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

ASTRAZENECA PHARMACEUTICALS, LP and Astrazeneca Pharmaceuticals, UK, Ltd,
Plaintiffs.
v.
MAYNE PHARMA (USA) INC,
Defendant.

Nos. 02 Civ.7936(WHP), 03 Civ.6487(WHP)

Dec. 28, 2004.

Background: Patentees sued alleged infringer, contending that filing of abbreviated new drug application (ANDA) with Food and Drug Administration (FDA) infringed patents related to pharmaceutical composition of propofol and edetate.

Holdings: After conducting *Markman* hearing, the District Court, Pauley, J., held that:
(1) patent provided unambiguous definition for term "edetate," and therefore court did not have to adopt purported ordinary and customary meaning of "salts of EDTA" proffered by alleged infringer;
(2) patentees' listing only of salts as examples of ethylenediamine tetraacetic acid (EDTA) derivatives did not require court to limit its construction of word "derivatives" to mean salts;
(3) as used in patent, "edetate" included EDTA as well as synthetic derivatives and structural analogs of EDTA, so long as they prevented significant growth of microorganisms for 24 or more hours;
(4) claim term "propofol" had to be given its ordinary and customary meaning of "2,6-diisopropylphenol"; and
(5) claim term "an amount of edetate" meant "an amount of edetate, greater than 0% but less than or equal to 0.1% by weight of the pharmaceutical composition, which is sufficient to meet the microbiological test recited in the claim phrase."

Ordered accordingly.

5,714,520, 5,731,355, 5,731,356. Construed.

Herbert F. Schwartz, Denise L. Loring, Gerald J. Flattmann, Fish & Neave, New York, New York, for Plaintiffs.

Jules E. Goldberg, Lawrence J. Reina, Tracy Z. Frisch, Charles H. Dougherty, Reed Smith LLP, New York, New York, for Defendant.

MEMORANDUM AND ORDER

PAULEY**, District Judge.**

AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. (collectively, "Plaintiffs" or "AstraZeneca") allege patent infringement by Mayne Pharma (USA) Inc. ("Defendant" or "Mayne"), formerly known as Faulding Pharmaceutical Company. In particular, AstraZeneca accuses Mayne of infringing U.S. Patent Nos. 5,714,520 (the " '520 patent"), 5,731,355 and 5,731,356 (collectively, the "asserted patents") by filing the Abbreviated New Drug Application ("ANDA") No. 76-452 with the Food and Drug Administration ("FDA").

This Court conducted a Markman hearing to construe three disputed claim terms in the asserted patents: (1) "edetate;" (2) "propofol;" and (3) "an amount of edetate sufficient...." After consideration of the parties' claim construction briefs and their presentations at the Markman hearing, this Court construes the disputed claim elements as set forth below.

BACKGROUND

AstraZeneca is the holder of the approved New Drug Application ("NDA") No. 19-627 for the manufacture and sale of propofol injectable emulsion. It owns the asserted patents. (Complaint, 03 Civ. 6487, dated Aug. 26, 2003 ("Compl.") para.para. 6, 8.) Those patents have a common specification and relate to a pharmaceutical composition of propofol and edetate.

AstraZeneca alleges that the filing FN1 of the "ANDA 76-452 was an act of infringementof one or more claims of the [asserted] patents, under the United States Patent Law, 35 U.S.C. s. 271(e)(2)(A)." FN2 (Compl. para. 10.) Mayne acquired ANDA No. 76-452 from Baxter Healthcare Corporation, and is now the applicant of record. (Compl. para. 13.) AstraZeneca filed its original lawsuit on October 4, 2002. (Compl. para. 12.)

FN1. ANDA 76-452 was filed by ESI Lederle, a division of Baxter Healthcare Corporation. (Compl. para. 9.)

FN2. 35 U.S.C. s. 271(e)(2)(A) provides:
It shall be an act of infringement to submit-(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.

During the pendency of the initial ANDA lawsuit, Mayne amended ANDA No. 76-452. (Compl. para. 14.) The amended ANDA sought approval "to engage in the commercial manufacture, use or sale of propofol injectable emulsion, 10 mg/mL, in a modified 20 mL vial, as well as in 50 mL and 100 mL vials before the expiration dates of the [asserted] patents." (Compl. para. 15.) AstraZeneca alleges that the "submission of [the] amendment to ANDA 76-452 was an act of infringement of one or more claims of the [asserted] patents, under the United States Patent Law, 35 U.S.C. s. 271(e)(2)(A)." (Compl. para. 23.)

The asserted patents include claims that recite the three disputed elements: (1) "edetate;" (2) "propofol;" and (3) "an amount of edetate sufficient...." However, for the purpose of this claim construction, both parties rely on the specification and, more particularly, claim 1 of the '520 patent. (Plaintiffs' Revised Claim Construction Brief, dated Aug. 25, 2004 ("Pl.Mem.") at 5, 11; Defendant's Claim Construction Brief, dated Aug. 17, 2004 ("Def.Mem.") at 2.) Accordingly, where necessary, this Court will cite only to the '520 patent.

DISSCUSSION

I. ***Canons of Claim Construction***

[1] [2] [3] "It is the *claims* that measure the invention." SRI Intern. v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed.Cir.1985) (en banc) (emphasis in original). Claim construction "is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them." Markman v. Westview Instruments, Inc., 517 U.S. 370, 384, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451 (Fed.Cir.1998) (en banc). Claim construction requires a district court to determine "what the words in the claim mean." Markman, 517 U.S. at 374, 116 S.Ct. 1384. However, a court must construe "only those [claim] terms ... that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. Am. Science & Eng'g, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

[4] [5] [6] To determine the proper meaning of claim elements, a court must first consider the intrinsic evidence, *i.e.,* "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). With this understanding, "the patent is [regarded as] an integrated document, with the claims 'pointing out and distinctly claiming,' 35 U.S.C. s. 112, the invention described in the rest of the specification." Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1337 (Fed.Cir.2004). Courts look to the intrinsic evidence because it comprises the public record, and public policy mandates that competitors be able to ascertain the metes and bounds of patent claims by reviewing the public record. *See* Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed.Cir.2002); Vitronics, 90 F.3d at 1583.

[7] [8] "Even within the intrinsic evidence, however, there is a hierarchy of analytical tools." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed.Cir.1998). A court's "analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. s. 112); *accord* Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1220 (Fed.Cir.2003); Digital Biometrics, 149 F.3d at 1344. Next, "[t]he written description is considered, in particular to determine if the patentee acted as his own lexicographer, as our law permits, and ascribed a certain meaning to those claim terms." Digital Biometrics, 149 F.3d at 1344. Finally, courts may consider a patent's prosecution history when reviewing the intrinsic evidence. *See* Vitronics, 90 F.3d at 1582.

[9] [10] [11] When examining a claim, "a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999); *accord* Brookhill-Wilk, 326 F.3d at 1220; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002). Dictionaries hold a "special place" in this type of analysis, and are considered along with intrinsic evidence. Texas Digital, 308 F.3d at 1202 ("categorizing [dictionaries] as 'extrinsic evidence' or even a 'special form of extrinsic evidence' is misplaced"); *accord* Teleflex, 299 F.3d at 1325; CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). Indeed, Federal Circuit cases "emphasize [ ] the use of technical and general-usage dictionaries in determining the ordinary meaning." Astrazeneca AB, 384 F.3d at 1337. "Under this approach, where the ordinary meaning of a claim is evident, the inventor's written description of the invention ... is relevant only insofar as it provides clear lexicography or disavowal of the ordinary meaning." Astrazeneca AB, 384 F.3d at 1337.

[12] [13] An exception to this "plain meaning" approach arises when the patentee assigns a novel or special meaning to a term. *See, e.g.,* Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed.Cir.2001). While "a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings," the patentee must clearly state the special definition of the term in the patent specification or prosecution history. Vitronics, 90 F.3d at 1582; *accord*

Texas Digital, 308 F.3d at 1204; Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996).

[14] [15] Because the specification is an important part of the intrinsic evidence, claims are construed in light of the specification of which they are a part. *See, e.g.,* ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed.Cir.1998). However, particular embodiments or examples appearing in the specification may not be read to limit the claim. *See* Johnson Worldwide, 175 F.3d at 992 ("[M]ere inferences drawn from the description of an embodiment of the invention cannot limit claim terms."); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1572 (Fed.Cir.1988) ("[P]articular embodiments and examples appearing in the specification will not generally be read into the claims."); *accord* Texas Digital, 308 F.3d at 1204; Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1338-39 (Fed.Cir.2001); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed.Cir.1995); Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988).

[16] Further, functional limitations expressed in the specification but not in the claim may not be read into the claim. *See* Interactive Gift Express, 256 F.3d at 1331 ("[C]are must be taken to avoid reading 'limitations appearing in the specification ... into [the] claims.' " (quoting Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989))); Transmatic, 53 F.3d at 1278 ("[T]he district court erred by importing unnecessary functional limitations into the claim."); Ecolab, 264 F.3d at 1367 ("Where the function is not recited in the claim itself by the patentee, we do not import such a limitation."); Sjolund v. Musland, 847 F.2d 1573, 1581 (Fed.Cir.1988) ("[W]hile it is true that claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.").

[17] Finally, as noted above, a patent's prosecution history may be examined when reviewing the intrinsic evidence. *See* Vitronics, 90 F.3d at 1582. "The prosecution history is relevant because it may contain contemporaneous exchanges between the patent applicant and the [patent office] about what the claims mean." Digital Biometrics, 149 F.3d at 1344.

[18] [19] When "intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims," a court may rely on extrinsic evidence. Vitronics, 90 F.3d at 1584; *see also* Interactive Gift Express, 256 F.3d at 1332 ("Relying on extrinsic evidence to construe a claim is 'proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence.' " (quoting Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed.Cir.1997))). Indeed, extrinsic evidence is helpful to the extent "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." Astrazeneca AB, 384 F.3d at 1337 (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed.Cir.2004)).

II. *The* '520 Patent

The '520 patent discloses a number of formulaic variations of the pharmaceutical composition that is the subject of the claimed invention. In particular, the '520 patent is directed to sterile pharmaceutical compositions containing propofol for use as anesthetics. These compositions comprise an oil-in-water emulsion of propofol which further contains an amount of edetate that is sufficient to retard the growth of microorganisms for over twenty-four hours if the composition is contaminated. (Col. 4, lines 38-45.) FN3 The oil-in-water emulsion is a distinct two-phase system in equilibrium that is kinetically stable, but thermodynamically unstable. (Col. 4, lines 46-50.)

FN3. Citations to "Col. [ ], line [ ]" refer to the column and line markers, respectively, in the '520 patent.

By way of background, propofol is an injectable anesthetic that has hypnotic properties and can be used as a general anesthetic for sedation. Propofol is marketed under the trademark "Diprivan" for use in treating humans and under the trademark "Rapinovet" for veterinary use. (Col. 1, lines 7-13.) However, microbial contamination of propofol compositions can cause nosocomial infection among intensive care unit (ICU) patients. As a result, a "giving set" FN4 used to administer propofol compositions must be changed every six to twelve hours. (Col. 2, line 62-Col. 3, line 3.) However, changing the giving set often is cumbersome and costly. (Col. 3, lines 4-19.) The inventors claim that their experiments have revealed that adding edetate to the composition obviates the need to replace the giving set at such short intervals. (Col. 4, lines 30-33.)

FN4. In layman terms, a "giving set" is the tube that connects an intravenous needle to the bag containing the pharmaceutical composition that is to be administered to the patient. (Col. 2, lines 58-61.)

Claim 1 of the '520 patent is as follows:

A sterile pharmaceutical composition for parenteral administration which comprises an oil-in-water emulsion in which propofol dissolved in a water-immiscible solvent, is emulsified with water and stabilized by means of a surfactant, and which further comprises an amount of edetate sufficient to prevent a no more than 10-fold increase in growth of each of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 and *Candida albicans* ATCC 10231 for at least 24 hours as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said composition at approximately 50 colony forming units per ml, at a temperature in the range 20-25 C., whereafter said aliquots are incubated at 20-25 C. and are tested for viable counts of said organism after 24 hours, said amount of edetate being no more than 0.1% by weight of said composition.

(Col. 11, lines 33-48.)

III. ***Disputed Terms***

As noted, there are three claim construction disputes: (1) the meaning of "edetate"; (2) the amount of "propofol" required; and (3) the minimum amount of edetate required. (Transcript of Claim Construction Hearing, dated Sept. 15, 2004 ("Tr.") at 8, 35.)

A. Edetate

The first disputed term of the '520 patent is "edetate." Claim 1 recites a pharmaceutical composition that comprises an oil-in-water emulsion having propofol solvent, which further comprises edetate. Plaintiffs suggest that the edetate ought to be defined as ethylenediamine tetraacetic acid ("EDTA") and "derivatives that are structurally related to EDTA regardless of how they are synthesized." (Pl. Mem. at 25; *see also* Tr. at 8; Declaration of Jules E. Goldberg, dated Aug. 17, 2004 ("Goldberg Decl.") Ex. P: Joint Claim Construction Statement.) Defendant urges this Court to adopt one of three definitions it proposes: (i) the salts of EDTA; (ii) EDTA and salts thereof; or (iii) EDTA and compounds synthesized from EDTA. (Def. Mem. at 2.)

[20] "The first step in claim construction is to determine the ordinary and customary meaning, if any, that would be attributed to the term by those skilled in the art." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1346 (Fed.Cir.2003); Astrazeneca AB, 384 F.3d at 1337 ("[T]he 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."). AstraZeneca contends that "[o]ne of ordinary skill in the art here would have a Ph.D. in pharmaceutics or pharmaceutical microbiology, or a B.S.

or M.S. with three to five years of experience and training in one or more of the following disciplines: pharmaceutics, industrial parenteral formulation, or pharmaceutical microbiology,or an M.D. with two or three years clinical experience administering parenteral products." (Pl. Mem. at 12-13; Declaration of Michele M. Winneker, dated Aug. 25, 2004 ("Michelle Decl.") Ex. 26: Expert Report of James Boylan, dated May 12, 2004, para.para. 43-44.) While Mayne disputes what one of one of ordinary skill in the art would know, it does not dispute AstraZeneca's characterization of the qualifications and experience such a person would have. (Defendant's Reply Memorandum, dated Aug. 31, 2004 ("Def. Reply Mem.") at 1-2; Goldberg Decl. Ex. K: Rebuttal Expert Report of Jeffrey Winkler, dated June 14, 2204.) Accordingly, this Court adopts AstraZeneca's description of one of ordinary skill in the art.

[21] When construing a claim, a court starts by looking at the "words of the claims themselves, both asserted and nonasserted." Vitronics, 90 F.3d at 1582. "Although words in a claim are generally given their ordinary and customary meaning, a patentee may 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. The parties do not dispute that the patentees manifested their intent to act as their own lexicographers in defining edetate. (Def. Mem. at 8.) Indeed, the '520 patent includes the patentees' express desire to impart a specific definition to edetate: "By the term 'edetate' we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof." (Col. 4, lines 51-52.) *See* Astrazeneca AB, 384 F.3d at 1339 (finding that inventors "deliberately acted as their own lexicographers" where they provided express definitions to the relevant claim elements); Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed.Cir.2001) (a patentee's redefinition away from the ordinary meaning of claim terms may occur expressly, when a patentee has "chosen to be his or her own lexicographer").

1. ***Defendant's First Proposed Definition***

[22] Defendant argues that even though patentees attempted to be their own lexicographers, they failed in their attempt, and therefore this Court must give edetate its "ordinary and customary meaning." (Def. Mem. at 9.) In particular, Mayne argues that the patentees failed in their attempts to define edetate clearly and that their attempted definition is ambiguous. (Mem.Def.8-9.) This Court disagrees.

[23] [24] [25] [26] "It is black letter law that a patentee can 'choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning.' " Jack Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1360 (Fed.Cir.2002) (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed.Cir.2001)); *accord* Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed.Cir.1999). "[A] definition of a claim term in the specification will prevail over a term's ordinary meaning if the patentee has acted as his own lexicographer and clearly set forth a different definition." 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371 (Fed.Cir.2003). This is because "[t]he 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. Further, the patentee may define a claim element more broadly than its ordinary meaning. *See* Jack Guttman, 302 F.3d at 1360.

Here, the patentees explicitly defined "edetate":

By the term "edetate" we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof, for example the disodium derivative is known as disodium edetate.

(Col. 4, lines 51-53.) Mayne, however, argues that the patentees' use of "EDTA and derivatives thereof" is ambiguous and unclear. Therefore, Mayne's continues that the Court must give edetate its ordinary and customary meaning, which it posits is "salts of EDTA." (Def. Mem. at 10-11.) Mayne excludes EDTA itself

from this first proposed definition.FN5

FN5. Mayne's first proposed definition for edetate excludes EDTA, but its second proposed definition includes EDTA. (Def. Mem. at 2, 9, 11.)

In ordinary English usage, "EDTA and derivatives thereof" means "EDTA and derivatives of EDTA." *See Webster's Third New International Dictionary* 2372 (1993) (definition of "thereof"). Indeed, the patentees expressly listed EDTA as an edetate and provide examples of EDTA derivatives that fit their definition, which conclusively establishes that the patentees intended to define edetate as "EDTA and derivatives of EDTA." (Col. 4, lines 52-57.) Further, when advancing its second proposed meaning for edetate, Defendant admits:

The passage from Column 4 of the '520 patent provides a clear and unambiguous interpretation of "edetate." In construing claim terminology, the court should look first to the intrinsic evidence and employ extrinsic evidence only when ambiguity arises. Based upon this reading of the Patents in Suit, no extrinsic evidence, *i.e*. dictionaries or expert evidence, is required to interpret the term "edetate."

(Def. Mem. at 13.) In light of Mayne's admission, its contention that patentees failed in their efforts to be their own lexicographers is absurd. Thus, this Court finds that the '520 patent clearly defines edetate and rejects Mayne's proposed definition of the term as "salts of EDTA."

2. *Defendant's Second Proposed Definition*

[27] Next, Mayne argues that if this Court were to consider the intrinsic evidence, edetate must be defined as "EDTA and salts thereof." (Def. Mem. at 11-14.) This Court disagrees.

Mayne acknowledges that the specification defines edetate as EDTA and derivatives of EDTA. (Col. 4, lines 51-52; Def. Mem. at 12.) However, it argues that because the patentees only listed salts of EDTA as examples of EDTA derivatives, this Court must limit its construction of the word "derivatives" to mean salts. (Def. Mem. as 11-12.) The '520 patent teaches, for example, that "the disodium derivative is known as disodium edetate." (Col. 4, lines 52-53.) The '520 patent further explains that "[i]n general suitable edetates of this invention are those salts having lower affinity for EDTA than calcium." (Col. 4, lines 53-55.) Finally, it states that "[p]articular derivatives of use in the present invention include trisodium edetate, tetrasodium edetate and disodium calcium edetate." (Col. 4, lines 55-57.) Because all these enumerated examples are salts of EDTA, Defendant argues that the word "derivatives" must be construed to mean salts. (Def. Mem. at 12.)

It is well established that examples enumerated in a specification may not be used to limit a claim term. Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1151 (Fed.Cir.2003) ("The general rule ... is that claims of a patent are not limited to the preferred embodiment, unless by their own language."); Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1328 (Fed.Cir.2002) (noting that the claimed invention may not be limited to preferred embodiments or specific examples in the specification); Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed.Cir.1998) (noting that limitations from the specification are not to be read into the claims). The portions of the '520 patents that Defendant points to for support of its proposed definition include phrases such as "for example," "in general" and "particular derivatives of use." These phrases make it clear that patentees were merely providing illustrations. No portion of the specification expressly limits the definition of derivatives to the enumerated examples or disclaims EDTA derivatives not specified. Further, the '520 patent explains that "[t]he nature of the edetate is not critical, provided that it fulfils the function of preventing significant growth of microorganisms for at least 24 hours in the event of adventitious extrinsic contamination." (Col. 4, lines 57-61.) Therefore, this

Court disagrees with Defendant that the cited examples in the specification restrict the definition of edetate to EDTA and salts of EDTA.

[28] Mayne argues that the prosecution history of the '520 patent also supports its contention that "edetate" must be defined as EDTA and salts of EDTA. (Def.Mem.13-14.) They cite to the October 15, 1996 Office Action and the patentees' June 18, 1997 Amendment and Response ("Response"). (Def. Mem. at 13-14; Goldberg Decl. Ex. H.) However, a review of the patentees' Response clearly shows that the patentees and the Patent Office were not defining "edetate," but instead were discussing the proper amount of edetate in the claimed pharmaceutical composition and the microbiological tests. Thus, the prosecution history does not restrict the definition of "derivatives" to salts.

3. *Defendant's Third Proposed Definition*

[29] Lastly, Defendant argues that the definition of "derivatives" must be limited to synthetic derivatives only. (Tr. at 47-48.) In contrast, Plaintiffs contend that "derivatives" must be defined as "compounds that have a similar structure to a parent compound" (Tr. at 9-10) and the definition includes both synthetic derivatives and structural analogs.FN6 (Pl. Mem. at 12.)

FN6. A synthetic derivative of a lead compound is one that is synthesized from that lead compound. (Winneker Decl. Ex. 30 at 260.) In contrast, a structural analog is a compound that has the same structural components as the lead compound, but may not be synthesizable from that lead compound. (Winneker Decl. Ex. 30 at 20-21.) Said differently, it may be possible to prepare the structural analog from the lead compound theoretically, but not practically. (Winneker Decl. Ex. 30 at 20-21.)

[30] Where "the patentee has clearly defined a claim term, that definition '[u]sually ... is dispositive; it is the single best guide to the meaning of a disputed term.' " Jack Guttman, 302 F.3d at 1360 (quoting Vitronics, 90 F.3d at 1582). However, the written description must unambiguously set forth a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term." Process Control, 190 F.3d at 1357; *accord* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed.Cir.1998) ("The patentee's lexicography must ... appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994))). Accordingly, as already stated, because there is no dispute that the patentees intended to define edetate, the sole question before this Court is whether they succeeded in defining edetate with "with reasonable clarity, deliberateness, and precision" for one of ordinary skill in the art.

The '520 patent teaches that edetate is to be construed as EDTA "and derivatives thereof." (Col. 4, lines 51-52.) The key disagreement between Plaintiffs and Defendant is with respect to the definition of "derivatives." (Col. 4, lines 51-52; *compare* Tr. at 9-10, *with* Tr. at 45-47.)

The specification does not expressly define the term. (Tr. at 9, 12.) The parties have cited to a plethora of dictionaries, treatises, scholarly articles and issued patents for support of their proffered definitions. (*See, e.g.,* Tr. at 14-16, 45; Pl. Mem. at 16; Winneker Decl. Exs. 28, 41, 43; Def. Mem. at 10, 12, 15, 17-19; Goldberg Decl. Exs. D-G, J, N-O, R-S.) While some of these sources express Mayne's limited definition, others define "derivatives" more expansively. (*Compare* Goldberg Decl. Ex. J: The American Heritage Dictionary 489 (4th ed. 2000) ("*American Heritage*"), *with* Winneker Decl. Ex. 41: *Webster's Third New International Dictionary* 608 (1971) ("*Webster's*")).

The Federal Circuit has explained that dictionaries, encyclopedias and treatises are reliable sources for determining the established meanings for the claim terms:

Dictionaries, encyclopedias and treatises, publicly available at the time the patent is issued, are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art. Such references are unbiased reflections of common understanding not influenced by expert testimony or events subsequent to the fixing of the intrinsic record by the grant of the patent, not colored by the motives of the parties, and not inspired by litigation. Indeed, these materials may be the most meaningful sources of information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology.

Texas Digital, 308 F.3d at 1202-03.

This Court begins its analysis by trying to establish the ordinary meaning of the disputed term with an examination of general purpose dictionary definitions. *See* Novartis Pharm. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1308 (Fed.Cir.2004); Texas Digital, 308 F.3d at 1203-04; *see also* Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed.Cir.2002).

American Heritage defines a derivative as "[a] compound derived or obtained from another and containing essential elements of the parent substance." *American Heritage* 489. *Webster's* defines a derivative more broadly: "a chemical substance that is so related structurally to another substance as to be theoretically derivable from it even when not so obtainable in practice (the methoxy of naphthalene)." *Webster's Int'l* 608. Thus, while some of the general purpose dictionaries provide support for Defendant's suggested definition for derivative, others define the term as proposed by Plaintiffs.

[31] Technical dictionaries can also assist claim construction by showing how those skilled in the art define "derivatives." Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed.Cir.2003) ("[A]s this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1373 (Fed.Cir.2001) (holding that courts may consult scientific dictionaries and technical treatises to determinethe ordinary meaning of a technical term to persons skilled in the art). Here, again, the cited sources provide divergent definitions. Defendant cites to treatises that support its limited definitions. For example, Mayne's cited treatises support its first proposition that "derivatives" ought to be defined as "salts of EDTA" (Def. Mem. at 10), as well as its third proposed definition of "EDTA and compounds synthesized from EDTA" (Def. Mem. at 15-16, 18). In contrast, Plaintiffs' cited references suggest that derivatives ought to include both synthetic derivatives and structural analogs. (Pl. Mem. at 13, 16.) The cacophony of dictionary definitions cited by the parties does not aid this Court's analysis of whether either definition is conclusively established.FN7

FN7. This Court notes that the Federal Circuit is currently examining the role of dictionaries in claim interpretation. Phillips v. AWH Corp., 376 F.3d 1382 (Fed.Cir.2004).

[32] [33] Where terms have multiple dictionary definitions "the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor." Texas Digital, 308 F.3d at 1203 (citing cases). "If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital, 308 F.3d at 1203. Therefore, this Court must examine the specification and the prosecution history to determine which definition or definitions are consistent with the spirit of the claimed invention. *See* Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1143 (Fed.Cir.1997) ("Although limitations may not be read into the claims from the specification, claims are to be read in view of the specification of which they are a part."); *see also* Dunhall Pharms., Inc. v. Discus Dental, Inc., 243 F.3d 564, 2000 WL 1608803 (Fed.Cir.2000)

("[W]hether or not a specific definition of a term is present in the specification, 'the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.' " (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed.Cir.1985))); Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1372 (Fed.Cir.2002).

The '520 patent teaches that disodium edetate, trisodium edetate, tetrasodium edetate and disodium calcium edetate are appropriate EDTA derivatives. (Col. 4, lines 51-57.) However, the '520 patent notes that the exact type of edetate is not important, as long as the chosen edetate can prevent significant growth of microorganisms for at least twenty-four hours if there is adventitious extrinsic contamination. (Col. 4, lines 57-64.) Thus, the specification supports a broad definition of edetate: EDTA or an EDTA derivative that can prevent significant growth of microorganisms for at least twenty-four hours.

[34] In support of their proffered definition, Plaintiffs, pointing to the background of the '520 patent, argue that patentees used "derivatives" broadly to describe both synthetic derivatives and structural analogs. (Pl. Mem. at 14.) For example, they note that the '520 patent lists the antifoaming agents dimethicone and simethicone as silicone derivatives, even though these agents are not synthetically derived from silicone. (Col. 3, lines 40-41; Winneker Decl. Ex. 32 at 48:15-51:21.) Defendant does not dispute that dimethicone and simethicone are structural analogs of silicone, but instead argues that the patentees did not use the word "structural analog" in their patent. (Tr. at 55-56.) Therefore, Mayne argues that patentees definition of derivatives in the context of EDTA does not incorporate structural analogs. (Tr. at 55-56.) However, it is unnecessary for patentees to expressly use the words "structural analog" to describe all the derivatives contemplated by their invention. *See* Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed.Cir.1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification"). Patentees may provide a broader definition by implication, such as by incorporating examples that go beyond the literal meaning. Vitronics, 90 F.3d at 1582 (noting that the specification may define claim terms by implication); *see also Markman,* 52 F.3d at 979-80.

Mayne cites *Astrazeneca AB* for the proposition that this Court ought to limit edetate's definition to "the particular compounds the Plaintiffs tested." (Correspondence from Jules Goldberg, dated Sep. 30, 2004.) The holding of *Astrazeneca AB* is inapposite to this case. There, the patentee disavowed the very features that it was attempting to incorporate into the claim definition: "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)." Astrazeneca AB, 384 F.3d at 1340. Here, by contrast, the patentees did not disavow structural analogs from their definition of derivatives or criticize their usage. Instead, as already discussed, the patentees' use of the word derivatives suggests that they intend their definition to incorporate compounds that are similar in structure to the parent compound.

It bears noting that this Court evaluates what the specification teaches one of ordinary skill in the art. As noted earlier, there is no dispute here that one of ordinary skill is fairly sophisticated in the art of the claimed invention. *See supra* at III.A. In light of the broader use of the term derivatives in the '520 patent and the teaching that the exact nature of edetate is not important as long as it fulfills the primary function of slowing significant microbiological growth, this Court finds that one skilled in the art would understand that the patentees intended to use the broader dictionary definition of derivatives. In particular, this court finds that one of ordinary skill in the art would understand that the patentees intended to define derivatives as "a chemical substance that is so related structurally to another substance as to be theoretically derivable from it even when not so obtainable in practice." Therefore, the proper definition of edetate includes EDTA as well as synthetic derivatives and structural analogs of EDTA, so long as they prevent significant growth of microorganisms for twenty-four or more hours.

[35] Accordingly, this Court defines edetate as "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized, and which can prevent a no more than 10-fold increase in growth of each of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 and *Candida albicans* ATCC 10231 for at least 24 hours."

B. *Propofol*

[36] The second disputed claim term is "propofol." Defendant argues that the correct construction of propofol includes "the additional features of (i) being present in any amount where not expressly limited; and (ii) being a phenol known to have anesthetic and antimicrobial activity." (Def. Mem. at 23.) Plaintiffs do not dispute that the claimed propofol must be a phenol known to have anesthetic and antimicrobial activity. However, arguing that the amount of propofol must not be construed such that the claimed invention is rendered inoperative (Pl. Reply Mem. at 16-18), they contend that propofol should be construed as "2,6-diisopropylphenol" (Tr. at 35).FN8

FN8. Plaintiffs had earlier argued that propofol should be construed as "2, 6-diisopropylphenol in an amount up to about 2%, unless expressly limited in the claim." (Goldberg Decl. Ex. P.) They no longer suggest this definition. (Tr. at 32-33.)

The claim language requires that the claimed composition include propofol as one of its components, but does not mention any specific amount of propofol. In particular, Claim 1 requires the propofol amount be such that the "sterile pharmaceutical composition [is suitable] for parenteral administration." There is no dispute, however, that the ordinary and customary meaning of propofol is "2,6-diisopropylphenol." (Tr. at 35, 76; *see also* Col. 1, lines 4-5.)

Because the claim language does not require any specific amount of propofol, this Court declines to read that limitation into the claim term. *See* Texas Digital, 308 F.3d at 1204; Advanced Cardiovascular, 261 F.3d at 1338-39; Johnson Worldwide, 175 F.3d at 992; Advanced Micro-Devices, 848 F.2d at 1572. Accordingly, this Court gives propofol its ordinary and customary meaning of "2,6-diisopropylphenol."

C. *Amount of* Edetate

[37] The final claim term in dispute is "an amount of edetate sufficient to prevent a no more than 10-fold increase in growth of each of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 and *Candida albicans* ATCC 10231 for at least 24 hours as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said composition at approximately 50 colony forming units per ml, at a temperature in the range 20 (deg.)-25 (deg.) C., whereafter said aliquots are incubated at 20 (deg.)-25 (deg.) C. and are tested for viable counts of said organism after 24 hours, said amount of edetate being no more than 0.1% by weight of said composition." (Col. 11, lines 37-48.) FN9

FN9. This dispute is directed only to those asserted claims that do not expressly recite an amount for edetate. (Def. Mem. at 21.)

Defendant argues that this claim term should be interpreted as meaning "edetate in any amount from zero up to no more than 0.1% by weight of the composition." (Goldberg Decl. Ex. P. at 5.) In support, it argues that "propofol itself possesses sufficient antimicrobial properties to allow the composition to pass the microbiological test when it is present in certain proportions relative to the water-immiscible solvent

component. In reading the claim as a whole, therefore, it is quite possible that no amount of edetate would be required to be added to the composition to pass the microbiological test, depending on the amount of the other ingredients (*e.g.,* propofol and oil) that are present in the composition." (Def. Mem. at 22.) Plaintiffs counter that the proper construction of "an amount of edetate" is "at least an amount of edetate which is sufficient in and of itself to meet the microbiological test recited in the claim phrase, regardless of the presence of other components in the composition, up to no more than 0.1% by weight of edetate." (Goldberg Decl. Ex. P. at 5.)

[38] Mayne's proposed definition encompasses the scenario of no edetate in the claimed composition. (Def. Mem. at 21.) Reading an express limitation out of the claim is contrary to case law. *See* Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed.Cir.1996) (holding that a court cannot construe claims to read an express limitation out of the claim or render it meaningless); Texas Instruments Inc. v. Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed.Cir.1993) (noting that it is improper to "read an express limitation out of the claims" or "render the disputed claim language mere surplusage"). Further, the specification of the '520 patent states:

Typically the edetate will be present in the compositions of the present invention in a molar concentration (with respect to the EDTA free acid) in the range $3x10^{-5}$ to $9x10^{-4}$. Preferably the edetate is present in the range $3x10^{-5}$ to $7.5x10^{-4}$ for example in the range $5x10^{-5}$ to $5x10^{-4}$ and more preferably in the range $1.5x10^{-4}$ to $3.0x10^{-4}$ most preferably about $1.5x10^{-4}$.

(Col. 5, line 1-7.) Thus, the preferred embodiment requires at least a $3x10^{-5}$555555 molar concentration of edetate, with $1.5x10^{-4}$ being the most preferred molar concentration. Mayne's suggested claim construction would exclude the preferred embodiment from the claimed invention. "Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics, 90 F.3d at 1583; *see also* Hoechst Celanese Corp. v. BP Chemics. Ltd., 78 F.3d 1575, 1581 (Fed.Cir.1996) ("[I]t is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.").

Further, the '520 patent describes that the use of edetate as an antimicrobial agent is one of the key features of the claimed invention: "We unexpectedly found that edetate ... was the only agent that would meet our requirements." (Col. 3, line 42-Col. 4, line 45.) Thus, it is clear that Claim 1 requires *an* amount of edetate to be present. The claim further requires, and both parties agree, that the proportion of edetate in the composition cannot exceed 0.1%. (Col. 11, line 46-48; Pl. Reply Mem. at 16; Def. Mem. at 23.)

Accordingly, this Court finds that one skilled in the art would read Claim 1 as "An amount of edetate, greater than 0% but less than or equal to 0.1% by weight of the pharmaceutical composition, which is sufficient to meet the microbiological test recited in the claim phrase."

CONCLUSION

For the foregoing reasons, the Court finds that the disputed terms in the '520 patent have the following meanings:

	Claim Term	***Meaning***
	"Edetate"	EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized, and which can prevent a no more than 10-fold increase in growth of each of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 and *Candida albicans* ATCC 10231 for at least 24 hours.
	"Propofol"	2,6-diisopropylphenol.

	"an amount of edetate ..."	An amount of edetate, greater than 0% but less than or equal to 0.1% by weight of the pharmaceutical composition, which is sufficient to meet the microbiological test recited in the claim phrase.

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