United States Court of Appeals for the Federal Circuit

04-1100

ASTRAZENECA AB, AKTIEBOLAGET HASSLE,
KBI-E, INC., KBI INC., and ASTRAZENECA LP,

Plaintiffs-Appellees,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Defendant-Appellant.

Lisa B. Pensabene, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for plaintiffs-appellees. With her on the brief were Michael P. McGraw and Christopher P. Borello.

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Appealed from: United States District Court for the Eastern District of Pennsylvania

Judge Michael M. Baylson

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KBI-E, INC., KBI, INC., and ASTRAZENECA LP,

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MUTUAL PHARMACEUTICAL COMPANY, INC.,

Defendant-Appellant.

DECIDED: September 30, 2004

Before MICHEL, Circuit Judge, ARCHER, Senior Circuit Judge, and BRYSON, Circuit Judge.

MICHEL, Circuit Judge.

Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc., KBI, Inc., and Astrazeneca LP (collectively, "Astrazeneca") sued Mutual Pharmaceutical Co., Inc. ("Mutual") pursuant to 35 U.S.C. § 271(e)(2), under which it is an "act of infringement" to submit an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") to obtain approval to market a drug that is claimed in a nonexpired patent. Astrazeneca alleged that Mutual infringed U.S. Patent No. 4,803,081 (the "'081 patent"), titled "New Pharmaceutical Preparations With Extended Release," by submitting an ANDA to the FDA seeking approval of extended-release felodipine tablets. After construing the asserted claims of the '081 patent, the United States District Court for the Eastern District of Pennsylvania granted Astrazeneca's motions for summary judgment

on infringement and validity. Astrazeneca AB v. Mut. Pharm. Co., Inc., 278 F. Supp. 2d 491 (E.D. Pa. 2003) (granting Astrazeneca's motion for summary judgment on Mutual's counterclaims and affirmative defenses concerning validity); 250 F. Supp. 2d 506 (E.D. Pa. 2003) (granting Astrazeneca's motion for summary judgment of infringement); 221 F. Supp. 2d 535 (E.D. Pa. 2002) (construing asserted claims). Holding that the district court erred in its claim construction by not recognizing the limiting effect of the '081 patent's specification and prosecution history, we reverse and remand for entry of judgment of noninfringement. Because we hold that the term "solubilizer" is limited to surfactants, we affirm the district court's judgment in favor of Astrazeneca on invalidity.

BACKGROUND

Astrazeneca markets extended-release felodipine tablets under the trade name PLENDIL®, for use in treating hypertension. Astrazeneca has obtained two patents related to PLENDIL®: U.S. Patent No. 4,264,611 (the "'611 patent") and the '081 patent. The '611 patent was directed to certain chemical compounds -- including felodipine -- having antihypertensive qualities. The application that matured into the '611 patent was filed on June 19, 1979; the patent issued on April 28, 1981, and is now expired. The '081 patent is directed to extended-release formulations for felodipine and other drugs having low solubility in water, with the formulations designed to increase the solubility and bioavailability of the drugs. The application that matured into the '081 patent was filed on April 3, 1987; the patent issued on February 7, 1989, and has not expired.

Mutual hopes to market generic felodipine tablets for treating hypertension. To this end, on June 6, 2000, Mutual filed an ANDA for extended-release 10 mg felodipine

tablets. Mutual subsequently amended its ANDA to add extended-release 2.5 mg and 5 mg felodipine tablets. Mutual avers that the FDA approved the ANDA in 2004.

On September 19, 2000, Astrazeneca sued Mutual for infringement of the '081 patent. On August 19, 2002, the district court issued its claim construction opinion. On March 14, 2003, the district court granted Astrazeneca's motion for summary judgment of infringement. On August 21, 2003, the district court granted Astrazeneca's motion for summary judgment on Mutual's counterclaims and affirmative defenses concerning validity, and denied Mutual's cross-motion for summary judgment on these same counterclaims and affirmative defenses. On November 14, 2003, the district court entered final judgment in favor of Astrazeneca.

Mutual timely appealed to our court, which has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). We heard oral argument on August 5, 2004.

DISCUSSION

On appeal, Mutual challenges the district court's rulings on claim construction, infringement, and validity. Mutual's challenge to the district court's rulings on validity is contingent on our affirming the district court's claim construction; Mutual concedes that if our court were to accept Mutual's position as to the proper scope of the asserted claims -- and reverse the district court's broader construction -- the claims as narrowed would not be invalid. We thus begin with claim construction.

The '081 patent has sixteen product claims and one process claim, of which Astrazeneca asserts product claims 8, 12, 14, and 15, and process claim 17. The asserted product claims are dependent directly or indirectly on claim 1:

> 1. A solid preparation providing extended release of an active compound with very low solubility in water comprising a solution or

> dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer, wherein the amount by weight of the solubilizer is at least equal to the amount by weight of the active compound, and a release controlling system to provide extended release.

'081 patent, col. 8, ll. 43-51 (emphasis added). Claim 17 is the process claim:

> 17. A process for making a solid preparation that provides extended release of an active compound with very low solubility in water comprising dissolving or dispersing an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer, the amount by weight of said solubilizer being at least equal to the amount by wight [sic] of the active compound, and incorporating the resulting solution or dispersion into a suitable release controlling system to form a pharmaceutical dosage unit.

Id. at col. 10, ll. 12-22 (emphasis added).

The claim construction dispute centers on the term "solubilizer," which is common to all asserted claims. The parties agree that as a general matter, artisans would understand the term "solubilizer" to embrace three distinct types of chemicals: (1) surface active agents (also known as "surfactants"), (2) co-solvents, and (3) complexation agents.[1] But Mutual has contended that in the context of the '081 patent's specification and prosecution history, "solubilizer" comprehends only surfactants. Because it is undisputed that Mutual's ANDA sought approval for extended-release felodipine tablets that use a co-solvent, not a surfactant, as a solubilizer, Mutual has argued that filing its ANDA was not an act of infringement under § 271(e)(2). The district court rejected Mutual's argument. Relying on the parties' agreement as to artisans' general understanding of "solubilizer," and on certain general-usage dictionary definitions of "solubilizer" and "solubility," the district court held that the "ordinary

[1] Doubtless because the parties agreed as to artisans' general understanding of "solubilizer," the parties decided not to introduce expert testimony as to the meaning of this claim term at the Markman hearing at the district court.

meaning" of "solubilizer" embraced the three types of chemicals noted above. See Astrazeneca, 221 F. Supp. 2d at 543-44. The district court held that the evidence intrinsic to the patent did not curtail this ordinary meaning. See id. at 543-48. The district court's lengthy and careful opinions relied extensively on our recent case law, which is unfortunately complex and inconsistent.

I. Applicable Law

We review the district court's claim construction de novo. E.g., Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). It is axiomatic that the claims mark the outer boundaries of the patent right to exclude. The critical challenge is to determine the meaning of the claims, i.e., their scope.

A long line of cases indicates that evidence intrinsic to the patent -- particularly the patent's specification, including the inventors' statutorily-required written description of the invention -- is the primary source for determining claim meaning. We have embraced that proposition frequently. See, e.g., Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Indeed, that proposition has been accepted doctrine in patent law for many years. See, e.g., Autogiro Co. of Am. v. United States, 384 F.2d 391, 397-98 (Ct. Cl. 1967) ("The use of the specification as a concordance for the claim is accepted by almost every court, and is a basic concept of patent law. Most courts have simply stated that the specification is to be used to explain the claims; others have stated the proposition in different terms, but with the same effect."); Musher Found., Inc. v. Alba Trading Co., 150 F.2d 885, 888 (2d Cir. 1945) (Hand, J.) ("As in the case of any other claim, a product claim may, and indeed

must, be read upon the specifications: its terms are no more than a shorthand from the fuller explanation which the specifications should contain."). On this view, the patent is an integrated document, with the claims "pointing out and distinctly claiming," 35 U.S.C. § 112, the invention described in the rest of the specification[2] and the goal of claim construction is to determine what an ordinary artisan would deem the invention claimed by the patent, taking the claims together with the rest of the specification. See, e.g., United States v. Adams, 383 U.S. 39, 49 (1966) ("[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."). Under this approach to claim construction, evidence extrinsic to the patent is useful insofar as it "can shed useful light on the relevant art -- and thus better allow a court to place itself in the shoes of a person of ordinary skill in the art" reading the claims alongside the rest of the specification. Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004).

Language in some of our recent cases suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined. See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002) ("[T]he presumption in favor of a dictionary definition [of a claim term] will be overcome where the patentee,

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[2] I.e., the invention vel non taught by the specification, as distinct from particular, idiosyncratic embodiments disclosed in the specification. See, e.g., Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("[T]his court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation to be a part of every embodiment." (citations omitted)).

acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.") (citations omitted). The language in these cases emphasizes the use of technical and general-usage dictionaries in determining the ordinary meaning. Id. Under this approach, where the ordinary meaning of a claim is evident, the inventor's written description of the invention, for example, is relevant only insofar as it provides clear lexicography or disavowal of the ordinary meaning. See, e.g., id.

Against this backdrop, the question becomes whether the intrinsic evidence takes priority in our construction of the claim term "solubilizer," or if instead the ordinary meaning of the term, as determined from sources such as treatises and dictionaries, controls our construction in the absence of intrinsic evidence of clear lexicography or disavowal. Given that the parties agree that the extrinsic meaning of solubilizer is broad, Astrazeneca unsurprisingly urges the latter approach to claim construction.

We need not decide which approach is proper as a matter of law,[3] as even under Astrazeneca's preferred methodology, the district court's claim construction must be reversed. The intrinsic evidence, we hold, clearly binds Astrazeneca to a narrower definition of "solubilizer" than the extrinsic evidence would support.

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[3] Resolution of this question may be approaching. See Phillips v. AWH Corp., __ F.3d __, Nos. 03-1269, 03-1286, 2004 WL 1627271 (Fed. Cir. July 21, 2004) (granting petition for en banc rehearing, to address broadly the law of claim construction).

II. Specification of the '081 Patent

The specification of the '081 patent begins by stating that

> [t]he present invention is related to pharmaceutical extended release preparations of active compounds with very low solubility, especially substituted dihydropyridines, and to methods of preparing such preparations.
>
> The object of this invention is to obtain a solid preparation with high extent of bioavailability and extended release of an active compound which normally has very low solubility.

'081 patent, col. 1, ll. 6-15. The specification continues with a "Background of the Invention" section, which states that

> [p]harmaceuticals with very poor water solubility present formulation problems due to their slow rate of dissolution. Their efficacy can by [sic] severely limited and large interindividual variations of absorption can occur. Examples of drugs with very low solubility are some substituted dihydropyridine compounds such as nifedipine and felodipine. The mentioned dihydropyridines are commonly classified as calcium antagonists, which are widely used for the treatment of cardiovascular disorders such as ischaemic heart disease and arterial hypertension. One of the mentioned dihydropyridines, namely felodipine, has a solubility of only .5 mg/l in water. . . .
>
> Several ways to increase drug absorption have been described in the prior literature. . . . Of particular relevance to the present invention is that surfactant solubilizing agents may be employed in order to increase the bioavailability of the drugs with very low solubility.

Id. at col. 1, ll. 18-30, 33-34, 46-49 (emphasis added). The specification proceeds with a "Description of the Invention," which states that

> [i]t is the object of the present invention to provide a preparation of a drug with very low solubility that shows prolonged and nearly constant rate of drug absorption for a long period of time and concurrently maintains a high extent of bioavailability. The object is reached by using a solubilizer which is mixed with the drug with very low solubility. The solubilizers suitable according to the invention are defined below. The active compound is preferably dissolved or dispersed in the solubilizer. The mixture of active compound (drug) and solubilizer can be diluted with water or intestinal juice without significant precipitation of the dissolved drug. In the solution the drug is included in a micelle-structure formed by the solubilizer. With other commonly used solubilizers or co-solvents

dilution may cause precipitation of the drug. The mixture of the drug and the solubilizer is incorporated into a pharmaceutical formulation, which gives prolonged release.

Drugs suitable for the extended release preparation according to the inventions are compounds characterized by their very low solubility, that is less than 0.1 per cent by weight in water. . . .

The solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents, especially such containing polyethyleneglycols as esters or ethers. They are preferably chosen from polyethoxylated fatty acids, hydroxylated fatty acids and fatty alcohols. It is especially preferred to choose the solubilizer from the group polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil. Commercially available solubilizers, which can be used are known under the trade names Cremophor, Myrj, Polyoxyl 40 stearate, Emerest 2675, Lipal 395 and HCO 50. A specially preferred solubilizer is Cremophor®RH 40 (BASF).

The active compound mixed with the solubilizer is incorporated into different kinds of known controlled release systems, e.g. a hydrophilic gel system, beads coated with a rate controlling membrane, which can be a diffusion retarding coating or a disintegrating coating or tablets with an inert porous matrix. According to the invention the solubilized drug is preferably combined with a hydrophilic gel system, namely a hydrophilic swelling matrix e.g. HPMC. This form of controlled release mechanism is a suitable way to control the release of the micelles of drug and solubilizer.

Id. at col. 2, ll. 67-68, col. 3, ll. 1-20, 33-58 (emphases added). The specification then provides five detailed working examples of drug formulations embraced by the invention.

Mutual contends that the specification limits the scope of the claim term "solubilizer" to surfactants, and we agree. First, we hold that the inventors deliberately acted as their own lexicographers. The "Description of the Invention" states that "[t]he solubilizers suitable according to the invention are defined below" (emphasis added), and two paragraphs later, states that "[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents" (emphasis added). Astrazeneca maintains that these statements simply refer to

preferred embodiments of "suitable" solubilizers. We might agree if the specification stated, for example, "a solubilizer suitable for the preparations according to the invention," but in fact, the specification definitively states "the solubilizers suitable for the preparations according to the invention" (emphasis added). Astrazeneca seems to suggest that lexicography requires a statement in the form "I define ____ to mean ____," but such rigid formalism is not required. See, e.g., Bell Atl. Network Servs., Inc., 262 F.3d at 1268 ("[A] claim term may be clearly redefined without an explicit statement of redefinition. . . . [T]he specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" (citation omitted)). Certainly the '081 specification's statement that "[t]he solubilizers suitable according to the invention are defined below" provides a strong signal of lexicography.

Second, we hold the specification clearly disavows nonsurfactant solubilizers. The inventors' lexicography alone works an implicit disavowal of nonsurfactant solubilizers, but the rest of the specification goes further. The "Description of the Invention" twice describes micelle structures as a feature of the novel formulation structure conceived by the inventors. See '081 patent, col. 3, ll. 11-12 ("In the solution the drug is included in a micelle-structure formed by the solubilizer."); id. at col. 3, ll. 56-58 ("This form of controlled release mechanism is a suitable way to control the release of the micelles of drug and solubilizer."). It is undisputed that surfactants are the only solubilizers believed to form micelle structures in watery environments. Indeed, immediately after the reference to the "micelle-structure formed by the solubilizer" of the invention, the specification criticizes other types of solubilizers -- and specifically co-

solvents -- as leading to undesirable precipitation. See id. at col. 3, ll. 12-14 ("With other commonly used solubilizers or co-solvents dilution may cause precipitation of the drug.").

Again, Astrazeneca contends that these statements in the specification simply address the features of preferred embodiments. Astrazeneca seems to suggest that clear disavowal requires an "expression of manifest exclusion or restriction" in the form of "my invention does not include ____." But again, such rigid formalism is not required: Where the general summary or description of the invention describes a feature of the invention (here, micelles formed by the solubilizer) and criticizes other products (here, other solubilizers, including co-solvents) that lack that same feature, this operates as a clear disavowal of these other products (and processes using these products). See, e.g., SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-45 (Fed. Cir. 2001) (construing claims to be limited to catheters with coaxial lumens where written description emphasized coaxial lumens as a feature of the invention and criticized catheters using other types of lumens). Indeed, Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313 (Fed. Cir. 2002), the first case to use the formulation "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope," cited as authority our decision in SciMed,[4] where we held the claims-in-suit were limited by written-description statements -- none of which was in the form "my invention does not include _____." See SciMed, 242 F.3d at 1342-44 (discussing the content of the written description at issue).

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[4] Teleflex stated: "The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, 299 F.3d at 1325 (citing SciMed, 242 F.3d at 1344).

Third, while it is of course improper to limit the claims to the particular preferred embodiments described in the specification, the patentee's choice of preferred embodiments can shed light on the intended scope of the claims. After defining the term "solubilizer," the "Description of the Invention" section goes on to list a number of solubilizers that are preferred or even "especially preferred":

> The solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents, especially such containing polyethyleneglycols as esters or ethers. They are preferably chosen from polyethoxylated fatty acids, hydroxylated fatty acids and fatty alcohols. It is especially preferred to choose the solubilizer from the group polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil. Commercially available solubilizers, which can be used are known under the trade names Cremophor, Myrj, Polyoxyl 40 stearate, Emerest 2675, Lipal 395 and HCO 50. A specially preferred solubilizer is Cremophor®RH 40 (BASF).

'081 patent, col. 3, ll. 33-47. At oral argument, Astrazeneca conceded that every one of these preferred solubilizers is a surfactant. Similarly, it is uncontested that in each of the five detailed working examples that follow the "Description of the Invention," the listed solubilizer is a nonionic surfactant identified by its commercial trade name (either "Cremophor" or "Myrj"). The fact that all of the solubilizers listed in the specification and used in the working examples were surfactants adds further support to the conclusion that the term "solubilizer" in the claims should be limited, according to the definition employed in the specification, to surfactants.

In sum, we hold that the specification of the '081 patent overcomes any "ordinary meaning" of "solubilizer" derived from extrinsic evidence, limiting the claim term to surfactants.

III. Prosecution History of the '081 Patent

Although the specification, by itself, compels the above claim construction, we briefly discuss additional confirmation for this construction: the patent applicants' remarks during the prosecution history of the '081 patent. On December 11, 1987, the examiner rejected the pending claims as anticipated by or obvious in light of several prior-art references. In response, the applicants submitted remarks that included the following:

> The second reference cited by the Examiner is U.S. Patent No. 4,673,564 to Kawata et al. ("Kawata"). Kawata discloses preparations in which an *amorphous* medical material such as *amorphous* nifedipine is combined with a "basic substance" and a solvent, mixed and then dried to form an amorphous powder which is then mixed with polyethylene oxide. Only one component of these formulations could be a "nonionic solubilizer" in the context of the present invention, however, in view of the definition on Page 4, line 33 – Page 5, line 6 of the specification, i.e., Kawata's *optional* 2nd component of the basic substance.

(Underlined emphasis added, italicized emphases in original.) This passage is notable for two reasons. First, the reference to the "definition" in the specification includes a citation to the sentence in the specification stating that "[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents." The applicants' characterization of this sentence in the specification as a "definition" confirms that the applicants acted as their own lexicographers to redefine "solubilizer" differently from its ordinary meaning. Second, the applicants highlighted the second component of the composition taught by the Kawata patent as the only component that "could be a 'nonionic solubilizer' in the context of the present invention." In its brief to our court, Astrazeneca concedes that "Kawata emphasizes surfactants for the second component." See also U.S. Patent No. 4,673,564, col. 2, ll. 56-61 ("As the

surface active agent of 2nd substance, there are anionic surface active agents such as sodium alkylsulfate, nonionic surface active agents such as polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil derivative, etc.") (emphasis added).

Finally, we note that near the end of the above-excerpted remarks to the examiner, the applicants stated: "Thus, none of the references disclose materials in which solutions or dispersions of the active material in a nonionic surfactant are formed into a solid preparation with extended release." (Emphasis added.) This general description of the applicants' invention substitutes the term "surfactant" for the term "solubilizer," further evidence that, in the context of the application, "solubilizer" embraced only surfactants.

IV. Conclusion as to Infringement and Invalidity

For the foregoing reasons, we conclude that the district court erred in its claim construction, and that properly construed, the claim term "solubilizer" must be limited to surfactants. Because all asserted claims include the term "solubilizer," and because Mutual's extended-release felodipine tablets use a co-solvent, not a surfactant, as a solubilizer, Mutual's tablets could not literally infringe the '081 patent.

Astrazeneca contends that even under this construction, the case should be remanded for further proceedings to address the doctrine of equivalents. We disagree. The specification's clear disavowal of nonsurfactant solubilizers precludes the application of the doctrine of equivalents to recapture the disavowed solubilizers. See, e.g., Gaus v. Conair Corp., 363 F.3d 1284, 1291 (Fed. Cir. 2004) ("Having disavowed coverage of [particular] devices . . . the patentee cannot reclaim that surrendered claim coverage by invoking the doctrine of equivalents."); SciMed, 242 F.3d at 1345 ("A

particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied.").

Thus, we must reverse the judgment of infringement and remand for entry of judgment of noninfringement. Mutual concedes that the '081 patent is not invalid if the term "solubilizer" is construed to include only surfactants. Because we hold that the term "solubilizer" is limited to surfactants, we affirm the district court's judgment in favor of Astrazeneca on invalidity.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED

COSTS

Costs to appellant.