United States District Court,
E.D. Pennsylvania.

QUIGLEY CORPORATION,
v.
GUMTECH, INC.

March 9, 2000.

MEMORANDUM

DALZELL**.**

The Quigley Corporation ("Quigley") has sued GumTech, Inc. and other associated entities (collectively, "GumTech") alleging infringement of a patent for a remedy for the common cold. We now consider the defendants' motion for summary judgment FN1, which argues that claims made during the prosecution of the patent bar a finding of infringement against defendants here.

FN1. Because the issues addressed are potentially dispositive, defendants filed the instant motion soon after their Answer to the Complaint, following a scheduling conference with the Court.

I. ***Background***

While there is sharp dispute surrounding the extent of the patent at issue here, the circumstances leading up to the current conflict may be set forth briefly. In March, 1985, the Patent and Trademark Office ("PTO") issued to George A. Eby, III, U.S. Patent No. 4,503,070 (the " '070 patent"). In November 1990, after a prolonged prosecution FN2, the PTO issued reissue patent No. Re 33,465, for a "Method for Reducing the Duration of the Common Cold", which is the patent we are concerned with here (the " ' 465 patent"). While the precise boundaries of the patented invention are in contention, we may say by way of introduction that the patent involves the application of zinc compounds to virus-infected tissues to reduce the symptoms of the common cold.FN3

FN2. The initial application for the reissue was made in April 1986. In fact, it would appear that the process surrounding the original '070 patent was equally drawn-out: prior to the successful prosecution of the ' 070 patent, Mr. Eby had abandoned two patent applications for similar inventions. Though defendants have provided the PTO files for these abandoned applications as Exhibits C and D to their motion for summary judgment, it does not appear that these applications have direct impact on the current motion except insofar as they were referenced essentially as prior related applications in the applications for the '070 and '465 patents.

FN3. Evidently, zinc compounds may inhibit the replication of the cold virus.

In the Fall of 1996, Mr. Eby licensed the '465 patent to Quigley, under the terms of which license Quigley is the sole distributor of cold remedy products falling under that patent.FN4 Quigley now markets a group of products using the patent, under the trademark "COLD-EEZE". These products are evidently all applied to the mouth in, for example, the forms of lozenges or chewing gum. GumTech also manufactures a product intended to relieve the symptoms of the common cold, under the trade name of ZICAM. ZICAM is a "nasal gel" containing "zincum gluconium" as its active ingredient, which is administered into the nose by the means of a nasal pump. *See* Ex. B, Pl.'s Brief in Opp'n to Defs.' Mot. for Summ J., ZICAM Packaging and Instructions.

FN4. In accord with the various defenses asserted in the Answer, GumTech avers that Quigley's ownership of the patent and the validity of the patent, among other facts, remain in dispute, but defendant has, for the purposes of its motion, assumed these in the favor of the plaintiffs since they are not material to this motion. We will do the same.

Quigley has sued GumTech for patent infringement, claiming that ZICAM is covered by one or more of the claims in the '465 patent. Following our initial scheduling conference, GumTech filed the instant motion as a means of allowing us immediately to resolve its affirmative defense that the arguments Mr. Eby made to the Patent Office during the prosecution of the '465 patent FN5 estop a finding that ZICAM infringes that patent.FN6

FN5. As well as the precursor '070 patent.

FN6. This was asserted as GumTech's First Affirmative Defense in the Answer, *see* Ans. para.para. 24-49.

II. ***Analysis***FN7

FN7. A summary judgment motion should only be granted if we conclude 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). In a motion for summary judgment, the moving party bears the burden of proving that no genuine issue of material fact is in dispute, *see* Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp., 475 U.S. 574, 585 n. 10 (1986), and all evidence must be viewed in the light most favorable to the nonmoving party, *see* id. at 587. Once the moving party has carried its initial burden, then the nonmoving party "must come forward with 'specific facts showing there is a genuine issue for trial,' " Matsushita, 475 U.S. at 587 (quoting Fed.R.Civ.P. 56(e)) (emphasis omitted); *see also* Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (holding that the nonmoving party must go beyond the pleadings to show that there is a genuine issue for trial).

The mere existence of some evidence in support of the nonmoving party will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue, *see* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). However, we must "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pennsylvania Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir.1995).

A. ***Pertinent Patent Law Standards***

The parties' arguments invoke a number of distinct legal standards. It will aid the analysis to outline these standards at the outset.

1. ***Literal Patent Infringement***

"To prove literal infringement, the patentee must show that the accused device contains every limitation in the asserted claims. If even one limitation is missing or not met as claimed, there is no literal infringement." Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999) (quoting Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed.Cir.1998)). "An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed.... The second step is comparing the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (citation omitted). With respect to the first step, "the court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim. As such, a patent covers the invention or inventions which the court, in construing its provisions, decides that it describes and claims." Markman, 52 F.3d at 979 (internal quotation marks omitted).FN8 Therefore, to the extent that the dispute here "turns solely on the legal question of the proper construction of the claims," it is amenable to summary judgment. Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1371 (Fed.Cir.1998).FN9

FN8. *Markman's* holding that claim construction was a matter for the court to decide, rather than for the jury, resolved prior inconsistencies in the Federal Circuit's jurisprudence, *see* Markman, 52 F.3d at 979, and was affirmed by the Supreme Court, *see* Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384 (1996).

FN9. Of course, to the extent that once we have completed the claim construction there are still factual issues outstanding, then the standards for summary judgment discussed in note 7 will come into play. That is, even after we determine, as a matter of law, what it is that the '465 patent covers, we still need to answer the question of the existence of disputed issues of material fact as to whether ZICAM in fact infringes.

In ascertaining the meaning of claims, we may consider the claims, the specification, and the prosecution history from the patent record itself. This "intrinsic" evidence is the most "significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). In addition, we may in some circumstances consider "extrinsic" evidence, such as "expert testimony, including evidence of how those skilled in the art would interpret the claims," Markman, 52 F.3d at 979, as well as dictionaries and learned treatises, *see* id. at 980-81. We now detail further the use of these sources in interpreting claims.

We first look "to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." Vitronics, 90 F.3d at 1582. Generally, words in the claims are "given their ordinary and customary meaning", though a meaning other than the ordinary one may be used "as long as the special definition of the term is clearly stated in the patent specification or file history." *Id*. (citing Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d. 1575, 1578 (Fed.Cir.1996) and Hormone Research Found., Inc. v. Genentech, Inc ., 904 F.2d 1558, 1562 (Fed.Cir.1990)).

Second, we examine the specification, which contains a "written description of the invention that must

enable one of ordinary skill in the art to make and use the invention." Markman, 52 F.3d at 979. Claims are read in light of the specification, of which the claims are a part, *see* Markman, 52 F.3d at 979, and we "review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. However, "[t]he written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." Markman, 52 F.3d at 980.

Third, we may consider the patent's prosecution history in interpreting the claims, *see* Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 980 ("The court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims."). The prosecution history is the complete record of proceedings before the PTO, and includes, *inter alia,* express representations the applicant made regarding the scope of the claims. *See* Vitronics, 90 F.3d at 1582. Moreover, we may also consider prior art cited within the history, *see* id. at 1583. On the other hand, "[a]lthough the prosecution history can and should be used to understand the language used in the claims, it too cannot enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 980 (internal quotation marks omitted).

Finally, "[t]he court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent." Markman, 52 F.3d at 980 (quoting Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1871)). "Extrinsic" evidence is anything outside of the patent and its prosecution history, to include expert and inventor testimony, dictionaries, and learned treatises, and can also be used to help explain scientific principles and to demonstrate the prior art at the time of the invention. *See* Markman, 52 F.3d at 980. Again, however, "[e]xtrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims," id. at 981.

2. *The Doctrine of Equivalents*

Under the doctrine of equivalents, "an accused product that does not literally infringe a claim may infringe 'if it performs substantially the same function in substantially the same way to obtain the same result.' " Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 797 (Fed.Cir.1990) (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950)). This doctrine "must be applied to individual elements of the claim, not to the invention as a whole" because each element of the claim is "deemed material to defining the scope of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S.Ct. 1040, 1049 (1997). "Whether an element of the accused device is equivalent to a claim limitation depends on 'whether the substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.' " Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed.Cir.1998) (quoting Warner-Jenkinson, 117 S.Ct. at 1054). Infringement under the doctrine of equivalents is a question of fact, and thus is for the jury, but there are several legal limitations on the doctrine that remain within the court's province. *See* K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1366 (Fed.Cir.1999).FN10

FN10. The doctrine of equivalents "exists in some tension with other core tenets of patent law, perhaps most notably the requirement that the patentee particularly point out and distinctly claim the subject matter which the applicant regards as his invention," and for this reason the doctrine is subject to legal limitations. K-2 Corp., 191 F.3d at 1366 (quoting 35 U.S.C. s. 112 para. 2).

The first conceptual limitation to which the doctrine of equivalents is subject is exactly that the doctrine is indeed limited. The doctrine "cannot allow a patent claim to encompass subject matter that could not have been patented; nor can it be used to ignore the actual language of the patent." K-2 Corp., 191 F .3d at 1367. Thus, for example, the doctrine of equivalents cannot allow a patent to expand to include things in the prior art or obvious variations of the prior art, nor can the doctrine "vitiate an element from the claim in its entirety," since each element is material to the extent of the claim. *Id*.

"The second conceptual limitation on the doctrine of equivalents is the idea that the patentee may not use the doctrine to recover subject matter that has been surrendered." *Id*. Thus, if the prosecution history shows that the inventor relinquished subject matter by amendment or argument, this subject matter cannot be brought back into the patent through the doctrine of equivalents, *see id*.FN11 With respect to this, particular subject matter that is disclosed in the specification but not claimed is deemed to have been surrendered, *see id*. at 1368.

FN11. This "prosecution history estoppel" is thus a second use of the prosecution history, the first being its use as an aid to interpreting the language of the claim during literal infringement analysis.

Having mapped out the legal rules to guide us in our endeavor here, we now turn to the analysis of the facts before us.

B. ***Is the*** '465 Patent ***Infringed?***

1. ***Literal Infringement***

a. ***Claim Interpretation***

Clearly, our analysis must begin with an examination of the language of the disputed claims. The independent FN12 claims of the ' 465 patent are:

FN12. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. s. 112. "One may infringe an independent claim and not infringe a claim dependent on that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552 n. 9 (Fed.Cir.1989).

1. The method of administering an agent to reduce duration of common cold symptoms in humans, which includes reducing the duration of nasal drainage, nasal congestion, headache, fever, myalgia, sneezing, sore throat, scratchy throat, cough, and hoarseness when such symptoms evince existence of a common cold, comprising:
applying, in the form of a lozenge, zinc gluconate to the oral mucosa of a human in need of treatment;

permitting zinc to remain in contact with the mucosa for a period of time necessary for lozenges to dissolve;

and applying additional dosages of zinc until the symptoms have disappeared.

....

4. A method for treating the common cold comprising:

(a) applying an effective dosage of zinc gluconate to the oral mucosa of a human in need of treatment;

(b) permitting the zinc thereof to remain in contact with the oral mucosa for a period of time necessary for it to saturate the oral mucosa; and

(c) applying additional dosages to [*sic*] zinc gluconate in like fashion until the cold has been treated.

....

18. A method for treating symptoms commonly associated with the common cold, the symptoms including nasal drainage, nasal congestion, headache, fever, myalgia, sneezing, sore throat, scratchy throat, cough or hoarseness to reduce the duration or severity thereof comprising:

(a) applying an effective dosage of zinc gluconate to the oral mucosa of a human in need of treatment;

(b) permitting the zinc thereof to remain in contact with the oral mucosa for a period of time necessary for it to saturate the oral mucosa; and

(c) applying additional dosages of zinc gluconate in like fashion until the severity or duration of the symptom has been reduced.

Ex. E, Defs.' Mot for Summ. J., U.S. Patent No. Re. 33,465.
With respect to Claim 1, we first observe that one of the elements of the claim is that the cold remedy be applied "in the form of a lozenge". As discussed above, literal infringement is found only where each and every limitation of the claim is found in the accused device, *see* Elkay Mfg., 192 F.3d at 980. Here, there is no dispute that ZICAM is not dispensed in lozenge form, and thus an allegation of literal infringement as to Claim 1 must fail. FN13

FN13. Quigley focuses its argument regarding literal infringement on Claim 4, and thus it appears that this finding with respect to Claim 1 is not disputed. Moreover, as Claims 2 and 3 are dependent on Claim 1, our finding that there is no literal infringement of Claim 1 means that there is no literal infringement of Claim 2 or 3, either.

Claims 4 and 18 FN14 present a harder question, because they do not appear to specify the method of delivery for the zinc compound.FN15 However, Claims 4 and 18 do specify that the zinc compound is to be applied to the "oral mucosa," and on this point the parties differ. GumTech argues that because its product is a "nasal gel" that is "applied intranasally", it simply cannot be said to apply a dose of zinc gluconate to the *oral* mucosa, and that, in addition, the nasal gel does not in any event remain in contact with the oral mucosa for a period of time sufficient to saturate the oral mucosa, as is required by the second element of

the claim. In support, GumTech offers the declaration of Gary Kehoe, president of GumTech International, who states that "The ZICAM nasal gel accused of infringement is not applied to the oral mucosa." Decl. of Gary Kehoe para. 3. GumTech also claims that statements Mr. Eby made in the process of prosecuting the ' 465 patent foreclose the application of that patent to "any method or product where zinc compounds are applied to the nasal mucosa, i.e., applied intranasally." Defs.' Brief in Supp. of Mot. for Summ. J. at 12.

FN14. It is worth noting that Claims 4 and 18 were added to the patent during the reissue process, while Claim 1 was in the original ' 070 patent. To the extent that Mr. Eby's efforts to obtain a reissue patent were meant to broaden the scope of the patented device, these two claims represent some of the fruits of that effort.

FN15. There does not appear to be dispute that the "zincum gluconium" present in ZICAM is in fact zinc gluconate, the subject matter of the ' 465 patent.

In response, Quigley argues first that ZICAM's nasal gel does indeed reach the "oral mucosa". Quigley notes that ZICAM's instructions direct the user to blow his nose before pumping in the gel, which, Quigley avers, results in the gel's application to the oral mucosa. Quigley also offers an affidavit by Dr. Andrew Goldberg, M.D.FN16, stating his opinion that ZICAM "delivers its spray gel to the user in such a way as to result in the application of zinc gluconium to the oral mucosa as that term is defined in United States Patent No. Re. 33,465." Ex. E, Pl.'s Opp'n to Defs.' Mot. for Summ. J., Affidavit of Dr. Andrew Goldberg, M.D. para. 4 (hereinafter "Goldberg Affidavit").FN17

FN16. An Ear, Nose, and Throat specialist at the Hospital of the University of Pennsylvania.

FN17. Quigley also argues that ZICAM must work on the oral mucosa because GumTech has in the past cited studies involving the application of zinc compounds to oral mucosa to support ZICAM's efficacy. In particular, Quigley cites several letters from GumTech's counsel to the National Advertising Division of the Council of Better Business Bureaus (the "NAD"). This organization is an industry self-regulation group that oversees claims made in national advertising, *see* Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 8 n. 9. In the Fall of 1999, Quigley, through the NAD, "challenged" the claims made regarding ZICAM's effectiveness. In response to this challenge, GumTech's counsel sent (at least) two letters, totaling thirty-seven single-spaced pages, to the NAD, which argued, in part, that the content of ZICAM's advertising was proper, *see* Exs. C & D, Pl.'s Opp'n to Defs.' Mot. for Summ. J., Ltrs. from Gary L. Yingling, Esq. to Andrea C. Levine, Esq. of Oct. 20, 1999 and Nov. 30, 1999.

Quigley's challenge, in part, claimed that GumTech relied on only one study to document ZICAM's effectiveness. In response to this, GumTech argued that ZICAM's effectiveness was supported by various studies of the effectiveness of zinc compounds on cold symptoms, as well as by the Homeopathic Pharmacopeia of the United States (the "HPUS") and homeopathic experts. Quigley points out that several of the studies cited by GumTech were studies supporting the effectiveness of zinc compounds applied to the *oral* mucosa, and that one of these was in fact Quigley's own study supporting the efficacy of COLD-EEZE. Quigley then argues that "GUMTECH's assertion that these studies support ZICAM's efficacy can only mean that GUMTECH *knows* that ZICAM delivers zinc gluconate to the oral mucosa" and that consequently ZICAM infringes on the '465 patent. Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 9.

We do not agree that the citation of these studies amounts to an admission that ZICAM works on the oral mucosa, nor that it creates an inference to that effect. For one thing, GumTech's letter citing the studies goes on to say that "[w]hile these three studies tested zinc in the form of a lozenge, the data from these studies can certainly be extrapolated to support the use of zinc generally in the treatment of the common cold. This is so especially in light of the fact that it appears to be a well-accepted theory that zinc ions would be most effective in treating the common cold if applied directly to the nasal cavity." Ex. D, Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 17. It is clear from the context that GumTech acknowledges that ZICAM does not fall within the direct ambit of the studies, and also that there is a claimed distinction between the subject of the studies-lozenges-and ZICAM's application to the "nasal cavity".

Moreover, that GumTech might seek to rely upon the studies of *oral* applications to support a *nasal* product is supported by the fact that elsewhere in its letter GumTech avers that under the practice of homeopathic medicine-and ZICAM is a "homeopathic" product according to its labelling-once an ingredient has been "proved" and listed in the HPUS, the form of dosage does not matter. Ex. D, Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 4-5. Therefore, it is not surprising that GumTech would argue that studies about the oral application of zinc would equally provide support for the nasal application of the same substance. We cannot therefore infer from GumTech's citation of these studies that ZICAM must operate on the oral mucosa or take this citation to be an admission of such a fact.
Quigley argues further that ZICAM is designed to remain in contact with the oral mucosa for a period of time sufficient for it to saturate that mucosa, the second element of Claims 4 and 18. Quigley points to ZICAM's packaging, which refers to a "constant release and long-lasting suspension of its active ingredient", Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 16. Finally, Quigley claims that ZICAM's instructions for use (directing repeated application of ZICAM, including the use of ZICAM for a forty-eight hour period after symptoms subside) fall under the last element of Claims 4 and 18, which discloses the application of additional doses "until the cold has been treated."

As with Claim 1, our analysis of the scope of Claims 4 and 18 must begin with their language. An obvious initial question is the meaning of the term "oral" used in the claim. The "ordinary and customary" meaning of "oral" would appear in this context to be "of or pertaining to the mouth, as a part of the body." X *The Oxford English Dictionary* 886 (2d ed.1989) (def.3(a)). However, in the specification of the '465 patent, "oral mucosa" is defined as the "lining of the mouth, tongue, and throat," U.S. Patent No. Re. 33,465 at col. 3 line 44, and since, as noted above, the specification may serve to provide definitions of terms used in the claims, we find that this is the proper definition of "oral mucosa" for the purpose of interpreting the claim. FN18 In particular, we note here that the patent's definition of "oral mucosa" clearly excludes nasal membranes from the patent claims. Thus, to the extent that ZICAM infringes the ' 465 patent, it must result from its application to the oral mucosa. As the parties dispute whether it is so applied, we will discuss this more below.

FN18. In its pleadings, Quigley states that "[t]he '465 Patent discloses and claims application of zinc gluconate to the 'oral' or 'pharyngeal' mucosa ... further defined in the specification as the lining of the mouth, tongue and throat.' " Pl.'s Opp'n to Defs .' Mot. for Summ. J. at 4. As noted in the text, we agree with the use of the definition from the specification, but we would note that this is not given in the specification as a definition for "pharyngeal" mucosa. In fact, "pharyngeal" mucosa would appear to be distinct from "oral" mucosa because the "Detailed Description of the Invention" in the specification states "Such method

involves administration of ... zinc compounds ... to oral, pharyngeal and/or nasal mucosal membranes." U.S. Patent No. Re. 33,465 at col. 2 lines 62-65. The pharyngeal mucosa is therefore not part of the patent claims, which mention only "oral". We note for reference that the pharynx-which, again, is an area of the body not part of the claims here-is "The cavity, with its enclosing muscles and mucous membrane, situated behind and communicating with the nose, mouth, and larynx, and continuous below with the oesophagus; forming a passage from the mouth for the food and drink, and from the nasal passages for the breath." XI *The Oxford English Dictionary* 664 (2d ed.1989).

Our next step in interpreting the language of the claim is to examine the prosecution history to find if that history further illuminates the "true meaning" of the '465 claims. During the prosecution of the '465 patent, the examiner on March 4, 1988 rejected all of the pending claims as obvious with respect to prior art and with particular reference to the art taught in, *inter alia,* the *Modern Drug Encyclopedia*FN19, which includes a listing for an "aqueous solution of zinc borate 2% .... *For use* as astringent, decongestant in common colds. *Applied* by spray ... 4 to 10 drops in each nostril or eye, several times daily." *Modern Drug Encyclopedia* 1168 (Marion E. Howard ed., 6th ed. n.d.).

FN19. Two different versions of this work are referenced. The examiner lists it as "ed. by Gutman or Howard", and an examination of the file contents reveals photocopied extracts of both an edition edited by Jacob Gutman and a later sixth edition edited by Marion E. Howard. There are no material differences between the pertinent entries in the two versions.

Subsequently, Mr. Eby, through counsel, filed a response with the PTO that sought to distinguish his invention from the art taught in the *Modern Drug Encyclopedia*.FN20 This response contains a number of statements that GumTech alleges to be of signal importance in defining the limits of the scope of the ' 465 patent's claims. Mr. Eby stated to the PTO that:

FN20. We note that the examiner's rejection included reference to other prior art besides the *Modern Drug Encyclopedia,* and Mr. Eby's response naturally sought to distinguish his invention from these other references as well, but it is the responses to the *Modern Drug Encyclopedia* that GumTech cites.

For example, Modern Drug appears to indicate utility only in connection with application to the nostril or eyes, and then only as an astringent or decongestant. However, Mr. Eby's invention is directed to the application of zinc ions to the *oral* mucosa, and excludes application to the nasal or opthalmic membranes. This is based on Mr. Eby's finding that application of ionizable zinc to the *oral* mucosa is an important aspect of the invention. By suggesting application to the nasal membrane or eyes, Modern Drug in fact teaches *away* from the invention by teaching routes believed to be inoperative.
Ex. F2, Defs.' Mot. for Summ. J., George Andrew Eby III Response to Official Action Mailed March 4, 1988 at 6 (emphasis in original). Later, Mr. Eby argues:
[The prior art] fails to teach or suggest the *claimed* invention. For example, none of the art contains *any* indication of the importance of application of zinc ions to the *oral* mucosa. Both Loose and Modern Drug, in fact, indicate to the contrary, with Loose indicating principally an application to the *eyes,* and Modern Drug requiring application to the *nostril or eyes*. Neither of these routes are included within the scope of the claimed invention-in fact, the inventor has found that application to the *oral* mucosa is critical, in that nasal application does not appear to provide a common cold treatment.

Id. at 9-10 (emphasis in original). Similarly, Mr. Eby also says, "Furthermore, the inventor has on various occasions tested a zinc gluconate spray intranasaly [*sic*], and it was not found to be effective in cold treatment." Id. at 5. In a separate, later declaration, Mr. Eby stated to the examiner that his early experiments in the area had included use of a "zinc gluconate nasal spray solution[ ]" and that these had resulted in "extreme nasal pain." George Andrew Eby III Declaration dated December 13, 1988 at 5.
At this stage in claim interpretation, the question before us with respect to these statements is whether they serve to reveal the true meaning of the language used in the claims themselves, with the proviso that, as discussed above, we cannot use the prosecution history to "enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 980. From its pleadings, it appears that GumTech would like us to take the prosecution history to show that the "true meaning" of the phrase "A method for treating ..." in Claims 4 and 18 to be "A method, not including those methods involving a nasal spray, for treating ..." FN21

FN21. As discussed above, the language of the claims and specification of the '465 patent show that the patent is restricted to applications of zinc compounds to the "lining of the mouth, tongue, and throat." Quigley does not claim that the prosecution history in any way changes that definition.

We find that the prosecution history cannot so limit our interpretation of the claim. Mr. Eby's communication with the PTO certainly makes clear that he is focused solely on application to the oral mucosa, and that application to other mucosa, in particular the nasal mucosa, is not a part of his claimed invention.FN22 Mr. Eby even, as quoted above, averred that he had found a nasal spray to be ineffective.FN23 Nonetheless, we cannot take these statements to change the meaning of the claim into a form palatable to GumTech. The plain language of Claims 4 and 18 refers to "A method." FN24 Were we to employ the prosecution history to exclude various methods from this locution, we would unquestionably be "diminishing" the limitation of the claim, which is exactly what we *cannot* do at this stage.FN25

FN22. Our findings above show that the claims of the patent are indeed limited to application of zinc gluconate to the "lining of the mouth, tongue, and throat."

FN23. We do note that the statement in the March 4, 1988 Response, at least, was made in the context of explaining why application to the nasal, as opposed to oral, mucosa was outside of his invention.

FN24. While we may be struck with the breadth of the "a method" locution in the patent claims, "[a]mbiguity, undue breadth, vagueness, and triviality are matters which go to claim *validity* ... not to interpretation or construction." Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989), and "[n]o matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them." *Id*.

FN25. In support of its argument that the prosecution history of the '465 patent forecloses application of that patent to ZICAM, and in particular in reply to Quigley's argument that counsel's statements during patent prosecution ought not be read to limit the patent claims, GumTech cites to a number of cases in which a court has in fact used prosecution history estoppel to limit the claims made by an inventor. Moreover, GumTech avers that, in general, the cases in which the prosecution history is used to limit the patent claims

greatly outnumber those in which courts find that the statements in the history were mistaken and do not give rise to estoppel. However, the cases to which GumTech points address circumstances in which the court employed prosecution history estoppel in the context of analysis under the doctrine of equivalents. As discussed above, the doctrine of equivalents is only employed following a finding that there is no literal infringement, and we are not yet at that stage. Instead, we are here still engaged in claim interpretation, where the standards are distinct from those pertaining to the doctrine of equivalents.

Also with respect to the use of prosecution history, the parties have devoted much space to briefing the claimed implications of Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050 (Fed.Cir.1989), and it is therefore appropriate to discuss it in some detail here. In *Intravet,* the inventor's counsel had, during the prosecution of the patent, accompanied an amendment of the claims sent to the PTO with a statement restricting the scope of the invention and the patent claims. *See* id. at 1054. This statement, however, was admittedly false-the invention was not limited in the way counsel stated. *See id*. Moreover, notwithstanding counsel's comment, the claims themselves were never amended in a way consistent with the comment, and the examiner subsequently approved them in the unamended form. *See id*. *Intravet* held that under such circumstances, in the context of interpreting the claims, the attorney's remark could not override the clear language of the claims. *See id*. The court noted that, in subsequently approving the patent, the examiner was not misled or deceived by the attorney's statements, and that the claims therefore controlled the interpretation. *See id*.

Quigley argues that under this holding, we cannot apply statements in the prosecution history to the patent claims. GumTech argues in reply that *Intervet* is applicable; the examiner here was indeed misled because she relied on the representations in Mr. Eby's communications in approving the patent. Both parties' claims with respect to *Intervet* have some merit. *Intervet* clearly stands for the proposition, as Quigley argues, that at the claim interpretation stage, stray remarks in the prosecution history cannot overcome the approved language of the claim themselves. On the other hand, there is no claim here that Mr. Eby's statements were not true with respect to the limits on his claims, and, in particular, they show that he restricted his claims to applications to the oral mucosa, and the claims themselves bear this out. In any event, we do not find the *Intervet* case to be dispositive in either party's favor.
This brings us to the end of the "claim interpretation" portion of the analysis. As discussed above, we find that the Claims of the '465 patent are restricted to applications of zinc gluconate to the lining of the mouth, tongue, and throat. We also find that the Claims do indeed extend to any method of delivery to the lining of the mouth, tongue, and throat, and in particular to a method of delivery to the oral mucosa that involves pumping the zinc gluconate through the nose.

We now move on to examine whether ZICAM infringes these claims.

b. ***Infringement Analysis***

As stated at the outset, once we have established the proper legal construction of the claims, the question of whether an accused product infringes these claims is one of fact. Here, GumTech argues that there is no disputed issue of material fact with respect to infringement, and that summary judgment is therefore appropriate. Specifically, GumTech contends that it is undisputed that ZICAM is not applied to the oral mucosa. It offers the Declaration of GumTech International's president, Gary Kehoe, who states that ZICAM is not applied to the oral mucosa. Also on the basis of Kehoe's Declaration, GumTech avers that ZICAM is a nasal gel, applied intranasally, and that it therefore cannot infringe on the '465 patent.

In response to this, Quigley offers the affidavit of Andrew Goldberg, M.D., who opines that ZICAM is in fact applied to the oral mucosa. GumTech raises a number of arguments as to why this affidavit ought not to guide our decision here. First, it argues that the affidavit does not, in any event, raise a genuine issue of material fact; second, it argues that the affidavit is defective because Goldberg is not competent to testify as he does.

GumTech contends that Goldberg's expert testimony cannot raise a genuine issue of material fact because Goldberg seeks to intrude into the province of the Court by defining how the term "oral mucosa" should be defined in the patent. While such a use of this affidavit may indeed be inappropriate, we do not think that this is the use to which the Goldberg Affidavit is put here. Above, we have concluded that "oral mucosa", as used in the '465 patent, means "the lining of the mouth, tongue, and throat". The Goldberg Affidavit states that "it is my opinion that when used as a nasal spray, the Zicam product delivers its spray gel to the user in such a way as to result in the application of zinc gluconium to the oral mucosa as that term is defined in United States Patent No. Re. 33,465." Goldberg Affidavit para. 4. On its face, and taking inferences in favor of the plaintiff as we must, this does not appear to present us with a legal conclusion, but instead provides a medical opinion that ZICAM, because of its constitution and means of administration, does reach the "oral mucosa". FN26

FN26. Goldberg's conclusions are cited by Quigley in a section of their brief headed "ZICAM is a Method for Treating the Common Cold Which Applies an Effective Dose of Zinc Gluconate to The Oral Mucosa ." *See* Pl.'s Brief in Opp'n to Defs.' Mot. for Summ. J. at 15. Clearly, the use of the Goldberg Affidavit goes to what it is that ZICAM does, not what the patent claims mean.

In support of its claim that such expert testimony does not create an issue of material fact, GumTech cites to Southwall Techs ., Inc. v. Cardinal IG Co., 54 F.3d 1570 (Fed.Cir.1995), Markman, 52 F.3d at 967, and Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792 (Fed.Cir.1990). None of these cases directs us to disregard Dr. Goldberg's testimony. *Southwall, Markman,* and *Becton* are easily distinguished because the expert testimony discussed-and disregarded-was in each case presented for the purpose of claim construction, *see* Southwall, 54 F.3d at 1577-78; Markman, 52 F.3d at 982, while the Goldberg Affidavit is proffered to present an issue of material fact at the infringement analysis stage.FN27

FN27. *Southwall* is a closer case with respect to this because the party presenting the expert evidence had, according to the court, conflated the processes of claim interpretation and literal infringement, *see* Southwall, 54 F.3d at 1577. However, even assuming that *Southwall* was an infringement analysis, this still would not compel us to disregard Goldberg's testimony. In *Southwall* the court's criticism of the expert testimony was that to the extent that the testimony attempted to define a term (specifically, "sputter-deposited dielectric"), the testimony did not go to how one "skilled in the art" would define that term, and therefore the expert opinions as to the meaning of the words were merely legal conclusions. *See* Southwall, 54 F.3d at 1577-78.

As noted in the text, we simply do not read Goldberg's Affidavit as an attempt to define "oral mucosa" for us. We also note that the question of what "oral mucosa" means to one "skilled in the art" is not raised in anyone's pleadings here. It appears that GumTech may be interpreting Dr. Goldberg's affidavit to say in effect "ZICAM is indeed applied into the nose, but I'm defining 'oral mucosa' to include the nose." Again, we do not read his statement that way.

Further, the only evidence that GumTech forwards to show that ZICAM is *not* applied to the oral mucosa is the declaration of GumTech International's president, Gary Kehoe, yet that declaration itself contains no definition of "oral mucosa" as Kehoe used it in making his factual declaration. Since the initial burden at summary judgment is on the movant, to the extent that the Goldberg Affidavit is no good, it is unclear how GumTech would meet its burden with the Kehoe Declaration.
In addition to this, GumTech argues that Dr. Goldberg is not competent to testify as he does because there is nothing in his affidavit showing that he reviewed the prosecution history of the patent. Here again we find that GumTech's analysis misses the point of the Goldberg Affidavit. GumTech cites to two cases in support of its competency claim, Datascope Corp. v. SMEC, Inc., 879 F.2d 820, 828 (Fed.Cir.1989) and Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1390 (Fed.Cir.1983). In *Datascope,* the district court had denied the plaintiff's claim that the defendant had willfully infringed its patent, and had justified that finding by noting that the defendant had obtained an opinion from its attorneys that the defendant's use did not infringe. The Federal Circuit reversed, holding that the attorney's opinion could not have reached certain important issues because there had been no review of the prosecution history. *See* Datascope, 879 F .2d at 828. Clearly, in *Datascope* the opinion in question went to legal questions regarding infringement, a readily distinguishable context from Dr. Goldberg's opinion about which mucosa ZICAM reaches.

Similarly, in *Underwater Devices* the court considered whether an attorney's opinion absolved the client of bad faith in its infringing activities, and found that the lawyer's failure to consult the prosecution history, among other things, prevented his opinion from being a proper infringement opinion. *See* Underwater Devices, 717 F.2d at 1390. Once again, this involves an opinion that was intended to go to the legal question of infringement, which is not what Dr. Goldberg's Affidavit goes to here.

We therefore find that Dr. Goldberg's testimony regarding to which mucosa ZICAM is actually applied, based as it is on his experience as a medical doctor, is competent despite his apparent failure to have reviewed Quigley's patent documents.

GumTech also argues that Mr. Eby had every opportunity to patent the nasal gel, but that he failed to do so both in prosecuting the original '070 patent and the reissue '465 patent. Moreover, GumTech avers, "Eby clearly surrendered any right to methods involving application of zinc via the nose by amending his patent claims in his original patent application to limit them to methods of applying zinc to the oral mucosa," and that Goldberg's affidavit should not allow Quigley to change that position. Defs.' Reply Brief in Supp. of Mot. for Summ. J. at 8. This argument ignores the claim that Quigley clearly makes here: that ZICAM is a product that delivers zinc gluconate to the oral mucosa through the nose.FN28 That is, according to Quigley, application of a spray to the nose is not inconsistent with application to the oral mucosa. This claim is exactly what the Goldberg Affidavit supports, not any claim about the meaning of any term in the patent.

FN28. In its pleadings, Quigley also, as noted above, argues that ZICAM's instructions for use, to include the instruction that users clear the nasal passageway prior to pumping ZICAM in, show that ZICAM is meant to go to the oral mucosa. In reply, GumTech argues that such statements, as mere claims within a pleading, are not in evidence, and that "there is no evidence in the record to establish that a user who follows [ZICAM's directions for use] will somehow miraculously 'saturate the lining of the throat, mouth and tongue.' " Defs.' Reply Brief in Supp. of Mot. for Summ. J. at 20. Again, this appears to reverse the burdens applicable here. GumTech seems to assume that there is some form of presumption in place in this case that simply because ZICAM is claimed to be a "nasal gel" and because it is administered through a nasal pump,

then it must work on the nasal mucosa and not the oral mucosa. However appealing this may be to a layperson's common sense, GumTech does not cite any authority that would allow us to give legal effect to such a presumption, especially here at the summary judgment stage, where inferences are taken for the non-moving party, nor is this anything of which we can take judicial notice. We are left, therefore, with, one the one hand, Kehoe's Declaration that ZICAM is not applied to the oral mucosa, and, on the other, Goldberg's Affidavit that it is indeed so applied.

The '465 patent, as the examiner approved it, clearly claims "a method" of application of zinc gluconate to the oral mucosa. According to Dr. Goldberg, GumTech has come up with a way to do that through the nose. GumTech says that this isn't so. This is on its face a dispute of material fact as to the infringement of the '465 patent by ZICAM, and therefore summary judgment may not be granted here on the question of literal infringement.FN29

FN29. As discussed at the outset of our discussion of Claims 4 and 18, GumTech also argues that ZICAM does not infringe the '465 patent because it in any event does not remain in contact with the oral mucosa for a period of time sufficient to saturate the oral mucosa, a requirement that is an element of the patent claims. Although we have found a disputed issue of material fact as to whether ZICAM reaches the oral mucosa, this of course does not necessarily foreclose summary judgment with respect to literal infringement on the grounds that ZICAM does not remain in contact with such mucosa long enough, since if ZICAM fails to meet any one of the elements of the patent claims, it does not literally infringe.

The only evidence that GumTech brings to bear on *this* issue appears to be the Gary Kehoe's declaration that ZICAM is not applied to the oral mucosa in the first place. On the other hand, the only evidence that Quigley brings to bear in opposition appears to be Dr. Goldberg's affidavit stating that ZICAM does reach the oral mucosa.

On balance, we find that GumTech's evidence as to the duration of ZICAM's application to the oral mucosa (or lack thereof) is not sufficient to show that there is no issue of material fact with respect to this duration. GumTech therefore does not carry its initial burden on summary judgment with respect to this issue, and we will not discuss it further.

2. ***Infringement Through the Doctrine of Equivalents***

The parties have extensively and fully briefed the question of infringement under the doctrine of equivalents: GumTech argues that it should be granted summary judgment on any infringement claims arising from the doctrine of equivalents, and Quigley has responded with arguments to the contrary. However, as discussed above, we employ the doctrine of equivalents only after a finding that there is no literal infringement. We have found above that there exist disputed issues of material fact as to whether there is literal infringement of the '465 patent by ZICAM, and consequently it would be premature for us to consider now the arguments under the doctrine of equivalents that are before us. Naturally, these arguments may be reasserted, if appropriate, later in these proceedings.

III. ***Conclusion***

We interpret the Claims in the '465 patent to extend to any method of applying zinc gluconate to the lining of the mouth, tongue, and throat. Under this claim interpretation, there exist disputed issues of material fact as to whether ZICAM infringes the '465 patent, and therefore the defendants' motion for summary judgment

on the allegations of infringement must fail.

ORDER

AND NOW, this 9th day of March, 2000, upon consideration of defendants' motion for summary judgment, plaintiff's response thereto, and defendants' reply thereto, and for the reasons stated in the accompanying Memorandum, it is hereby ORDERED that defendants' motion for summary judgment is DENIED.

E.D.Pa.,2000.
Quigley Corp. v. Gumtech, Inc.

Produced by Sans Paper, LLC.