338,301 (the "'301 patent"), entitled "Lung Tissue Extract Useful For Treating Hyaline-Membrane Disease And Method For Producing The Extract," was issued on July 6, 1982 to Tokyo Tanabe

as assignee. U.S. Patent No. 4,397,839 (the "'839 patent"), entitled "Surface Active Material And Process For Preparing Same," was issued on August 9, 1983 to Tokyo Tanabe as assignee. Both patents relate to pharmaceutical compositions used to treat respiratory distress syndrome ("RDS") in premature babies. The '301 patent expires on May 21, 2000 and the '839 patent expires on June 1, 2005.

On February 3, 1984, Tokyo Tanabe granted defendant Abbott Laboratories ("Abbott") an exclusive license for the '301 and '839 patents (collectively "the Tokyo Tanabe patents"). After being granted the license, Abbott developed a commercial product based on the Tokyo Tanabe patents called "Survanta." Abbott then sought approval from the United States Food and Drug Administration ("FDA") to market Survanta. On July 1, 1991, the FDA approved Survanta for the treatment of RDS in premature babies. At the same time, the FDA granted Abbott a seven-year period of market exclusivity under the Orphan Drug Act, 21 U.S.C. s.s. 360aa-360dd.

The Orphan Drug Act creates a financial incentive for the development of drugs for rare diseases or conditions. A "rare disease or condition" is one which affects less than 200,000 persons in the United States or which affects more than 200,000 persons and for which there is no reasonable expectation that the cost of developing and marketing the drug will be recovered from sales in the United States, 21 U.S.C. s. 360bb(a)(2).

The most important financial incentive under the Act is a seven-year period of market exclusivity granted to the first designated drug that is approved by the FDA for a particular disease or condition. 21 U.S.C. s. 360cc(a). The FDA enforces this market exclusivity by denying all subsequent applications for the "same drug" used for the same therapeutic purpose. 21 C.F.R. s. 316.3(b) (12).

Plaintiff ONY, Inc. ("ONY") has developed a product known by the trade name "Infasurf," which, like Survanta, is used to treat RDS in premature babies. In June 1991, ONY entered into an agreement with plaintiff Forest Laboratories, Inc. ("Forest") to develop and market Infasurf.

In June 1994, Abbott informed ONY and Forest that, in Abbott's opinion, there was reason to believe that Infasurf infringes the Tokyo Tanabe patents.

On March 13, 1995, ONY submitted a new drug application ("NDA") to the FDA for approval to market Infasurf. On May 24, 1996, the FDA notified ONY that Infasurf and Survanta are the "same drug" for purposes of the Orphan Drug Act. *See* 21 C.F.R. s. 316.3(b) (13). Accordingly, under the Act, the FDA would not approve the sale of Infasurf until July 1, 1998, the date on which Abbott's period of market exclusivity was to expire.

On March 8, 1996, ONY and Forest commenced the instant action seeking a declaratory judgment that Infasurf does not infringe the Tokyo Tanabe patents. They also seek a declaratory judgment that the Tokyo Tanabe patents are invalid or that, in the alternative, Tokyo Tanabe and Abbott should be estopped from enforcing the patents under the doctrine of equitable estoppel.

Tokyo Tanabe and Abbott counterclaimed that Infasurf infringes the Tokyo Tanabe patents. They claim that such infringement is willful. They seek a permanent injunction that would prevent plaintiffs from manufacturing and marketing Infasurf until after both patents expire.

Trial commenced on June 10, 1998. The FDA approved the sale of Infasurf on July 1, 1998.

DISCUSSION

I. *Claims at Issue*

Claim 1 of the '301 patent reads as follows:

Surface active material containing phospholipid, neutral lipid, total cholesterol, carbohydrate, protein and water, which material is obtained from lung tissue of a mammal with or without further phospholipid, characterized in that the phospholipid content is 75.0-95.5%, the neutral lipid content is 1.8-14.0%, the total cholesterol content is 0.0-3.0%, the carbohydrate content is 0.1-1.5%, the protein content is 0.5-5.0% and water content is 1.7-6 .0%, all based on the dried weight of said material, the minimum and maximum surface tension ranges of the material estimated by Wilhelmy's method wherein the material is added dropwise to the surface of physiological saline in an amount of 0.3-0.8 Sg per square centimeter of surface area thereof being 2.1-8,6 dynes/cm and 48.2-58.0 dynes/cm when surface areas are 21.0 cm^2 and 45.6 cm^2 respectively.

Claim 1 of the '839 patent reads as follows:

A surface active material comprising (1) phospholipid, neutral fat, total cholesterol, free fatty acids, carbohydrate, protein and water, all of which are obtained from the lung tissue of a mammal, and (2) optionally at least one additional component selected from the group consisting of a phosphatidylcholine, a neutral fat and a free fatty acid, characterized in that the overall phospholipid content is 68.6-90.7%, the overall neutral fat content is 0.3-13.0%, the total cholesterol content is 0.0-0.8%, the overall free fatty acid content is 1.0-27.7%, the carbohydrate content is 0.1-2.0%, the protein content is 0.0-3.5%, and the water content is 2.1-5.2%, all based on the dry weight of the material, the surface tension of the material as measured at 15 (deg.)-25 (deg.)C, by Wilhelmy's method in which the material is added dropwise to the surface of physiological saline' in an amount of 0.3-0.8 (mu)g per square centimeter of the surface area thereof being 30.1-47.5 dynes/cm when the surface area is 54.0 cm^2.

The parties disagree over the proper construction of the following elements of these claims: (1) "surface active material;" (2) "based on the dry [or dried] weight of [the] material;" (3) "obtained from lung tissue of a mammal;" and (4) the Wilhelmy surface balance element.FN2

FN2. Claim 1 of the '301 patent is the only independent claim in that patent. Likewise, Claim 1 of the '839 patent is the only independent claim in that patent.

II. *Legal Principles*

The analysis of a claim of literal patent infringement involves two steps: the proper construction of the asserted claim and a determination of whether the accused method or product infringes the asserted claim as properly construed. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first step, claim construction, is a matter of law that must be addressed by the court rather than the jury. Markman, 517 U.S. at 390.

In construing an asserted claim, the court must look first to the intrinsic evidence of the record, *i.e.,* the

patent itself, including the claims, the specification and, if in evidence, the prosecution history. *See* Markman, 52 F.3d at 979. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, lnc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

First, the Court must look at the words of the claims themselves to find the scope of the patented invention. *Id*. (citations omitted); Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619-20 (Fed.Cir.1995) ("First, and most importantly, the language of the claim defines the scope of the protected invention."). The words used in a claim are generally given their ordinary and customary meaning. Vitronics, 90 F.3d at 1582; York Prods. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). A patentee may, however, choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history. Vitronics, 90 F.3d at 1582 (citations omitted).

The court must construe the language in the patent claims in the same manner the claims would be construed by one "skilled in the art." Hoechst Celanese Corp. v. BP Chams., Ltd., 78 F.3d 1575, 1578 (Fed.Cir.), *cert. denied,* 519 U.S. 911, 117 S.Ct. 275, 136 L.Ed.2d 198 (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 prosecution history that the inventor used the term with a different meaning."); Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed.Cir.1985).FN3 A person "skilled in the art" possesses an appropriate level of knowledge and experience in the technical field in question.

FN3. The Court admits some confusion as to the procedure for resolving issues of claim construction. In *Markman,* the Supreme Court held that issues of claim construction should be decided as a matter of law by the trial court. The Federal Circuit has stated the claims should be construed in the same manner as they would be construed by one skilled in the art. However, as discussed in more detail *infra,* the Federal Circuit has also made clear that when construing a claim, the trial court should rely on extrinsic evidence, including expert testimony from those skilled in the art, in only rare cases. It would seem that such a procedure leaves the trial judge in the difficult position of having to interpret sometimes complex scientific end technological claim elements in the same manner as one skilled in the an, but without any input from such individuals.

The other claims in the patent provide an important and often decisive tool for discerning the meaning of a particular term or phrase in the asserted claim. *See* Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988) ("[T]he scope of a particular claim can often be determined on inspection of other claims."); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570 (Fed.Cir.1983) ("Significant evidence of the scope of a particular claim can be found on review of other claims."). Each claim of a patent is presumed to cover a different invention. Autogiro Co. of Am. v. United States, 181 Ct.Cl. 55, 384 F.2d 391, 404 (Ct.Cl.1967). Accordingly, courts may not construe a patent claim in a manner that renders other claims in the same patent meaningless or superfluous. *Id.;* Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054-55 (Fed.Cir.), *cert. denied,* 488 U.S. 825, 109 S.Ct. 75, 102 L.Ed.2d 51 (1988); Marion Merrell Dow, Inc. v. Baker Norton Pharmaceuticals, Inc., 948 F.Supp. 1050, 1054 (S.D.Fla.1996); R2 Medical Sys., Inc. v. Katecho, Inc., 931 F.Supp. 1397, 1434 (N.D.Ill.1996) ("[A]n interpretation of a claim should be avoided if it would make that claim read identically to another claim in the same patent."); Lucas Aerospace, Ltd. v. Unison Indus., L. P., 890 F.Supp. 329, 332 (D.Del.1995). Where claims use different language, those differences are presumed to reflect differences in the scope of the claims. Tandon Corp. v. United States

Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987). In other words, a court cannot construe claims to read an expressed limitation out of a claim, thereby making two distinct limitations synonymous. *See* Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1557 (Fed.Cir.1995) ("We must give meaning to all the words in (the] claims."); Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed.Cir.1993) ("Indeed, to construe the claims in the manner suggested by Tl would read an expressed limitation out of the claims. This, we will not do because '[c]ourts can neither broaden or narrow claims to give the patentee something different than what he has set forth.' "); Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1563 (Fed.Cir.1991) ("When the language of a claim is clear, as here, and a different interpretation would render meaningless express claim limitations, we do not resort to speculative interpretation based on claims not granted.").

After examining the claims themselves, the court must next review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. Vitronics, 90 F.3d at 1582. The specification is the section of the patent that contains a written description of the invention that enables a person "of ordinary skill in the art to make and use the invention." Markman, 52 F.3d at 979. "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 1582. "Claims must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 979. "[T]he specification is always highly relevant to the claim construction analysis" and is usually dispositive. Vitronics, 90 F.3d at 1582. "[It] is the single best guide to the meaning of a disputed term." *Id*.

It is important to keep in mind that although the specification is highly relevant to determining the definition of terms used in the claims, the claims themselves define the precise scope of the patent. Autogiro, 384 F.2d at 395 ("The claims of the patent provide the concise formal definition of the invention."). References in the specification to a particular or preferred embodiment FN4 or to an illustrative example do not limit the scope of the patent claim. Specialty Composites, 845 F.2d at 987. "The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." Markman, 52 F.3d at 980. Thus, the fact that a particular embodiment disclosed in the specification is narrower than a claim does not mean that the claim should be limited to that particular embodiment. *See* Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994) ("[C]laims are not to be interpreted by adding limitations appearing only in the specification. Thus, although the specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments."). The court must be careful not to confuse the patentee's use of the specification as a dictionary-to define particular words and phrases in the claim, which is proper-with reading limitations into the claim from the specification "wholly apart from any need to interpret what the patentee meant by particular words or phrases in the. claim." E.I, du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.), *cert. denied,* 488 U.S. 986, 109 S.Ct. 542, 102 L.Ed.2d 572 (1988). "Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims." Specialty Composites, 845 F.2d at 987 (emphasis in original).

FN4. An "embodiment" is a way to make and use the invention. McCarthy, J., *McCarthy's Desk Encyclopedia of Intellectual Property* at 28 (1991).

When construing a claim, the court may also look at the prosecution history of the patent, if in evidence. Markman, 52 F.3d at 980. The prosecution history contains the complete record of all of the proceedings

before the United States Patent and Trademark Office ("PTO"), including any express representations made by the patent applicant regarding the scope of the claims. As such, the record before the PTO is often of critical significance in determining the meaning of the claims. Vitronics, 90 F.3d at 1582. Included within an analysis of the prosecution history may be an examination of the prior art cited therein. FN5 *Id*. As with the specification, however, the prosecution history can and should be used only to understand the claim language; it cannot enlarge, diminish, or vary the limitations in the claims. Markman, 52 F.3d at 980 (internal quotations and citations omitted).

FN5. "Prior art" is the existing body of technological information against which an invention is judged to determine if it is patentable as being a novel and nonobvious invention. McCarthy, J., *McCarthy's Desk Encyclopedia of Intellectual Property* at 261 (1991).

There may be instances in which intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims, and in those instances, extrinsic evidence may also properly be relied on to understand the technology and to construe the claims. Vitronics, 90 F.3d at 1584. Extrinsic evidence is that evidence which is external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, technical treatises and articles, and prior art.FN6 *Id*. In most situations, however, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. *Id*. at 1583. The Federal Circuit has warned that situations where extrinsic evidence may properly be relied on shall be rare, and that district courts should treat opinion testimony on claim construction with the utmost caution. Vitronics, 90 F.3d at 1585. Inventor testimony is particularly disfavored because the inventor's subjective intent as to claim scope, when unexpressed in the patent documents, is irrelevant to the claim construction analysis. Id. at 1584.

FN6. Prior art documents and dictionaries are more objective and reliable than expert testimony, Vitronics, 90 F.3d at 1585.

Extrinsic evidence, if used by the court, has a limited role. "[E]xtrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language." Id. at 1584. Nor may it contradict the import of other parts of the specification. *Id*.

If, after examining the intrinsic and extrinsic evidence, the court still finds that the claim is ambiguous, then the court must adopt the narrower definition of the claim-that is, the definition that tends to show noninfringement-because the patentee is ultimately responsible for drafting the claim language. *See* Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951 (Fed.Cir.1993). In other words, any ambiguity in the claim language must be resolved against the patentee as the drafter of the patent. The court may not interpret a claim more broadly than written to cure a drafting error made by the patentee. "That would unduly interfere with the function of claims putting competitors on notice of the scope of the claimed invention." Hoganas, 9 F.3d at 948.

III. "*Surface Active Material*"

Claim 1 of both the '301 and '839 patents initially describes the invention as a "surface active material" and then goes on to state the composition of the "surface active material." Plaintiffs argue that the phrase

"surface active material," as used in the patents, means the lung surfactant extract material, which is in solid form FN7, before it is combined with a pharmaceutically acceptable carrier, such as physiological saline, to form a "pharmaceutical composition" that can be administered to premature babies. Thus, according to plaintiffs, the composition of the "surface active material" must be determined or measured for infringement purposes before it is made into a "pharmaceutical composition."

FN7. Plaintiffs store the lung surfactant extract material in liquid chloroform.

Defendants, on the other hand, argue that the phrase "surface active material" should be construed to cover any material, of whatever form, that exhibits surface tension reducing properties. Thus, according to defendants, the phrase "surface active material," as used in the patents, covers both the solid lung surfactant extract material before the physiological saline is added to form a "pharmaceutical composition" and the "pharmaceutical composition" itself, since the "pharmaceutical composition" also has surface tension reducing properties. In other words, defendants argue that the phrase "surface active material" covers both the solid precursor to Infasurf, known as CLSE, and Infasurf itself, which is in liquid form. Consequently, according to defendants' argument, plaintiffs can be found to infringe Claim 1 of the patents if *either* CLSE *or* Infasurf includes each and every element of that Claim.FN8

FN8. It is important to determine whether the composition of the "surface active material" is measured before or after the physiological saline is added because the addition of the saline solution, which is mostly water, changes the chemical composition of the lung surfactant extract material. For example, the addition of water causes a hydrolosis process that increases the amount of free fatty acids.

The Court finds that plaintiffs' proposed construction of the phrase "surface active material" is the correct one. Both the claim language and the language in the specifications show that the term "surface active material," as used in Claim 1 of the patents, means the lung surfactant extract material in dry form before it is suspended in physiological saline to form a "pharmaceutical composition" and that the chemical composition of the "surface active material" must be determined for infringement purposes before it is made into a "pharmaceutical composition."

Claim 7 of the '301 patent and Claim 9 of the '839 patent conclusively demonstrate that "surface active material" and "pharmaceutical composition," as used in the patents, are different claim terms with different meanings. Claim 7 and Claim 9 provide as follows:

Claim 7

A pharmaceutical composition useable for the treatment of hyaline-membrane disease comprising an effective amount of surface-active material as set forth in claim 1 and a pharmaceutically acceptable non-toxic carrier thereof.

Claim 9

A pharmaceutical composition useable for the treatment of respiratory distress syndrome comprising an effective amount of a surface active material as set forth in claim 1 and a pharmaceutically acceptable carrier thereof.

As defined by the patentee, the "pharmaceutical composition" inventions covered by Claims 7 and 9 are made by combining the "surface active material" set forth in Claim 1 of the patents with a pharmaceutically

acceptable carrier, such as physiological saline. Thus, according to the patent claims themselves, the "surface active material" is only a part or subset of the "pharmaceutical composition."
If, as defendants argue, the phrases "surface active material" and "pharmaceutical composition" were to be used interchangeably, then Claims 7 and 9 of the patents would teach that a "pharmaceutical composition" may be made by combining a "pharmaceutical composition," which is already comprised of the "surface active material" and physiological saline, with more physiological saline. Such a construction obviously does not make sense. The only way Claims 7 and 9 make sense as written is if "surface active material" means the lung surfactant extract material before it is suspended in physiological saline to form the "pharmaceutical composition." And, if that is what "surface active material" means for purposes of Claims 7 and 9, then it must mean the same thing for purposes of Claim 1.

Clearly, the patentees intended to give the terms "surface active material" and "pharmaceutical composition" distinct meanings. If the term "surface active material" was meant to include a "pharmaceutical composition," then there would have been no reason to include Claims 7 and 9 in the patents. As stated above, it is well established that a claim term must be interpreted so as not to make any other claim in the patent meaningless or superfluous.

Defendants' proposed construction would require the Court to ignore the distinction between the terms "surface active material" and "pharmaceutical composition" and to give these terms the same meaning. As stated above, however, the Court may not rewrite the patent. The patentees could have, had they wished, drafted Claim 1 to define "surface active material" and "pharmaceutical composition" synonymously. They chose not to do so.

Plaintiffs' proposed construction is not only supported by the claims themselves, but is confirmed by the specifications of the '301 and '839 patents. Throughout the '301 and '839 patents, when the patentees refer to the dried active ingredient before it is converted to a pharmaceutical composition, they use the term "surface active material." When they refer to a preparation including a pharmaceutical carrier, such as saline, they use the words "pharmaceutical composition." The terms "surface active material" and "pharmaceutical composition" are never used interchangeably or synonymously. For example, in the '301 patent, in characterizing the "Field and Background of the Invention," the patentee specifically distinguished between "a surface active material having a new chemical composition" and a "pharmaceutical composition ... containing the active material." Likewise, the '839 patent' s "Field and Background of the Invention" section distinguishes between "a surface active material having a new chemical composition" and a "pharmaceutical composition ... comprising the surface active material as active ingredient."

Further, under "Summary of the Invention," the '301 patent states: "According to one feature of the present invention there is provided a surface-active material." After describing the method of making that material, the Summary goes on to state: "According to a still further feature of the present invention there is provided a pharmaceutical composition ... containing the surface active material as defined above."

The '839 patent has a similar recitation under "Summary of the Invention." First, the "surface active material" is described and the method of making it is discussed. Then the Summary states that "still another feature of the present invention" is a "pharmaceutical composition" comprising surface active material as previously described in the Summary.

More evidence supporting plaintiffs' proposed construction is found in the ' 839 patent's illustrative examples and Table VII. The '839 patent repeatedly teaches that the final step in the process of making a

"surface active material" of the "invention" is to "lyophilize" or freeze dry the material. The '839 patent contains eleven examples that are directed to surface active materials and their preparation. In each example, the final product is described as a "surface active material" in a lyophilized or freeze-dried solid state and is measured in grams (a unit of measurement used to measure solids) rather than milliliters (a unit of measurement used to measure liquids). The "surface active material" produced in each example was then analyzed for its chemical composition. The results of these analyses are set forth in Table VII of the '839 patent and provide the basis for the ranges of the amounts of the ingredients of the '839 surface active material as set forth in Claim 1 of the '839 patent. Thus, the eleven illustrative examples and Table VII confirm that the "surface active material" claimed in Claim 1 of the '839 patent is a dry product and that its chemical composition is to be determined before it is combined with physiological saline to form a "pharmaceutical composition."

Further support for plaintiffs' proposed construction is the fact that, separate and distinct from the eleven examples of how to produce a "surface active material," the '839 patent provides two examples of how to produce a "pharmaceutical composition," an ingredient of which is the "surface active material." For example, the '839 patent includes an example of a "pharmaceutical composition" that is made by introducing 60 mg of the "surface active material" and 6 ml of physiological saline into an ampule and storing the ampule under sterile conditions. Claim 13 of the '839 patent is directed to that example, calling for a "pharmaceutical composition" comprised of the "surface active material" set forth in Claim 1 and a water-based carrier of physiological saline. By including these separate examples of pharmaceutical compositions, the drafters of the patent once again distinguished the terms "surface active material" and "pharmaceutical composition."

Defendants argue that the plaintiffs' proposed construction of the phrase "surface active material" is too restrictive because the patent contains no requirement that the composition of the "surface active material" be measured at any particular point in time. Therefore, according to defendants, because the patents do not set forth a specific point in time at which the chemical composition of the "surface active material" described in Claim 1 of the patents is to be measured, the chemical composition may be measured for infringement purposes either before or after the lung surfactant extract material is made into a "pharmaceutical composition." The Court finds this argument unpersuasive.

Contrary to defendants' argument, the patents do require that the chemical composition of the "surface active materia" be measured *before* the lung surfactant extract material is added to physiological saline to form a "pharmaceutical composition." This timing requirement is a function of the way the claims are written. As stated earlier, the "pharmaceutical composition" inventions covered by Claim 7 of the '301 patent and Claim 9 of the '839 patent are made by combining the "surface active material" set forth in Claim 1 of the patents with a pharmaceutically acceptable carrier, such a physiological saline. Thus, according to the patent claims themselves, the "surface active material" is a precursor ingredient of the "pharmaceutical composition." Because the "surface active material" is a precursor to the "pharmaceutical composition," it must logically be formed or exist before It is made into a "pharmaceutical composition." Therefore, the term "surface active material," as used in Claims 7 and 9, must mean the lung surfactant extract material before it is combined with physiological saline to form a "pharmaceutical composition." And, as stated before, if that is what "surface active material" means for purposes of Claims 7 and 9, then it must mean the same thing for purposes of Claim 1. Accordingly, the term "surface active material," as used in Claim 1, is limited to the lung surfactant extract material before it is combined with physiological saline.

Continuing the analysis, it follows that the chemical composition of the "surface active material" must be

measured before it is added to the water-based saline solution. Once the "surface active material" is added to the physiological saline, the resulting product is, as stated in Claims 7 and 9 of the patents, a "pharmaceutical composition." At that point, the "surface active material" described in Claim 1 of the patents in effect no longer exists. Any subsequent measurement of the chemical composition of the resulting product would only provide a measurement of the composition of the "pharmaceutical composition," not the "surface active material" as defined by the patent. FN9

FN9. As stated previously, it is undisputed that the chemical composition of the lung surfactant extract material changes when it is added to water.

Defendants further argue that plaintiffs' proposed construction must fail because there is nothing in Claim 1 or any place else in the patent "which limits the inventions to *use* in their dried weight state. Indeed, there is no effective way to administer surfactant in a dried form." *See* Defendants' Claim Construction Memorandum at 21, n. 12 (emphasis in original). Not only is this argument unpersuasive, it actually supports the construction proposed by plaintiffs. Based on the above-referenced statement in defendants' Claim Construction Memorandum and the discussions at oral argument, it appears undisputed that lung surfactant extract material in its dry, pre-suspension state is not useable to treat premature babies. It must be added to a pharmaceuticaily acceptable carrier before it can be administered. Claim 9 of the '839 patent claims a "*pharmaceutical composition* useable for the treatment of respiratory distress syndrome." FN10 (emphasis added). This "useable' language included in Claim 9, which deals with a "pharmaceutical composition," is omitted from Claim 1, thereby implying that, when referring to "surface active material" in Claim 1, the drafters of the patent were referring to lung surfactant extract material in its dry, pre-suspension state, at which point it is not useable to treat premature babies.FN11

FN10. Claim 7 of the '301 patent contains similar language.

FN11. Because the meaning of "surface active material" can be discerned from the language in the patents themselves, the Court need not consider the prosecution history or any extrinsic evidence.

In sum, for the reasons stated, the Court will adopt plaintiffs' construction of the phrase "surface active material" and will instruct the jury as follows:

The claims of both the '301 and '839 patents include the phrase "surface active material." "Surface active material" means lung surfactant extract material before it is combined with a pharmaceutical carrier such as physiological saline.

IV. "*Based on the Dry Weight*"

For the same reasons discussed with regard to the phrase "surface active material," the Court adopts plaintiffs' proposed construction of the term "based on the dry weight" and will instruct the jury as follows:

The '301 patent includes the phrase "based on the dried weight of the surface active material. The '839 patent includes the phrase "based on the dry weight" of the surface active material. These two phrases mean the same thing. They mean the dry weight of the lung surfactant extract material before it is combined with

a pharmaceutical carrier. For example, with respect to the '839 patent, the limitation requiring 1.0-27.7% free fatty acids content "based on the dry weight of the material" refers to the free fatty acids content of the surface active material before it is combined with, for example, physiological saline to make a pharmaceutical composition.

V. "*Obtained from Lung Tissue of a Mammal*"

Claim 1 of both the '301 and the '839 patents states that the surface active material is "obtained from lung tissue of a mammal." The parties appear to agree that there are two generally accepted methods for obtaining lung surfactant from the lungs of mammals. One method, which is the one used by plaintiffs, is called the lavage method, in which the surfactant is washed off the surface of lungs that have been removed intact from the mammal. The other method, which is the one used by defendants, is called the mincing method, in which the lungs are minced and then go through a process to extract the lung surfactant from the minced tissue. Plaintiffs argue that the "obtained from lung tissue" claim limitations in the '301 and '839 patents refer only to the mincing method. Defendants, on the other hand, argue that the "obtained from lung tissue" claim limitations are broad enough to include both the mincing method and the lavage method. The Court finds defendants' interpretation of the "obtained from lung tissue" language to be the correct one.

None of the claim language in either of the patents limits the method by which the lung surfactant can be derived. Nor is there any express limitation on the definition "obtained from lung tissue" included in the specification.

Defendants' interpretation is supported by the presence of Claim 13 in the ' 301 patent and Claim 16 in the '839 patent, both of which describe the mincing method for obtaining the surfactant from the lung tissue of a mammal. If the "obtained from lung tissue" language was already limited to the mincing method, then these claims would be unnecessary and superfluous. As stated above, a claim construction that would make other claims of the patent superfluous must be rejected.

Plaintiffs argue that the "obtained from the lung tissue" language should be construed as only including the mincing method because all of the examples cited in the patents teach a mincing technique for obtaining the lung surfactant. They also point out that neither patent says anything about obtaining the lung surfactant through the lavage method. This argument must be rejected, however, because, as stated above, it is well settled that particular embodiments appearing in a specification cannot be read to limit. the claims when the claim language is broader than such embodiments. Although the language in a specification may be used to interpret claim limitations, it may not create claim limitations.

Plaintiffs further argue that inclusion of the word "tissue" in the claims confirms that they are directed to the mincing process. Plaintiffs argue that the term "lung tissue" is narrower than the term "lung" itself, and that had the patentees wished to include the lavage method within the scope of the claims, the claims would not have included the word "tissue." The Court finds this argument unpersuasive. Lung surfactant is produced by cells located within the lung tissue. Thus, the use of the word "tissue" is simply a more accurate description of where the surfactant is obtained and does not connote a certain procedure for obtaining the lung surfactant.

Accordingly, for the reasons stated, the Court will adopt the defendants' interpretation of the phrase "obtained from lung tissue of a mammal" and will instruct the jury as follows:

The claims of the '301 and '839 patents include the phrase "obtained from lung tissue of a mammal." The phrase "obtained from lung tissue of a mammal" means that the components included within the surface active material are acquired from the lung tissue of a mammal. The manner in which the material is acquired from the lung tissue is not limited to any specific process. Thus, the phrase "obtained from lung tissue of a mammal" can mean either the mincing process or the lavage process.

VI. ***Wilhelmy Surface Balance Element***

The Court has reserved decision on the proper construction of the Wilhelmy surface balance element. During the trial, the parties shall present testimony regarding the operation of the Wilhelmy surface balance test and the proper method of interpreting data obtained therefrom. The Court finds that such evidence is necessary to assist it in understanding the technology involved in the measurement of the surface tension of surfactants and the interpretation of results achieved by the Wilhelmy method.

IT IS SO ORDERED.

W.D.N.Y.,1998.
Forest Laboratories, Inc. v. Abbott Laboratories

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