

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

VDP PATENT, LLC,
Plaintiff.

v.

WELCH ALLYN HOLDINGS, INC., d/b/a Welch Allyn, Inc., and Harold Ellis Drugs and Surgicals Inc,
Defendants.

No. 06 Civ. 5821 (GEL)

June 28, 2007.

Background: Holder of a patent directed to a method for flushing out earwax with water sued a manufacturer of medical equipment and a distributor for the manufacturer, claiming infringement. Defendants moved for summary judgment.

Holdings: The District Court, Gerard E. Lynch, J., held that:

- (1) term "otoscope," within the meaning of the patent, was a viewing device, rather than an access device;
- (2) patent holder was not estopped from arguing that defendants' no-otoscope method was an infringing equivalent; but
- (3) triable fact issues precluded summary judgment as to whether the defendant's product was infringing under the doctrine of equivalents.

Motion granted in part and denied in part.

5,944,711. Construed.

Michael B. Weiss, Cahill Gordon & Reindel LLP, New York, NY, for Plaintiff.

Douglas J. Nash and John D. Cook, Hiscock & Barclay, LLP, Syracuse, NY, for Defendants.

OPINION AND ORDER

GERARD E. LYNCH, District Judge:

Plaintiff VDP Patent, LLC ("VDP"), accuses defendants Welch Allyn Holdings, Inc., d/b/a Welch Allyn, Inc. ("Welch Allyn"), a manufacturer of medical equipment, and Harold Ellis Drugs and Surgicals, Inc., a distributor of Welch Allyn's products, of infringing VDP's U.S. Patent No. 5,944,711 ("711 patent"), by

selling a certain ear-washing system. The '711 patent is directed to a method for flushing out cerumen, or earwax, with water, requiring among other elements use of an otoscope. Defendants move for summary judgment of noninfringement on the ground that their product does not constitute or make use of an otoscope within the meaning of the term as it is used in the '711 patent. Plaintiff advances a different definition of "otoscope," and argues that if its definition is adopted, a triable issue remains as to whether defendants' product literally infringes its patent. In the alternative, plaintiff contends that the accused method, even on defendants' definition of "otoscope," may yet be found to infringe its patent under the doctrine of equivalents.

For the reasons stated below, defendants' motion will be granted as to the claim of literal infringement but denied as to the claim of infringement under the doctrine of equivalents.

BACKGROUND

Plaintiff's invention improves upon prior methods for removing earwax from a person's ear canal using water. Previously syringes, capable of delivering only limited amounts of water, had been used to flush out the ear. Patients whose ears were being thus irrigated had had to rely on a waterproof apron for protection from the likely splatter each time the syringe was removed to permit drainage and begin a fresh flushing.

Inventor Daniel J. Pender recognized the benefit of a method that would involve a continuous flow of water in and out of the ear, via a tightly fitted device, until irrigation was completed, thereby avoiding splattering of the patient. He filed the application resulting in the '711 patent in December 1997. An office action rejecting the application's single claim issued in November 1998. The applicant successfully responded the next month, and the application was allowed in May 1999.

The final '711 patent contains only one claim, Claim 1, which covers:

A method of irrigating a pat[i]ent's ear using an otoscope of a type having an operating mode of flushing cerumen therefrom with body temperature water, said method comprising the steps of [providing an otoscope,] FN1 configuring a tip of said otoscope in a cylindrical shape in cross section and of a selected outside diameter, selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said tip into said ear canal, establishing at a site of engagement of said different diameters of said tip and said ear canal opening a friction fit obviating fluid leakage externally of said site, providing a source of body temperature water and a return sump therefore, and continuously flowing said body temperature water from said source into and removing water and cerumen from said ear of said patient for return to said sump through said tip until the removal of cerumen is completed, whereby a maintained said fluid leakage seal during said continuous flowing of said body temperature water obviates a splattering of said patient.

FN1. The parties agree that this bracketed phrase should appear in the claim and that it was erroneously omitted by the U.S. Patent and Trademark Office ("PTO") from the printed version of the Patent.

(Weiss Decl., Ex. A, '711 Patent, col. 4.)

This motion concerns the meaning of the term "otoscope" as used in this claim. Defendants would define an otoscope to be "an instrument fitted with lighting and magnifying lens systems and used to facilitate visual

examination of the auditory canal and eardrum." (D. Mem. at 4.) It is undisputed that defendants' accused product does not include an otoscope fitting this description. Plaintiff, however, would define the term as "a medical device which provides access to the ear canal via a tip (or speculum) for the purposes of examination, diagnosis, and/or treatment of the ear canal and/or eardrum." (P. Opp. at 1-2.) The key conceptual difference between the two definitions is that defendants style the otoscope as a *viewing* device, while plaintiff casts it as an *access* device (that does not necessarily facilitate viewing).

To support their respective definitions, the parties have submitted the record of the patent itself, comprising the specification, the single claim, and the prosecution history, in addition to other documentary evidence and the opinions of certain witnesses. This record will be described as appropriate during discussion of the issues.

DISCUSSION

I. Summary Judgment Standard

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits ... show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A "genuine issue of material fact" exists if the evidence is such that a reasonable jury could find in favor of the non-moving party. *Holtz v. Rockefeller & Co.*, 258 F.3d 62, 69 (2d Cir.2001). The moving party bears the burden of establishing the absence of any genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). In deciding a summary judgment motion, the court must "resolve all ambiguities and draw all reasonable references in the light most favorable to the party opposing the motion." *Cifarelli v. Vill. of Babylon*, 93 F.3d 47, 51 (2d Cir.1996). The nonmoving party, however, may not rely on "conclusory allegations or unsubstantiated speculation," *Scotto v. Almenas*, 143 F.3d 105, 114 (2d Cir.1998), and "must do more than simply show that there is some metaphysical doubt as to the material facts," *Matsushita Elec. Indus. Co., Ltd., v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

II. Literal Infringement

A. Legal Standards

[1] [2] [3] To determine whether a patent has been infringed, it is necessary first to resolve any dispute about the meaning or scope of the invention claimed in the patent. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed.Cir.1997). Interpretation of a patent claim, which defines a patentee's rights, is a matter of law reserved entirely for the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Whether an accused method or product infringes a properly construed claim is a question of fact. *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996).

[4] Summary judgment of no literal infringement may be granted only "when no reasonable jury could find that every limitation recited in the properly construed claim ... is .. found in the accused device." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed.Cir.2001). On this summary judgment motion, the only limitation with respect to which literal infringement is disputed involves the use of an otoscope.FN2 Construing the definition of "otoscope" as used in the ' 711 patent, the parties agree, will determine whether defendants are entitled to a judgment of no literal infringement as a matter of law.

FN2. The Court has not yet been asked, nor is it necessary to the instant decision, to construe all of the limitations of the '711 patent' s claim. While the parties essentially agree that construction of the claim term "otoscope" will dispose of any literal-infringement issue, because the claim is clearly limited to require use of an otoscope, they have not stipulated to a specific understanding of all the limitations of the claim. Plaintiff, for instance, proposes that, "for purposes of claim construction, the critical inventive elements of Dr. Pender's invention are: (a) use of an ear-irrigating instrument having a tip of defined dimensions which creates a watertight seal between the ear wall and the tip, and (b) a continuous flow of warm water in and out of the ear to remove cerumen." (P. Opp. at 3.) Defendants differently describe the claim as "allow[ing] the doctor to: (a) clean the ear canal by delivering and then removing a flow of warm water to the inside of the ear; and (b) look deep into the ear to determine if it is clean without removing the modified otoscope from the ear." (D. Mem. at 2.)

As the equivalence-infringement claim survives, and may ultimately require resolution on a "limitation-by-limitation basis," *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566 (Fed.Cir.1996); *see also Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) ("Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."), the parties may require a further opportunity to argue in detail the construction of other aspects of the claim. *See also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed.Cir.1996) (trial court need not conclusively interpret claims at an early stage in a case). For now, it is sufficient to address the otoscope issue.

[5] In construing a patent claim, courts are to look first to the intrinsic evidence of record: the claim, specification, and prosecution history. *Vitronics Corp.*, 90 F.3d at 1582. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language," because the court's task is to construe the meaning of a disputed term " *as [it] is used in the claim.*" *Id.* at 1580, 1582 (emphasis added). Intrinsic coherence is also emphasized by statute-the specification must describe an invention in "full, clear, concise, and exact terms," 35 U.S.C. s. 112, para. 1-and thus "the inventor's intention, as expressed in the specification, is regarded as dispositive." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed.Cir.2005) (*en banc*) (citation omitted).

[6] [7] Courts may also consider evidence extrinsic to the patent in issue, including expert and inventor testimony, dictionaries, and treatises. *Phillips*, 415 F.3d at 1317. Such extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* Indeed, where "an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term," it is not merely inadvisable but also "improper" to rely on extrinsic evidence. *Vitronics Corp.*, 90 F.3d at 1583. The primacy of the patent evidence rests on the premise that "competitors are entitled to review the public [patent] record, ... ascertain the scope of the ... claimed invention and, thus, design around [it] [Neither a] patentee [nor an alleged infringer] may ... proffer an interpretation for the purposes of litigation that would alter the indisputable public record." *Id.* For this reason extrinsic evidence that is publicly accessible in advance of litigation, such as prior-art documents and dictionaries, is preferable for the purpose of claim construction to such extrinsic evidence as expert testimony. *Id.* at 1585.

[8] [9] A claim term should be afforded its "ordinary and customary meaning," which 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" reading the patent.FN3 *Phillips*, 415 F.3d at 1312-13. The "ordinary and customary meaning" standard is consistent with the emphasis on intrinsic evidence: The inventor, whose explanations constitute the intrinsic record,

may be presumed to be, if anyone is, a person of ordinary skill in the art relevant to the invention. *See* Phillips, 415 F.3d at 1313 ("That starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art."). The question is not the inventor's private or subjective intention, but the meaning that would be given his words by a person skilled in the art in the context of the patent.

FN3. Neither party offers, let alone attempts to support, a description of the person of ordinary skill in the art in this case. In briefing this motion, the parties address the nature of the person of ordinary skill in the art only in the context of the credibility of expert witnesses. However, nothing in this decision depends on crediting either one of the proffered witnesses as such a person. In the absence of any argument or showing to the contrary, the Court adopts for purposes of resolving this motion the vantage point of a person of ordinary skill in the "field of invention," Phillips, 415 F.3d at 1313, that is named in the '711 patent itself: the field of "ear irrigation procedure" (Weiss Decl., Ex. A, '711 Patent, col. 1).

B. Construction of "Otoscope"

[10] In this case, the intrinsic evidence dictates an interpretation of the disputed claim term, "otoscope," in accordance with defendants' proposed construction. Consideration of extrinsic evidence thus is not necessary to the decision; the extrinsic evidence submitted by plaintiff, even though considered, does nothing to negate such a construction.

1. Intrinsic Evidence

Plaintiff argues that "[t]here is nothing in the language of Claim 1 of the '711 patent that limits the term 'otoscope' to a device including a light and a lens that is used for visualizing the ear canal" (P. Opp. at 6)-in other words, to defendants' proposed definition. Yet the claim describes a method involving "us[e of] an otoscope of a type having an operating mode of flushing cerumen" from the ear with water, and the insertion of a specially configured tip of the otoscope tightly into the ear canal for flushing "*until the removal of cerumen is completed.*" (Weiss Decl., Ex. A, '711 Patent, col. 4, emphasis added.) The reference to a point of completion implies the necessity of incorporating into the claimed method a means for observing the progress of earwax removal. Plaintiff points to nothing in the claim that explains how such observation could be effected other than by use of a device such as that which defendants have defined the claim's "otoscope" to be. It is true that, as plaintiff contends, the method claimed does not "[explicitly] include visualization of the ear canal." (P. Opp. at 7.) Yet the method clearly if implicitly contemplates visualization of some aspect of the earwax-removal process. Because defendants' definition of "otoscope" would satisfy that visualization aspect of the claimed method, while plaintiff's definition would leave mysterious how such visualization could occur, the language of the claim supports acceptance of defendants' definition.

[11] For the same reason, the specification, which "is the single best guide to the meaning of a disputed term," Vitronics Corp., 90 F.3d at 1582, supports accepting defendants' definition of "otoscope" rather than plaintiff's. Plaintiff correctly points out that the portions of the specification distinguishing the prior art do not "include any reference to visualization of the ear." (P. Opp. at 8.) However, as with the claim, the lack of explicit mention of visualization in the specification does not establish that "the key elements of Dr. Pender's invention ... have nothing to do with visualization." (*Id.*) Rather, the specification's focus on "maintaining the patient splatter-free" (Weiss Decl., Ex. A, '711 Patent, col. 1), via a flushing mechanism

that does not "ha[ve] to be removed from time to time during the ear canal irrigation procedure" (*id.*), would plainly teach a person of ordinary skill in the art reading the patent that some means would be required for observing the progress of that procedure without removing the flushing device. A careful reading of the specification supports this view. The specification states that "[u]nderlying the present invention is the recognition that an operating mode which contemplates the use of a continuous warm water supply under pressure is one which obviates the removal of the ear-irrigating instrument prior to an *observed completion* of cerumen removal." (Weiss Decl., Ex. A, '711 Patent, col. 2, emphasis added.)

Moreover, the specification describes a preferred embodiment as involving an "otoscope [with] ... a flushing water delivery and removal head [,] ... a view port lens telescoped, ... [and] a fiber optic light source," permitting "observation through the lens [to see if] removal of cerumen is completed." (*Id.*, cols. 2-3.) While it is well established that descriptions of possible embodiments do not by themselves limit a claim, *see* Phillips, 415 F.3d at 1323, the description in this case is relied upon not to limit the claim to the particular embodiment described, but rather to help determine what a term of the claim would mean to an ordinary skilled person in the field reading the claim in the context of the specification. *See* Phillips, 415 F.3d at 1313 ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). As with the claim, adoption of plaintiff's definition of "otoscope" would leave mysterious how the visualization of earwax-removal as clearly contemplated-and instructively, if not dispositively, described-in the specification would occur. The language of the specification, therefore, in conjunction with the language of the claim itself, supports acceptance of defendants' definition, to satisfy the visualization aspect of the claimed method.FN4

FN4. The preferred embodiment specifies a particular lens type and light source. These preferences are particular to the embodiment described, but they illustrate the point that the "otoscope" in question has *some* capacity for visualization-as surely as it has a capacity for "flushing water delivery and removal" (Weiss Decl., Ex. A, '711 Patent, col. 2), which plaintiff concedes is central to the invention.

Finally, the prosecution history also supports acceptance of defendants' definition. "[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes [than the language of the claims and specification themselves]." Phillips, 415 F.3d at 1317. Even allowing for such ambiguity and construing it in plaintiff's favor, the '711 patent's prosecution history at best provides no reason to doubt that defendants' definition of "otoscope" is the most consistent with the claim and specification; at worst for plaintiff, it affirmatively supports defendant's definition.

In her only rejection of the '711 patent application, on November 20, 1998, the PTO examiner wrote that "Claim 1 is confusing because it is unclear if an otoscope is used or not. The preamble suggests using the otoscope, while the body of the claim is merely directed to the tip of the otoscope. It is suggested that applicant add a step of 'providing an otoscope' to clarify that an otoscope is used." (Weiss Decl., Ex. C, Prosecution History of ' 711 Patent, Office Action para. 8.) The patentee subsequently amended the claim to add precisely the suggested language (*see id.*, Response to Office Action), as reflected in what the parties agree should be treated as the final version of the claim.

That the patentee complied with a PTO directive to modify the claim language to clarify that "an otoscope is used"-as opposed to merely the tip of an otoscope-without more does not do anything to define what the

term "otoscope" means in this context. At most, this aspect of the prosecution history only cements that the '711 patent claim "requires the use of an otoscope" (D. Mem. at 6), a proposition that is not contested on this motion.

In her rejection of the '711 patent application, however, the PTO examiner went on to evince an understanding of "otoscope" that accords more closely with defendants' proposed definition than with plaintiff's. Rejecting the claim as obvious in light of certain prior art, she wrote:

Goldenberg discloses the use of an otoscope in combination with a middle ear fluid sampling device for the purpose of removing a specimen from the ear. *The purpose of the otoscope is to provide visual control of the Goldenberg device ...* [Prior art] Grossan is cited to exemplify that irrigating the ear canal with a friction fitting end portion ... is well known. Accordingly, it would be obvious to one of ordinary skill in the art to use the Goldenberg device with an otoscope to irrigate and clear the ear canal as taught by Grossan, for the purpose of having an ear cleaning device which is *fitted with an otoscope for greater visual control of ear irrigation.*

(Weiss Decl., Ex. C, Prosecution History of '711 Patent, Office Action para. 10, emphases added.) The prosecution history may serve as evidence of how the patent examiner and the inventor understood an aspect of a claim and of whether their understandings excluded any particular interpretation. *See Phillips*, 415 F.3d at 1317; *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995). The language of her rejection makes clear that the examiner regarded the otoscope in the context of this patent application to mean a device for viewing inside the ear canal.

Plaintiff does not address this particular passage of the rejection at all. However, the submitted evidence of the inventor's response to that rejection could be taken at least as rendering ambiguous whether the *inventor* shared the examiner's apparent understanding of "otoscope." The patentee sought "[r]econsideration of the rejection ... on the basis of Goldenberg in view of Grossan," arguing that Goldenberg was "non-analogous art" and that "Grossan clearly does not disclose or suggest establishing a site of a friction fit by selection of the outside diameter of the otoscope tip so it is slightly oversized in relation to the patient's ear canal." (Weiss Decl., Ex. C, Prosecution History of '711 Patent, Response to Office Action at 4-5.) This response evidently sufficed, as the examiner thereafter approved the application for issuance of a patent. The response statements do not directly counter the examiner's apparent understanding of "otoscope"-indeed, they could be taken to accept that understanding without objection. However, it could also be argued that the response succeeded in negating any applicability of Goldenberg, and thus Goldenberg's version of an "otoscope," as irrelevant, and that it expressed the patentee's understanding of "otoscope tip," not of an entire otoscope, leaving the examiner's understanding uncorroborated.

None of this prosecution history, however, affirmatively supports adoption of plaintiff's definition of "otoscope" as a non-viewing device over defendant's definition. At best, construed in plaintiff's favor, it leaves construction of the term to hang, as already discussed, on the claim and specification. The fairest analysis of the prosecution history, though, is that, because the examiner clearly understood "otoscope" in the context of the application to mean a device for viewing inside the ear canal, it is likely that a person of ordinary skill in the art viewing the patent evidence would similarly understand the term.

2. Extrinsic Evidence

While it is not necessary to do so, as the intrinsic evidence suffices for choosing between the two proffered

constructions of the disputed claim term, the Court has reviewed the extrinsic evidence submitted by plaintiff and determined that none of it counsels against adopting defendants' definition, and indeed, that resort to dictionaries supports defendants' interpretation.

Plaintiff first points to the primary definition of "otoscope" found in the online Oxford English Dictionary ("OED"): "Originally: an instrument resembling a stethoscope, used to listen for the sound of air in the middle ear or Eustachian tube (now *rare* or *disused*). Later (in full *acoustic* otoscope): an instrument that measures sound reflected from the tympanic membrane, used chiefly to detect fluid in the middle ear." OED Online, www.oed.com (search for "otoscope") (emphases in original). The first use of the term "acoustic otoscope" noted in the explanatory examples following that definition is dated 1984. *See id.* The secondary definition provided is: "An instrument used for visual inspection of the ear." *Id.*

Courts may consult and even rely on dictionary definitions when construing claim terms, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1322-23. The primary source for defining a disputed term must remain the intrinsic evidence of the patent itself, because "elevating the dictionary to such prominence" problematically "focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Id.* at 1321. Such a focus is undesirable, because "[t]he patent system is based on the proposition that claims cover only the invented subject matter The use of a dictionary definition can conflict with that directive because the patent applicant did not create the dictionary to describe the invention." *Id.*

Here, plaintiff's proffered dictionary entry, defining an otoscope as an acoustic device, not only contradicts the definition ascertainable, as discussed, on a reading of the patent's intrinsic evidence, but also fails to support plaintiff's interpretation of "otoscope" as an access device. The online OED's primary definition does not describe the referenced otoscope as providing access to the ear canal.

Moreover, the dictionary's acoustic definition suggests that its relevance as the principal meaning of "otoscope" is historic. Currently, the acoustic reference is "*rare* or *disused*," and at least as early as 1984, the OED suggests, this meaning required express specification by the term "acoustic otoscope." In contrast, the secondary definition, referencing "visual inspection," is not described as archaic or outmoded. The "ordinary and customary meaning of a claim term" is to be gauged as of "the time of the invention, i.e., as of the effective filing date of the patent application," Phillips, 415 F.3d at 1313, and the '711 patent application was filed in December 1997. Thus, the primary dictionary definition advanced by plaintiff does nothing to persuade against adopting defendants' construction of "otoscope" as supported by the intrinsic patent evidence.

For similar reasons, plaintiff's evidence that "the earliest otoscopes" lacked lights and lenses and were used to "provide access to the ear canal" (P. Opp. at 12, citing C. Keith Wilbur, M.D., *Antique Medical Instruments* (4th Ed. 2000)), cannot be taken to counter defendants' suggested construction. As the title of the reference makes clear, it relates to "antique," rather than contemporary, understandings. In any case, the treatise's need to remind readers that "the earliest otoscopes" *lacked* lights and lenses strongly suggests, by negative implication, that the understanding of the device by those familiar with its use at the time of this invention would include such means of visual inspection.

Defendants' construction, in contrast, is supported by a definition provided in a leading online medical dictionary: "an instrument fitted with lighting and magnifying lens systems and used to facilitate visual

examination of the auditory canal and eardrum." (*See* Nash. Decl., Ex. 3, printout of Medline Plus: Medical Dictionary by Merriam-Webster, definition of "otoscope;" also at www.nlm.nih.gov/medlineplus/medlineplusdictionary.html, search for "otoscope.") Other dictionaries similarly support defendants' proposed understanding. Supporting the OED's conclusion that the use of the term to reference primarily an acoustic device was long outdated by the time the instant patent application was filed, Funk and Wagnalls Standard College Dictionary (1966) already promotes "[a]n instrument for viewing or examining the interior of the ear" to pride of place as the principal definition, noting that the term can "also" refer to an "instrument for auscultation [in turn defined as "a listening"] of the ear." Webster's New Universal Unabridged Dictionary Deluxe Second Edition (1983) provides the same two meanings, in the same order. Like the OED, these sources make no reference to plaintiff's preferred definition of the term as a means of introducing other instruments into the ear.

The very derivation of the word, moreover, provides further support for defendants' construction. The American Heritage Dictionary of the English Language (4th ed. 2000) defines the suffix "-scope" as "[a]n instrument for viewing or observing," for example, a bronchoscope, derived from the Greek "skopein," to see. Though some words containing this suffix may involve only metaphorical "seeing" (as with the stethoscope and acoustic otoscope), all appear to involve methods of enhancing perception, and none suggests a usage that involves a means of introducing instruments to inaccessible locations without some sense—most often, literal—of "seeing."

The other extrinsic evidence submitted by plaintiff is similarly unpersuasive. Plaintiff cites Welch Allyn's U.S. Patent No. 4,380,998 ("998 patent"), as referencing different kinds of otoscopes, but it fails to explain how that patent, for a "soft tip speculum" (Dep. of Stephen Burnett, Ex. 10), may be considered within the same field of invention ("ear irrigation procedure") as the subject patent. (*See* P. Opp. at 13.) Moreover, even assuming that the reference can properly be considered, it at best supports a conclusion that the term "otoscope" may sometimes be understood in the sense plaintiff advocates: "Two types of otoscopes are used by physicians in examining and/or treating the ear. One is an operative instrument through which other smaller instruments are passed to gain access to various parts of the inner ear The other is a diagnostic instrument which is used to visually observe the functional activity of the ear." (*See* P. Opp. at 13, citing '998 Patent, col. 1.) Plaintiff does not claim that its invention entails any operation-type procedure,^{FN5} and it provides no other rationale explaining why, if the word may have two different senses, the claim in issue should be construed in accordance with one rather than the other of the two understandings of "otoscope" identified in the '998 patent.

FN5. Defendants contend that even operating otoscopes, including the type seemingly distinguished from visual-observation otoscopes in the Welch Allyn '998 patent, "permit visualization within the ear," and that plaintiff has omitted certain evidence from its submissions that would show as much. (D. Rep. at 5.) It is not necessary to this decision to resolve this dispute about the extrinsic evidence.

Finally, plaintiff offers the testimony of a purported expert against adoption of defendants' construction. However, this testimony largely recites the extrinsic documentary evidence about "the earliest otoscopes" and operating otoscopes, which, as already discussed, does nothing for plaintiff's case. (*See* Decl. of Jack J. Wazen, M.D. para. 6, 7.) All it offers in addition is the witness's endorsement of plaintiff's proposed construction of "otoscope," apparently based on his 30 years' experience using otoscopes in the field of otolaryngology. (*See id.* para. 1, 4, 5.) As claim construction presents a question of document interpretation, and the standard interpretation rule requires that a term should be defined in a way that

comports with the document as a whole, the adoption of an expert's testimony about a definition will depend on whether the definition "fully comports with the specification and claims and so will preserve the patent's internal coherence." *Markman*, 517 U.S. at 390, 116 S.Ct. 1384. Because "[a]ny other rule would be unfair to competitors who must be able to rely on the patent documents themselves," "expert testimony ... may not be used to vary or contradict the claim language." *Vitronics Corp.*, 90 F.3d at 1584. Even where there is intrinsic ambiguity that credible expert testimony purports to clarify, courts are not compelled to rely on such testimony. *Markman*, 517 U.S. at 387, 116 S.Ct. 1384 (Courts may "avail themselves" of expert testimony but "are not ... obliged to blindly follow" it.) (citation omitted). Therefore, even if the Court were to deem the intrinsic evidence insufficient to support adopting defendants' construction of otoscope, which it does not, and even if plaintiff's witness were to be credited as a qualified expert, the testimony would be rejected as advancing a definition that contradicts the internal coherence of a patent that requires a means for visualizing earwax removal.FN6

FN6. Whether deliberately or not, witness Wazen does not specifically state that he understands an otoscope, in the context of the '711 patent, *not* to enable visualization of the ear canal via light and lens.

Because the intrinsic evidence dictates an interpretation of the disputed claim term in accordance with the defendants' proposed construction; because, even if it were properly considered, the extrinsic evidence suggests no reason to adopt plaintiff's proposed construction instead; and because understanding the otoscope to be an instrument fitted with a light and lens and used for visual examination of the inner ear means defendants' device, which undisputedly lacks such features, cannot literally have infringed the otoscope-requiring '711 patent, judgment of no literal infringement is granted to defendants.

III. Infringement Under the Doctrine of Equivalents

[12] [13] [14] Plaintiff contends that, even if defendants' product cannot be found literally to infringe the claim of the '711 patent, because it lacks an otoscope as defined in this case, it may nevertheless be found to infringe under the doctrine of equivalents. A device that "performs substantially the same function in substantially the same way to obtain substantially the same result" as a patented device infringes under the doctrine of equivalents. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950); *see also* *Texas Instruments*, 90 F.3d at 1566 (infringement under the doctrine of equivalents will be found where "the differences between the accused product or process and the claimed invention are insubstantial"). A patentee may claim those "insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* ("Festo II"), 535 U.S. 722, 733, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). Whether an accused device infringes under the doctrine of equivalents is a question of fact, *Abraxis Bioscience, Inc. v. Mayne Pharma (USA), Inc.*, 467 F.3d 1370, 1375, 1380 (Fed.Cir.2006), to "be determined against the context of the patent, the prior art, and the particular circumstances of the case," *Graver Tank*, 339 U.S. at 609, 70 S.Ct. 854.

Defendants argue that plaintiff's claim under the doctrine of equivalents fails as a matter of law, for two separate reasons. Neither warrants summary judgment.

A. Prosecution History Estoppel

[15] [16] First, defendants argue that plaintiff is estopped from utilizing the doctrine of equivalents. A patentee may be estopped from asserting equivalence-infringement "for subject matter relinquished when a

patent claim is narrowed during prosecution." *Conoco, Inc. v. Energy & Environmental Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed.Cir.2006). Such prosecution history only operates to estop an accuser if (1) an amendment made during the prosecution "narrowed the literal scope of a claim" and (2) "the reason for that amendment was a substantial one relating to patentability." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* ("Festo III"), 344 F.3d 1359, 1366 (Fed.Cir.2003).

Defendants argue that plaintiff is estopped from asserting equivalence-infringement as to the otoscope element of the claim, because the inventor during prosecution narrowed the claim in a way that should be taken to have relinquished any equivalence argument as to non-otoscope devices. Plaintiff amended its claim in response to a rejection of the patent application that cited the second paragraph of 35 U.S.C. s. 112 and deemed the submitted claim language to be "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Weiss Decl., Ex. C, Prosecution History of '711 Patent, Office Action para. 8.) FN7 The examiner wrote, "Claim 1 is confusing because it is unclear if an otoscope is used or not. The preamble suggests using the otoscope, while the body of the claim is merely directed to the tip of the otoscope. It is suggested that applicant add a step of 'providing an otoscope' to clarify that an otoscope is used." (*Id.*) The preamble of the claim FN8 as submitted to the PTO read, "A method of irrigating a patient's ear using an otoscope of a type having an operating mode of flushing cerumen therefrom with body temperature water ..." (Weiss Decl., Ex. A, ' 711 Patent, col. 4.) Next, the proposed body of the claim stated, "... said method comprising the steps of configuring a tip of said otoscope ... [,] selecting a tip outside diameter that is slightly oversized ... [,] inserting said tip into said ear canal, [etc.]." (*Id.*)

FN7. Plaintiff does not and cannot seriously contend that overcoming this statute-based indefiniteness rejection did not constitute a "reason for [the] amendment [that] ... was a substantial one relating to patentability" meeting the second half of the *Festo III* estoppel test. 344 F.3d at 1366.

FN8. "The preamble of a patent claim consists of the words at the beginning of the claim that precede the transitional phrase It ... provides a context in which to understand the specific statements of included components set out in the body." 1 *Moy's Walker on Patents* s. 4:99 (4th ed. 2006). For instance, in a claim which states, "We claim: 1. An improved sealable vial comprising [*sic*]: a tubular body sealed at one end and having an aperture formed at the opposite end; a deformable sealing insert attached to the tubular body ...; and a cap for attachment to the tubular body ...," the preamble consists of the phrase, "[a]n improved sealable vial." *Id.*, quoting claim 1 of U.S. Patent No. 4,390,111.

In response to the examiner's indefiniteness rejection, the inventor amended the claim to add three words to the body, changing it from "... said method comprising the steps of configuring a tip of said otoscope ..." to "... said method comprising the steps of *providing an* otoscope, configuring said a tip of said otoscope ..." (Weiss Decl., Ex. C, Prosecution History of '711 Patent, Response to Office Action at 2, emphasis added.) Defendants interpret this amendment as having a narrowing effect-in other words, rendering the claim post-amendment to cover a different, more confined universe of possible devices than it covered pre-amendment. Specifically, defendants contend that the inventor narrowed the claim to require use of an otoscope in its entirety, where before the claim had at most required use of an otoscope tip (not the light or lens): "An invention that requires an otoscope (i.e., Claim 1 as issued) is narrower than an invention that does not require an otoscope (i.e., Claim 1 before it was amended)." (D. Rep. at 8.)

To the contrary, however, the patent record supports plaintiff's explanation of the amendment as not narrowing but merely "clarify[ing]" the claim. (P. Opp. at 16.) The record shows that it was always discernible, if perhaps at first unclearly expressed, that the claimed method required use of an otoscope, as here construed, in its entirety. *See* Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1377 (Fed.Cir.2001) (amendment did not narrow claim when it "did nothing more than make express what had been implicit in the claim as originally worded"). The portions of the final specification, including a drawing depicting a light and lens that supports the construction of "otoscope" in this case, are effectively identical to the materials initially submitted to the PTO as part of the patent application. Indeed, the PTO examiner's rejection shows that she understood the method to require use of an otoscope in its entirety and merely wished the applicant to avoid any misperception that only the otoscope's tip was required; she did not suggest that the inventor choose to claim either the tip or the entirety of the otoscope, but rather suggested-with the apparent assumption that the entirety was always intended-"that applicant add a step of 'providing an otoscope' to *clarify* that an otoscope is used." (Weiss Decl., Ex. C, Prosecution History of '711 Patent, Office Action para. 8, emphasis added.)

[17] The rest of the examiner's office action-finding the claim to be obvious in light of a prior-art use of an otoscope for "visual control" (Weiss Decl., Ex. C, Prosecution History of '711 Patent, Office Action para. 10), as discussed above-also supports interpreting the claim amendment as merely clarifying an extant use of an entire otoscope rather than newly narrowing the claim to provide for such use. Defendants point to nothing, in the applicant's response amending the claim or anywhere else in the record, contradicting this interpretation of the amendment. (*See id.*, Response to Office Action.) While even an amendment to clarify a claim description may give rise to estoppel, it will do so only where the amendment is also deemed to have narrowed the proposed claim. *See* Festo II, 535 U.S. at 737, 122 S.Ct. 1831 (estoppel may apply " *if a s. 112 amendment is necessary and narrows the patent's scope-even if for the purpose of better description*") (emphases added); *see also* 5B-18A Donald S. Chisum, *Chisum on Patents*, s. 18.05 [2] (2007) ("An estoppel does not arise where the applicant amends a claim [to comply with the second paragraph of 35 U.S.C. s. 112] for purposes of clarity without substantially changing its meaning," thus not "indeed narrow[ing] the claim element."). Here, because the amendment cited did not "narrow[] the literal scope of [the] claim," Festo III, 344 F.3d at 1366, but merely clarified an extant and already evident use of an entire otoscope, plaintiff is not estopped from arguing that defendants' no-otoscope method is an infringing equivalent to the '711 patent's method.

B. Sufficiency of Plaintiff's Proof

[18] [19] Second, defendants argue that, even if plaintiff is not estopped from arguing infringement under the doctrine of equivalents, summary judgment should nevertheless be awarded to them, because plaintiff has failed to indicate sufficient proof of its claim. To prove a claim of infringement under the doctrine of equivalents, "a patentee must provide particularized testimony and linking argument as to the insubstantiality of the differences between the claimed invention and the accused device or process, or with respect to the function, way, result test when such evidence is presented to support a finding of infringement under the doctrine of equivalents." *AquaTex Industries, Inc. v. Techniche Solutions*, 479 F.3d 1320, 1328 (Fed.Cir.2007).FN9 It is true, as defendants point out, that plaintiff on this motion has neither indicated any particularized proof nor explained even in argument form how defendants' non-otoscope device could be found to be equivalent to plaintiff's otoscope-incorporating device. While the Court of Appeals' rationale in dictating this evidentiary burden-essentially, to assist lay factfinders in assessing the relative characteristics of often obscure materials-would seem to carry varying urgency depending on the nature of the subject matter in question, plaintiff here has not met even a threshold version of its burden. *See id.* at 1329

("[W]hen the patent holder relies on the doctrine of equivalents, as opposed to literal infringement, the difficulties and complexities of the doctrine require that evidence be presented to the ... fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents.").

FN9. The "function, way, result inquiry" entails "[a]n analysis of the role played by each element in the context of the specific patent claim ... [to determine] whether a substitute element matches the function, way, and result of the claimed element." *AquaTex Industries*, 479 F.3d at 1326 (internal quotation marks and citations omitted).

However, given the procedural history of this case, plaintiff's seeming deficiency of evidence and argument on this front appears to be the product of its perception of the stage of litigation, and not necessarily to suggest a shortcoming on the merits. The Court's previous opinion in this case, No. 06 Civ. 5821, 2007 WL 14609 (S.D.N.Y., Jan. 2, 2007), resolving a dispute as to how the litigation should go forward, defined the nature of the instant motion quite specifically, based on its understanding of the bases of defendants' motion. The parties were ordered to focus their briefing and discovery on two discrete issues: how the term "otoscope" as used in the patent should be construed, and whether plaintiff was precluded from proceeding under the doctrine of equivalents due to prosecution history estoppel. That directive may and should fairly be read not to encompass the issue of whether defendants' product constitutes an equivalent to plaintiff's invention with respect to the claim as properly construed.FN10 Although perhaps not ideal in terms of efficiency, it is nevertheless fair to permit this case to head down the multi-stage pretrial path well trodden by other patent-infringement litigants.

FN10. Indeed, defense counsel appears to have assured plaintiff's counsel that this motion was not to seek judgment on the merits of equivalence and that defendants would not object to plaintiff's taking further discovery on the issue. (*See* Dep. of Burnett at 146-47, exchange between counsel.) To the extent that defendants now seek a dispositive rejection of plaintiff's proof of equivalence prior to such discovery, their motion is ill advised.

Such course is especially advisable as the existing record, even though it is not taken as having been developed with an eye to proving equivalence, nevertheless suggests genuine issues of material fact as to the similarity between defendants' product and plaintiff's claimed method. For instance, as discussed with respect to the issue of literal infringement, the claimed method requires some mode for observing the progress of earwax removal; the otoscope performs that function. Defendants would define the observation-requirement of the claim more narrowly, as a step of "look[ing] deep into the ear to determine if it is clean." (D. Mem. at 2.) However, the patent nowhere explicitly emphasizes the importance of looking *into the ear* to observe the progress of earwax removal; plaintiff has submitted evidence describing defendants' challenged product that suggests a more superficial means for observing such progress. (*See* Weiss Decl., Ex. B, printout of Welch Allyn web pages describing challenged product.) Whether this aspect of defendants' product is equivalent to plaintiff's otoscope, and whether the product is equivalent with respect to every other limitation of the claim, presents a question of fact that should not be determined until, at the earliest, after the parties have had an opportunity for further discovery.

CONCLUSION

For the foregoing reasons, defendants' motion for a judgment of noninfringement is granted as to the claim of literal infringement but denied as to the claim of infringement under the doctrine of equivalents.

SO ORDERED.

S.D.N.Y., 2007.

VDP Patent, LLC v. Welch Allyn Holdings, Inc.

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