United States District Court,
D. New Jersey.

DAIICHI PHARMACEUTICAL CO., LTD. and Daiichi Pharmaceutical Corporation,
Plaintiffs.
v.
APOTEX, INC. and Apotex Corp,
Defendants.

No. Civ. 03-937(WGB)

Aug. 8, 2005.

Background: Japanese drug manufacturer and its New Jersey-based subsidiary brought patent infringement action against a generic drug manufacturer, alleging infringement of patent for a patent disclosing a topical method for the treatment of otopathy with an antibiotic. Parties moved to construe disputed claim terms.

Holdings: The District Court, Bassler, J., held that:
(1) "otopathy," within meaning of patent referred to a bacterial ear infection, not to any disease of the ear;
(2) "effective to treat" within meaning of patent meant "safe and efficacious to treat"; and
(3) "intratympanically injected through a puncture of the tympanic membrane" within meaning of patent meant "introduced into the middle ear with an instrument such as a syringe."

Ordered accordingly.

5,401,741. Construed.

James P. Flynn, Epstein, Becker & Green, P.C., Newark, NJ, Brian P. Murphy, David Leichtman, Morgan Lewis Bockius LLP, New York City, for Plaintiff.

Adorno & Yoss, LLP, Wayne, NJ, Robert B. Breisblatt, Julie A. Katz, Michael A. Krol, Welsh & Katz, Ltd., Chicago, IL, for Defendant.

OPINION

BASSLER**, Senior District Judge.**

Plaintiffs are Daiichi Pharmaceutical Co. Ltd., a Japanese drug manufacturer, and its New Jersey-based subsidiary, Daiichi Pharmaceutical Corporation (collectively, "Daiichi"). This lawsuit concerns Daiichi's U.S. Patent No. 5,401,741 (the " '741 patent"), entitled a "Topical Preparation for Treating Otopathy."

Daiichi brings this action against Apotex Inc., a Canadian-based generic drug manufacturer, and its subsidiary, Apotex Corp. (collectively, "Apotex") for willful patent infringement under the Hatch-Waxman Act, 35 U.S.C. s. 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. s.s. 2201 and 2202, and 35 U.S.C. s. 271(a), (b) and/or (c).

Jurisdiction and venue in this district are proper pursuant to 28 U.S.C. s.s. 1331, 1338(a), 1391(b), and 1400(b).

This Opinion addresses the proper interpretation of the '741 patent claims.

I. BACKGROUND

Daiichi owns the '741 patent, which was issued by the U.S. Patent and Trademark Office ("PTO") in March 1995. FN1 The '741 patent discloses a "Topical Method for the Treatment of Otopathy," and sets forth the following seven claims: FN2

FN1. The '741 patent was originally issued to its three inventors, Kiichi Sato, Akira Handa, and Takeji Kitahara.

FN2. As its title indicates, the '741 patent is a "method" patent, as compared to a machine, composition, or manufacture patent. One treatise explains: "the 'elements' of a method claim, instead of being structural parts, are, and must be, acts or manipulative steps that are performed upon an article, workpiece, or chemical substance. It is the transformation or reduction of the article, workpiece, or chemical substance to a different state or thing that is the essence of a method claim." Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* (5th ed.2004) (emphasis in original).

Claim 1: A method for treating otopathy which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otopathy in a pharmaceutically acceptable carrier to the area affected with otopathy.
Claim 2: The method of claim 1 wherein the said otopathy is otitis media.

Claim 3: The method of claim 2 wherein the said otopathy is otitis externa.

Claim 4: The method of claim 2 wherein the concentration of ofloxacin in the pharmaceutically acceptable carrier is about 0.05 to about 2% w/v.

Claim 5: The method as claimed in claim 4, wherein the dosage form of ofloxacin is an aqueous solution.

Claim 6: The method as claimed in claim 5, wherein the aqueous solution of ofloxacin is applied to the external auditory canal by instillation.

Claim 7: The method as claimed in claim 6, wherein the aqueous solution of ofloxacin is intratympanically injected through a puncture in the tympanic membrane.

(Declaration of Michael A. Krol in Support of Apotex' Claim Construction Brief ("Krol Decl."), Exh. A.) The '741 patent is not due to expire until March 2012. (Daiichi Brief in Support of Claim Construction ("Daiichi Br."), at 1.)

At the time that Daiichi's researchers began working on the '741 patent, a number of antibiotics were available for the treatment of bacterial ear infections. Unfortunately, these antibiotics, whether administered to patients systemically (by ingestion or injection), or topically (by application to the surface of the infected area), were associated with certain adverse side effects. For example, patients given oral antibiotics, such as amoxicillan, were known to develop bacterial resistance, thereby reducing or eliminating the effectiveness of the antibiotic. (*Id*. at 7.)

Topical administration of antibiotics, while an improvement over systemic administration, presented its own risks.FN3 Specifically, when certain antibiotic compounds were applied to the surface of the middle ear they could "migrate" into the inner ear, causing structural damage and resulting in permanent hearing loss and/or impairment of balance-side-effects referred to in the field as "ototoxicity." (*Id*., at 8-9.)

FN3. To understand these risks, it is helpful to know that the ear consists of three chambers: (1) the outer ear, including the external auditory canal, which focuses sound waves on the tympanic membrane (commonly known as the ear drum); (2) the middle ear, which conducts sound; and (3) the inner ear, which transmits sound vibrations to the auditory nerve for processing into sound. (Daiichi Br., at 4.) The tympanic membrane separates the external auditory canal from the middle ear. (*See* Daiichi Br., at 2-4.)

The risk of ototoxicity is not limited to topical administration of antibiotic compounds directly to the middle ear. Rather, if the compound is applied to the surface of the external auditory canal of patients whose tympanic membranes are ruptured-a condition which can develop in patients with middle ear infections-the drug may migrate first to the middle ear, and then to the inner ear, thereby presenting the same risks of ototoxicity. (*Id*. at 8.)

There are therefore at least two situations which present the risk of ototoxicity. First, when a patient suffers from otitis media, a bacterial infection of the middle ear. Second, when a patient suffers from otitis externa, a bacterial infection of the external auditory canal, with a ruptured tympanic membrane.FN4 This latter situation is particularly troublesome for treating physicians because in many cases of otitis externa, the swelling of the external auditory canal makes it difficult, if not impossible, to know if the tympanic membrane is intact prior to initiating antibiotic therapy. (*Id*. 4-5.)

FN4. *Otitis media* and *otitis externa* are characterized by localized pain, swelling, and inflammation. *Otitis externa* is commonly referred to as "swimmer's ear." (*Id*.)

The method described in the '741 patent was intended to overcome these risks, by setting forth a method for the topical administration of ofloxacin-a previously known antibiotic compound-to both the external auditory canal and the middle ear, while significantly reducing the risk of ototoxicity and antibacterial resistance. (Krol Decl., Exh. A; Daiichi Br. 8-11.)

In 1997, two years after the issuance of the '741 patent, the Food and Drug Administration ("FDA") approved Daiichi's FLOXIN(R) Otic product, which is covered by the terms of the '741 patent and is the first antibiotic ear drop approved by the FDA for use in both the external auditory canal and the middle ear.

(Id., at 6.)

In early 2003, Daiichi received notice that Apotex, a Canadian-based generic drug manufacturer, had filed with the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") for Ofloxacin Otic Solution. Arguing that Apotex' Ofloxacin Otic Solution is a generic "copy" of its FLOXIN(R) Otic product, Daiichi filed this suit in March 2003. The amended complaint (the "Amended Complaint"), filed in May 2004, alleges willful infringement of all seven claims of the '741 patent.

Apotex denies Daiichi's allegations and raises the following defenses: (1) patent invalidity; (2) anticipation; (3) obviousness; (4) unenforceability; (5) noninfringement; (6) noninfringement of claim 7; and (7) misuse. In addition, Apotex has filed a counterclaim against Daiichi, which has since been severed from the main action and stayed pending trial on the issue of infringement.

In accordance with Magistrate Judge Madeline Cox Arleo's October 9, 2003 pretrial scheduling order, the parties have now substantially completed discovery, including depositions.

The sole issue currently before the Court is the proper interpretation of the '741 patent claims. The parties have fully briefed the issue and, on July 22, 2005, the Court conducted a *Markman* proceeding. This Opinion sets forth the Court's conclusions with respect to claim construction.

II. LEGAL FRAMEWORK

[1] There are two steps in a patent infringement action. First, the claims must be properly construed in order to determine their scope and meaning. Second, the claims as properly construed must be compared to the accused device or process. CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1152 (Fed.Cir.1997), *cert. denied,* 522 U.S. 1109, 118 S.Ct. 1039, 140 L.Ed.2d 105 (1998). As previously mentioned, this Opinion addresses only the first step, which is a threshold issue of law for the court to decide. Markman v. Westview Instruments, 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

A. Analytical Framework

[2] "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1311, 2005 WL 1620331, at (Fed.Cir.2005) (internal quotation marks omitted). Accordingly, a court, in construing the terms of a patent, should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

[3] [4] The words of a claim "are generally given their ordinary and customary meaning." Phillips, 415 F.3d 1303, 1311, 2005 WL 1620331, at *5 (internal quotation marks omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.*

[5] The ordinary meaning of a term cannot, however, be construed in a vacuum; rather, a court must "must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed.Cir.2005). The court does so to "determine whether the inventor used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582.

[6] [7] For example, "the specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Phillips, 415 F.3d 1303, 2005 WL 1620331, at *13 (internal quotation marks omitted). Similarly, a patent's prosecution history may clarify the meaning of a claim, particularly in light of exchanges between the patent applicant and the PTO. *See* Northern Telecom, Ltd. v. Samsung Elec. Co., 215 F.3d 1281 (Fed.Cir.2000). Thus, the claim language, the specification, and the patent prosecution history-collectively referred to in patent law as the "intrinsic record"-are the foundation of claim construction analysis and will, in most instances, resolve any ambiguity in a disputed claim term. Vitronics, 90 F.3d at 1582-83 ("Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.")

[8] Only in the rare circumstance in which there is still doubt as to the meaning of a claim after the court has examined the intrinsic record, should a court look to extrinsic evidence such as treatises, technical references, and expert testimony, to resolve any doubts or ambiguities. Id., at 1583.

III. DISCUSSION

With these principles in mind, the Court turns first to a discussion of the "ordinary person skilled in the art," and then to an analysis of each disputed claim term.

A. Ordinary Person Skilled in the Art

[9] [10] The person having ordinary skill in the art is a hypothetical person who is presumed to know all of the relevant art within the field of invention and any analogous technical fields. *See* Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed.Cir.1985). The purpose of this standard is to "provide[ ] an objective basis from which to begin claim interpretation." FN5 Phillips, 415 F.3d 1303, 1311, 2005 WL 1620331, at *5.

FN5. The "ordinary person" standard has been compared to the "reasonable person" standard used in tort law. *See* Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed.Cir.1987).

[11] The Court of Appeals for the Federal Circuit instructs that the ordinary person is not a judge, a layman, a person skilled in remote arts, or the inventor. Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 697 (Fed.Cir.1983). Rather, "[a] person of ordinary skill in the art is ... presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research, or by extraordinary insights ..." Standard Oil, 774 F.2d at 454.

In *Envtl. Designs,* the Court of Appeals for the Federal Circuit set forth the following non-exhaustive list of factors for a court to use in ascertaining the level of ordinary skill in the art: (1) the inventor's educational background; (2) the kinds of problems confronted in the art; (3) solutions found previously; (4) the level of sophistication of the technology; (5) the speed of innovation in the art; and (6) the educational level of active workers in the field. 713 F.2d at 696. At the same time, the Court of Appeals noted that these factors may or may not apply to the facts of a given case.FN6 *Id.* ("Not all such factors may be present in every case, and one or more of these factors may predominate in a particular case.").

FN6. One commentator has observed that the Federal Circuit has provided very little guidance on how to define the "ordinary person skilled in the art," despite the fact that this issue is central to resolving many

patent disputes. Joseph P. Meara, Just Who Is the Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage, 77 Wash. L.Rev. 267, 268 (2002).

Here, Daiichi argues that the ordinary person skilled in the art is "a general practitioner or pediatrician of modest experience." (Daiichi Br., at 13.) By contrast, Apotex argues that it is "a physician with detailed understanding of ear diseases, e.g., an otolaryngologist, and a pharmaceutical scientist, such as a pharmacist with an advanced degree (Pharm. D. or Ph.D.), or another worker in the field with expertise in medicinal chemistry and pharmaceutical formulation." (Apotex Moving Brief on Claim Construction ("Apotex Br."), at 11.) Noting that the parties offer little more than conclusory arguments concerning this issue in their briefs, the Court finds that two prior decisions, one issued by the Court of Appeals for the Federal Circuit and one by an Indiana district court, are especially helpful.

The first case, Merck and Co., Inc. v. Teva Pharm. USA, Inc., 347 F.3d 1367 (Fed.Cir.2003), cited by Daiichi, involved a patented method for treating osteoporosis, through the administration of a bisphosphonic acid. At the center of the claim construction dispute was whether the term used to refer to the acid in the patent should be read to encompass the active agent contained in the accused product.

Rejecting the testimony of the defendant's expert witness, a chemist, the Court of Appeals affirmed the district court's conclusion that, in this case, a person skilled in the art would have: (1) a medical degree; (2) experience treating patients with osteoporosis; (3) and knowledge of the pharmacology and usage of bisphosphonates. *Id*. at 1371.

In the second case, Eli Lilly & Co. v. Teva Pharmaceuticals, 2004 WL 1724632 (S.D.Ind. July 29, 2004) (unpublished decision), an Indiana district court used similar reasoning. The case involved several patents for the use of fluoxetine, more commonly known as Prozac(R), for the treatment of depression and anxiety. Plaintiff sued for patent infringement when the defendant, a generic drug manufacturer, sought FDA approval to sell a generic version of fluexotine for the treatment of premenstrual syndrome ("PMS").

[12] In analyzing the defendant's obviousness defense,FN7 the district court stated that, "to limit 'one of ordinary skill in the art' to clinical researchers would be too restrictive." *Id*. The district court went on to conclude that the ordinary person skilled in the art would be a "medical doctor (an OB/GYN, a family practice physician, or a psychiatrist) who: (1) regularly sees and treats patients suffering from PMS; and (2) is familiar with the prior art." *Id*. at *33.

FN7. A patent claim is invalid under 35 U.S.C. s. 103(a) "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Velander v. Garner, 348 F.3d 1359, 1363 (Fed.Cir.2003).

The Court sees no reason why the logic employed in *Merck* and *Eli Lilly & Co*. should not apply to the facts of this case. Here, the ordinary person skilled in the art would have a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics. This person would be, as Daiichi argues, a pediatrician or general practitioner-those doctors who are often the "first line of defense" in treating ear infections and who, by virtue of their medical training, possess basic pharmacological knowledge.

B. Disputed Terms

Having determined that the ordinary person skilled in the art is a person with a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics, the Court now turns to the disputed claim terms themselves.

In their briefs filed with the Court, each party submitted a chart setting forth its proposed claim language. After reviewing the charts and observing that the parties disagreed as to almost every term used in the patent, the Court asked the parties to submit a jointly prepared claim construction chart, so as to identify the material terms in dispute. The jointly prepared chart was of limited usefulness and the parties were asked, at the *Markman* proceeding, to identify exactly which terms the Court was being asked to interpret. The parties agreed that the Court need only address the following three terms: (1) "otopathy"; (2) "effective to treat;" and (3) "intratympanically injected through a puncture of the tympanic membrane." The Court addresses each of these three terms in order.

1. "otopathy"

[13] The parties disagree as to the proper interpretation of "otopathy," a term used in Claims 1, 2, and 3 of the patent. Daiichi argues that it should be construed to mean "otitis externa and/or otitis media." By contrast, Apotex argues that it should be construed as "any disease of the ear." The Court does not find either argument persuasive.

[14] The doctrine of claim differentiation requires each claim to have a different scope. As the Court of Appeals for the Federal Circuit explains:

There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

Comark Comms., Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998).

Daiichi's proposed construction plainly violates the principle of claim differentiation. Claims 1, with Daiichi's proposed language italicized, reads as follows:

Claim 1

A method for treating otitis externa *and/or* otitis media which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otitis externa *and/or* otitis media in a pharmaceutically acceptable carrier to the area affected with otitis externa *and/or* otitis media.

Such a construction would clearly render Claims 2 and 3 redundant:

Claim 2

The method of claim 1 wherein the said otopathy is otitis media.

Claim 3

The method of claim 2 wherein the said otopathy is otitis externa.

The Court declines Daiichi's invitation to cast aside well-settled principles of claim construction analysis in construing the disputed term.

[15] Rather, the proper course is to adhere to the rule that "[t]he presence of a dependent claim that adds a particular limitation raises the presumption that the limitation in question is not found in the independent claim." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed.Cir.2004); *see also* Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302-03 (Fed.Cir.2003). Accordingly, the fact that Claim 2 is limited to otitis media and Claim 3 to otitis media and otitis *externa* persuades this Court that Claim 1 is *not* limited to otitis media and/or otitis externa.

The Court notes that, at the *Markman* proceeding, Daiichi raised one argument, not previously presented in its briefs, concerning the issue of claim differentiation. The argument is that all of the claims are in fact different under its proposed interpretation because: (1) Claim 2 relates to otitis media*;* (2) Claim 3 relates to otitis externa*;* and (3) Claim 1 refers to otitis media and otitis *externa*. Daiichi's argument simply does not work.

It is well-established that "[c]laims in dependent form shall be construed to include all limitations of the claim incorporated by reference into the dependant claim." *See* 37 C.F.R. s. 75(c). Therefore, Claim 3 must be read to include all of the limitations contained in Claim 2, which would mean that the "otopathy" referred to in Claim 3 is both otitis externa *and* otitis media, rendering Daiichi's proposed interpretation of Claim 1 redundant.

Daiichi's proposed construction is not only contradicted by the language of the claims themselves, it is also inconsistent with the patent specification as whole. Several sections of the specification explicitly state that otitis externa and otitis media are *among* the types of otopathy, *not the only* types of otopathy, to which the '741 patent is directed. For example, the specification states:

The otopathy on which the preparation of the present invention is effective *includes* inflammatory otopathy, *such as* otitis media and otitis externa ...

(Krol Decl., Exh. A (emphasis added).) Another section of the specification states:

The preparation according to the present invention exhibits marked improvements over the conventional drugs in terms of not only ototoxicity but also tissue distribution and excellent therapeutic effects on otopathy, *particularly* otitis media and otitis externa.

(Id. (emphasis added).) FN8 In light of the claim language and the specification, the Court fails to see a principled basis for adopting Daiichi's proposed construction.

FN8. Daiichi points out that *otitis media* and *otitis externa* are the only forms of bacterial ear infections known to be susceptible to topical administration of ofloxacin. In the Court's view, that fact does not foreclose the possibility that the term "otopathy," as used in the '741 patent, was intended to encompass more than just *otitis media* and *otitis externa*. As one treatise on patent drafting explains, "[i]t is the claim

drafters job to have written the claims in the application to not only cover what they attorney and the inventor/client could at the time of the application prosecution have envisioned as competing products, but to cover competitive products which neither the inventor nor the attorney thought of or could even have imagined at the time ..." Faber, *supra* note 2, at s. 10:1-1.

Unfortunately, Apotex' proposed construction is no more persuasive. Apotex argues that the "plain and ordinary meaning" of the term "otopathy," and the one which the Court should adopt, is "any disease of the ear." In support of its argument, Apotex points out that during the patent prosecution process, Daiichi submitted to the PTO an excerpt from Dorland's Medical Dictionary, 26th edition, which defines "otopathy" as "any disease of the ear." (Krol Decl., Exh. I.) Apotex' argument is unconvincing for two reasons.

First, Daiichi represents to the Court that it submitted Dorland's Medical Dictionary definition of "otopathy" to the PTO only because Daiichi was required to do so pursuant to Patent Office Rule 56, 35 C.F.R. s. 1.56. Specifically, the Dorland's Medical Dictionary definition had been submitted during the prosecution of the foreign counterpart to the '741 patent and, therefore, was required to be disclosed to the PTO pursuant to Daiichi's duty of good faith and candor. (Daiichi Brief in Response to Apotex' Brief on Claim Construction ("Daiichi Reply"), at 5.) In fact, the record shows that the Patent Examiner crossed the definition off of Daiichi's Form PTO-1449, indicating, as the Form PTO-1449 itself instructs, that the Patent Examiner did not rely on Dorland's Medical Dictionary in its consideration of the '741 patent application. Apotex offers nothing to rebut these facts.

The second, and perhaps more important, reason why the Court rejects Apotex' proposed construction is the recent and much-anticipated *Phillips* decision, in which the Court of Appeals for the Federal Circuit, sitting en banc, issued a strongly worded caution against the blind use of dictionary definitions in claim construction analysis. As stated in *Phillips:*

The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent ... *heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is its specification.*

Phillips, at 1320, 2005 WL 1620331, *14 (emphasis added). The Court of Appeals further elaborated, "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." *Id.* This Court finds the Court of Appeals' warning in *Phillips* especially pertinent here.

Neither the Court, nor Daiichi, dispute that the term "otopathy" may be literally translated into "a disorder of the ear." That does not, however, mean that this is how the term should be construed in the context of the '741 patent. Rather, viewing the disputed term from the perspective of the ordinary person skilled in the art, as this Court is required to do, precludes such an interpretation.

A pediatrician or general practitioner, let alone an otolaryngologist, would know that ofloxacin is an anti-bacterial agent whose only therapeutic purpose is to kill or eradicate bacteria. The pediatrician or general practitioner would therefore assume that the otopathy to which the '741 patent is directed must be amenable to antibiotic treatment-that is, infections caused by the presence of bacteria.FN9 Accordingly, the Court

concludes that the most sensible construction of the term otopathy, as used in the '741 patent, is "bacterial ear infection."

FN9. The only other drugs mentioned in the patent specification are also antibiotics, including fradiomycin, kanamycin, chloramphenicol, and cefmenoxime. (Krol Decl., Exh. A.)

2. "effective to treat"

[16] Daiichi argues that the phrase "effective to treat" otopathy means "safe and efficacious to treat." (Daiichi Br., at 21.) Apotex disagrees, and argues that the term "safe" should not be read into the patent claim. The Court agrees with Daiichi.

[17] It is proper to interpret terms and phrases appearing in the claim in light of the fundamental purpose and significance of the invention. Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559 (Fed.Cir.1992); *In re Research Corp. Techs., Inc.,* No. 97-2836, 1998 U.S. Dist. LEXIS 23150 at (D.N.J. Oct. 16, 1998). Doing so in this case amply supports Daiichi's argument that "[s]afety was a paramount concern of the inventors" of the '741 patent. (Daiichi Br., at 22.)

In describing the background to the invention, the patent specification recites the following:

Conventionally employed topical preparations for treating otopathy ... have ototoxicity as side effects or therapeutic effects thereof tend to be decreased due to emergence of resistant microorganisms.

* * * * * *

In order to overcome the above-described problems, the inventors have conducted extensive investigations and, as a result, have reached the present invention.

* * * * * *

Ofloxacin is of high safety. Acute toxicity (LD_{50}) of ofloxacin was found to be 5450 mg/kg (p.o.) in mice, 200 mg/kg or more (p.o.) in dogs, and from 500 to 1,000 mg/kg (p.o.) in monkeys.

* * * * * *

The preparation according to the present invention exhibits marked improvements over the conventional drugs in terms of not only otoxicity but also tissue distribution and excellent therapeutic effects on otopathy ...

(Krol Decl., Exh. A.) In addition, the specification describes a number of animal studies involving the ototoxic effects of topically applied ofloxacin and data concerning the drug's safety.

In light of the extensive discussion of side-effects and safety in the patent specification, the Court concludes that it is proper to construe the disputed term "effective to treat" as "efficacious and safe." FN10

FN10. In addition, at least one district court has construed the term "effective" so as to implicitly include

minimization of side effects. Purdue Pharma. L.P. v. F.H. Faulding & Co., 48 F.Supp.2d 420.437 (D.Del.1999), *aff'd,* 230 F.3d 1320 (Fed.Cir.2000) (construing "effective to treat pain" to mean "an individual patient is provided with adequate pain relief ... without unacceptable side effects").

3. "intratympanically injected through a puncture of the tympanic membrane"

[18] Apotex argues that term "intratympanically injected through a puncture of the tympanic membrane," as used in Claim 7 of the patent, means "introduced into the middle ear with an instrument such as a syringe." (Apotex Br., at 25.) Daiichi urges a broader interpretation, in which the term means "forced into the middle ear through a puncture of, or a tympanostomy tube within, the tympanic membrane." (Daiichi Br., at 30.) The Court agrees with Apotex' interpretation of the disputed term.

Daiichi argues that Claim 7 should be read to include, but should not to be limited to, the use of a syringe. The basis for this argument is that since the '741 patent is directed to the treatment of otitis media with a perforated tympanic membrane, there would be no need to use a syringe to force the antibiotic into the middle ear cavity. According to Daiichi, Claim 7 should be construed to include the instillation of ofloxacin drops into the external auditory canal, as set forth in Claim 6, which are then forced, i.e. "injected," through the ruptured tympanic membrane using a method referred to as "pumping the tragus." FN11

FN11. "Pumping the tragus" essentially means wiggling the ear so as to exert pressure on the fluid in the external auditory canal.

Noting that the language of Claims 6 and 7 does nothing to support this interpretation, the Court finds that a close reading of the patent specification precludes this Court from adopting Daiichi's proposed construction. Specifically, in several sections of the specification, "intratympanic injections" are distinguished from the instillation of ear drops. The specification states:

Dose forms of the topical preparation of the present invention include sprays, otic solutions, *e.g. intratympanic injections and ear drops,* ointments and the like.

* * * * * *

In administration of the ofloxacin solution, several 0.5 ml-doses per day are applied to the external auditory canal by spreading, spraying or *instillation, or intratympically injected* through a puncture of the tympanic membrane.

(Krol Decl., Exh. A. (emphasis added).) Indeed, even Daiichi's own expert, Dr. Angelo Agro, testified at her deposition, that an ordinary person skilled in the art would not have known at the time the '741 patent was issued that "intratympanically injected" meant "pumping the tragus." As Agro testified:

Q: At the time of the invention, were any ototopical preparations being intratympanically injected in the fashion you are describing [pumping the tragus]?

A. No.

(Krol Decl., Exh. M, Transcript of Deposition of Angelo Agro, M.D., 115:5-11.)

Had Daiichi intended the act as its own lexicographer and defined the term "intratympically injected" to mean "pumping the tragus," it was certainly free to do so by clearly defining the term in the patent specification. Having failed to do so, the Court finds that the most sensible construction of the term is, as Apotex argues, "introduced into the middle ear with an instrument such as a syringe," an interpretation that is consistent with the generally known meaning of the word "injection."

IV. CONCLUSION

For the reasons set forth in this Opinion, the Court declares that:

(1) the term "otopathy" as used in the claims of U.S. Patent No. 5,401,741 is properly construed to mean "bacterial ear infection;"

(2) the term "effective to treat" as used in the claims of U.S. Patent No. 5,401,741 is properly construed to mean "safe and efficacious to treat;" and

(3) the term "intratympanically injected through a puncture of the tympanic membrane" as used in the claims of U.S. Patent No. 5,401,741 is properly construed to mean "introduced into the middle ear with an instrument such as a syringe."

An appropriate Order follows.

ORDER

This matter having come before the Court on the motions of DAIICHI PHARMACEUTICAL CO., LTD. and DAIICHI PHARMACEUTICAL CORPORATION ("Plaintiffs") and APOTEX, INC. and APOTEX CORP. ("Defendants") to construe certain disputed claim terms in U.S. Patent No. 5,410,741 (the "741 patent"); and

The Court having considered the submissions of the parties; and

The Court having conducted a hearing pursuant to Markman v. Westview Instr., 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996); and

For the reasons set forth in the Opinion issued this day; and

For good cause shown;

It is on this 5th day of August 2005 ORDERED that:

(1) the term "otopathy" as used in the claims of the U.S. Patent No. 5,401,741 is properly construed to mean "bacterial ear infection;"

(2) the term "effective to treat" as used in the claims of the U.S. Patent No. 5,401,741 is properly construed to mean "safe and efficacious;" and

(3) the term "intratympanically injected through a puncture of the tympanic membrane" as used in the claims of U.S. Patent No. 5,401,741 is properly construed to mean "introduced into the middle ear with an instrument such as a syringe."

D.N.J.,2005.
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