IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE QUIGLEY CORPORATION	:	CIVIL ACTION
	:	
v.	:	
	:	
GUMTECH INTERNATIONAL, INC., et al.	:	NO. 99-5577

MEMORANDUM

Dalzell, J. April 19, 2000

Having on March 9, 2000 disposed of defendants' motion for summary judgment in this patent infringement action, we turn our attention now to the motion for a preliminary injunction plaintiff, The Quigley Corporation, filed. We heard testimony over four trial days that commenced on March 31, 2000, and received post-hearing memoranda from the parties, and are now in a position to decide Quigley's motion for preliminary relief.

This Memorandum constitutes our findings of fact and conclusions of law in accordance with Fed. R. Civ. P. 52(a).

I. Background

As we canvassed the background of this patent dispute at length in our March 9, 2000 opinion, we will not rehearse those facts again. See Quigley Corp. v. GumTech, Inc., No. 99-5377 WL 264130 at *1 (E.D. Pa. Mar. 9, 2000). Suffice it to recapitulate by noting that we are dealing here with United States Reissue Patent No. Re 33,465, for a "Method of Reducing the Duration of the Common Cold", which we refer to here, as we did on March 9, as the "'465 patent". As will be seen in much greater detail, this patent involves the application of zinc

glucanate to virus-infected tissues to reduce the duration of the common cold.

Quigley here alleges that GumTech's nasally injected Zicam is covered by one or more of the claims in the '465 patent, in particular claims 4 and 18:

> 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.
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> * * *
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> 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.

The specification of the '465 patent, but not the claims, includes this language:

> Means of application include, but are not limited to, the following direct, indirect, carrier, and special means or any combination of means. Direct application of zinc

> compounds may be by nasal sprays, nasal drops, nasal ointments, nasal washes, nasal injections, packings, or indirectly through use of throat troches or lozenges, or through the use of mouth washes or gargles, or through the use of inhalants or ointments applied to the nasal nares, the bridge of the nose, or the face or any combination of these.

'465 patent at col. 3, ll. 5-13.[1]

Quigley seeks preliminary relief that would enjoin GumTech and related entities from making, using, or selling Zicam. Quigley also asks us to require defendants to remove all Zicam products from retail stores' shelves as well as to compel them to withdraw Zicam from all wholesalers and distributors.

II. Preliminary Injunction Standard

"A preliminary injunction requires the assessment of four factors: [(1)] the likelihood of movant's success on the merits, [(2)] the irreparability of harm to the movant without an injunction, [(3)] the balance of hardships between the parties, and [(4)] the demands of the public interest." Mentor Graphics Corp. v. Quickturn Design Sys., 150 F.3d 1374, 1377 (Fed. Cir. 1998).

Of course, a preliminary injunction is "extraordinary relief", see, e.g., New England Braiding Co. v. A.W. Chesterton,

[1]See Def.'s Ex. 31, p. [293]. The specification does not serve to broaden the claims, and there is much language in the specification that is completely outside the claims. For example, later in the specification the inventor, George A. Eby, III, lists many different zinc compounds that would be "pharmaceutically acceptable", but the claims are now limited to zinc gluconate.

Inc., 970 F.2d 878, 882 (Fed. Cir. 1992), and even if there is a likelihood of success on the merits, a motion for preliminary injunction should be denied if equity so requires, see, e.g., Eli Lilly & Co. v. American Cyanamid Co., 82 F.3d 1568, 1578 (Fed. Cir. 1996); Illinois Tool Works, Inc. v. Grip-pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990). Indeed, a preliminary injunction cannot be granted without a showing of both a likelihood of success on the merits and irreparable harm, see Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1555-56 (Fed. Cir. 1994). Conversely, though, we need not necessarily find that the "balance of hardships" favors the plaintiff in order to grant the preliminary injunction, see Hybritech Inc. v. Abbott Lab., 849 F.2d 1446, 1457 (Fed. Cir. 1988).

Moreover, in the patent infringement context, a "likelihood of success on the merits" means a likelihood of success both with respect to patent validity and with respect to infringement, see Reebok Int'l, 32 F.3d at 1555-56. On the other hand, "[a] strong showing of likelihood of success on the merits coupled with continuing infringement raises a presumption of irreparable harm to the patentee." Id. at 1556.

Although not from a patent infringement case, it is pertinent here to take particular note of Chief Judge Becker's recent observations in Adams v. Freedom Forge Corp., App. No. 99-3570, 2000 WL 251639 (3d Cir. Mar. 7, 2000), where he detailed "our respect for the extraordinary nature of the preliminary injunction power." Slip op. at 18. This power "should not be

exercised unless the moving party shows that it specifically and personally risks irreparable harm" and, quoting earlier authority, Chief Judge Becker stressed for the panel that "'the dramatic and drastic power of injunctive force may be unleashed only against conditions generating a presently existing actual threat.'" Id., quoting Holiday Inns of Am., Inc. v. B & B Corp., 409 F.2d 614, 618 (3d Cir. 1969)(emphasis added in Adams).[2]

We are particularly mindful of how "dramatic and drastic" such a power would be if exercised here. Both Quigley and GumTech are publicly held corporations. GumTech, according to its most recent SEC Form 10-K (Pl.'s Ex. 53) (filed March 24, 2000) had, as of December 31, 1999, over 5,000 shareholders whose common stock capitalization, as of April 3, 2000, was $133 million. Two-thirds of GumTech's 1999 sales came from the sale of Zicam,[3] and thus the entry of any preliminary injunction that at all resembles what Quigley seeks here would likely constitute a corporate death sentence.

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[2]In Adams's footnote 12, Chief Judge Becker also quotes with approval Warner Bros. Pictures v. Gittone, 110 F.2d 292 (3d Cir. 1940), wherein an earlier panel wrote, "We have pointed out frequently that the granting of a preliminary injunction is an exercise of a very far-reaching power, never to be indulged in except in a case clearly demanding it.". Id.

[3]According to GumTech's 1999 10-K, Pl.'s Ex. 53 at 11, Zicam produced net sales of $9,589,803, compared with chewing gum sales of $5,910.221. "The bulk" of Zicam's sales happened in the last "quarter of 1999 after widespread national publicity . . . resulted in unexpectedly high demand for this new product." Id. at 13. Besides selling Zicam, GumTech sells a number of chewing gum products such as "Brain Gum" which, according to GumTech's 10-K, "[i]mproves brain function", id. at 5.

III. Likelihood of Quigley's Success on the Merits

In our March 9, 2000 Memorandum, we canvassed a number of threshold legal issues that GumTech had brought to our attention in the context of a Rule 56 motion. We covered, for example, questions of literal patent infringement and the doctrine of equivalents, and we interpreted Claims 4 and 18. We concluded that "the Claims of the '465 patent are restricted to applications of zinc gluconate to the lining of the mouth, tongue, and throat." Quigley Corp., 2000 WL 264130, at *7. We further held "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." Id.

We then turned, still in the context of a Rule 56 motion, to an infringement analysis, and examined the affidavit of Quigley's expert, Andrew Goldberg, M.D.[4] We concluded that Dr. Goldberg's affidavit "on its face [presented] a dispute of material fact as to the infringement of the '465 patent", id. at *9, and therefore denied the motion for summary judgment.

In a very real sense, our analysis of Quigley's motion for a preliminary injunction begins where our analysis of GumTech's motion for summary judgment left off. We see no reason to revisit any of the issues we canvassed on March 9, but of course our infringement analysis is now done on the merits, and

[4]An ear, nose, and throat specialist on the faculty of the Hospital of the University of Pennsylvania.

not as an enterprise of discerning whether material issues of fact exist. It is also worth noting that the parties, both in their presentation of evidence and in their legal arguments, very much begin where our March 9 Memorandum left off.

A. Standing

GumTech has challenged Quigley's standing to bring this suit, and as this is logically a threshold question, we will address it first.

1. Quigley's Licensee Status

We begin by examining the law pertaining to standing in a patent context.

> The Patent Act of 1952 provides "a patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281 (1988). The term patentee includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d) (emphasis added). Thus, the statute requires that the parties to an infringement suit will have the patentee on one side and the accused infringer on the other. Without the patentee as plaintiff, the remedies provided in the patent statute are unavailable except in extraordinary circumstances . . . .

Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1030 (Fed. Cir.), cert denied, 516 U.S. 907, 116 S. Ct. 274 (1995).

However, an "assignee" of the patent may bring suit, see id. "Where a patentee makes an assignment of all significant rights under the patent, such assignee may be deemed the effective 'patentee' under the statue and has standing to bring a

suit in its own name for infringement." Id. Conversely, though, the holder of a non-exclusive license has no standing to bring suit because such a licensee suffers no legal injury from infringement, see id. at 1031. "The key question for determining standing of a licensee is whether the licensee as a matter of law has an exclusive property interest in the patent itself, not whether the licensee in fact has been harmed by a third-party infringer." Id. (internal quotation marks omitted). The Ortho Pharmaceutical panel identified two policy reasons behind this requirement: first, the infringer should be immune from a second suit by the owner of a patent once sued by a licensee, and, second, the patent owner should be able to choose his forum to sue, and not be the subject of the will of his licensees. See id. (citing and quoting A.L. Smith Iron Co. v. Dickson, 141 F.2d 3, 6 (2d Cir. 1944) (Hand, J.)).

While a licensee who owns "some of the proprietary sticks from the bundle of patent rights" may be a co-plaintiff along with the patent owner, only a party with an assignment of rights has standing to sue alone. See Ortho Pharm., 52 F.3d at 1031. However, if a licensee has "co-plaintiff" status, then it may bring suit "in the name of the licensor, whether or not the license so provides and regardless of the patentee's cooperation." Id. at 1032.

Thus, with respect to standing, there are three types of entities that may be plaintiffs in an infringement suit: (1) the patentee/patent owner; (2) an assignee of the patent (who may

sue alone); and (3) a licensee with some proprietary rights (who may sue in the name of the patentee).

As noted above, to be an "assignee", one must have "all significant rights under the patent," Ortho Pharm., 52 F.3d at 1030. With respect to the "licensee with some proprietary rights" designation, "[t]he proprietary rights granted by any patent are the rights to exclude others from making, using or selling the invention in the United States. A patent license may have the effect between the parties to the license of transferring some of those proprietary rights from the patentee to its licensee." Id. at 1031-32. Such a license is more than just a bare agreement not to sue for use of the patent, and instead makes the licensee a beneficial owner of some part of the patentee's bundle of rights to exclude, see id. at 1032. Thus, such a license is called an "exclusive" license,[5] though a license may not be truly "exclusive" just because the word "exclusive" is in the license.

> Determining whether a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant. . . . Because patent rights are rights to "exclude others"[,] see 35 U.S.C. § 154(a)(1), a licensee is an exclusive licensee only if the patentee has promised, expressly or impliedly, that "others shall be excluded from practicing the

[5]That is, in this context, "exclusive license" does not mean "the only license" as it might in ordinary parlance, but instead means "a license that gives the licensee the right to exclude others".

> invention" within the field covered by the license. Put another way, an exclusive license is "a license to practice the invention" accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave.

Textile Prods., Inc. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998) (citations omitted).

Here, Quigley is clearly an "exclusive" licensee. On August 24, 1996, it entered into a licensing agreement with George A. Eby III, the patentee, which, by its own terms, was intended to vest in Quigley the "sole and exclusive rights to make, use, and sell various products . . . under [the '465 patent]." Pl.'s Ex. 37 ¶ 1. The Agreement's term is the entire term of the '465 patent, see id. ¶ 2, and the Agreement forbids Eby from interfering with Quigley's exclusive rights to manufacture and sell products containing zinc gluconate, as well as from granting any licenses on the '465 patent to any other persons or entities, see id. ¶ 9. Since Eby essentially promised through this provision that anyone other than Quigley would be excluded from the use of the '465 patent, we conclude that Quigley's license was an "exclusive" one for the purposes of standing.

On the other hand, it also seems clear that Quigley was not an "assignee" of the '465 patent. Under the terms of the Agreement, Eby reserved the right to license the patent to others if Quigley failed to make its required royalty payments, see id. ¶ 9(b). Limitations such as this show that Quigley does not hold

all of the rights under the patent, and thus cannot be considered an assignee.

As an exclusive licensee, as discussed above, Quigley is, strictly speaking, not permitted to sue to enforce the patent alone, but must have the patent's owner as a co-plaintiff. Also as noted above, though, an exclusive licensee is permitted to sue in the name of the patent owner, "whether or not the license so provides and regardless of the patentee's cooperation." Ortho Pharm., 52 F.3d at 1032. Here, though Guy Quigley, Quigley's president and CEO, testified that it was his understanding that the licensing agreement gave Quigley the responsibility[6] to sue to protect the '465 patent, the licensing agreement itself contains no such provision. On the other hand, Guy Quigley also testified that Eby has no interest in any involvement in this suit, a fact evidenced by his refusal to make himself available for a deposition.[7]

It would seem, then, that suit by Quigley in Eby's name would indeed be without his cooperation. Consequently, the literally nominal involvement of Eby in this suit as a plaintiff or co-plaintiff would make absolutely no difference in the prosecution of this case or in its merits. To dismiss this case

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[6]That is, not just the right, but the duty to sue to protect the patent.

[7]This behavior on Eby's part is difficult to explain since his licensing agreement with Quigley gives him a royalty based on a percentage of Quigley's sales. Thus, as Quigley prospers, so does Eby, and thus one might think Eby would not so shrink from involvement.

for lack of standing, then, would mark a triumph of form over substance which would be contrary to the interests of justice and serve no interest under the patent laws. We therefore find that on the particular facts of this case, Quigley, an exclusive licensee, has standing as a sole plaintiff.[8]

2. Double Patenting Concerns for Standing

GumTech also argues that even as an exclusive licensee, Quigley has no standing to bring suit because of the "double patenting" relationship between the '465 patent and Eby's other patents. GumTech makes two distinct arguments on the basis of double patenting: the first of these regards standing, which we address here, and the second concerns patent validity, which we will discuss below. In order to reach the standing argument, it will first be necessary to rehearse the law regarding double patenting.

One basic principle in patent law is that an inventor may not receive two patents for the same invention, a practice

[8]As noted above, however, one of the policy concerns behind the need for co-plaintiff status for licensees is to prevent an alleged infringer from being subject to two suits on the same patent, one from the licensee and another from the owner. GumTech may be rightly concerned here with respect to the '465 patent: to the extent that we allow Quigley to go forward as a sole plaintiff, Eby could arguably initiate his own suit later on. However, as discussed in the text, Eby has represented to Quigley that Quigley has the duty to sue and that Eby has no interest in suit. This, combined with Eby's remoteness from this litigation, in which he has such a powerful economic interest, confirms that GumTech's fear is unwarranted. Thus, we find that by these representations, and given the laws of standing for patent cases, Eby has foreclosed his ability to sue GumTech in the future on the '465 patent.

referred to as "double patenting", see 35 U.S.C. § 101; In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997) (discussing "same invention" double patenting and noting that the "statute thus permits only one patent to be obtained for a single invention"). A related doctrine is that of "obviousness-type double patenting", which the Federal Circuit describes as:

> . . . a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not "patentably distinct" from the claims of a first patent. The doctrine has also been phrased as prohibiting claims in the second patent which define "merely an obvious variation" of an invention claimed in the first patent.

In re Braat, 937 F.2d 589, 592 (Fed. Cir. 1991) (citations omitted); see also Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1332, 1326 (Fed. Cir. 1999). The question of whether double patenting exists is a matter of law, see id.

An inventor faced with an obviousness-type double patenting objection from the Patent and Trademark Office (hereinafter “PTO”) may "cure" that objection by filing a "terminal disclaimer". A terminal disclaimer is a "[v]oluntary limitation of the term of the later-issued patent" so that it is limited to the term of the earlier-issued patent, so long as they are owned by the same person. Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 873 (Fed. Cir. 1991). However, filing such a disclaimer is not an admission of the obviousness of the later-filed claimed invention in light of the earlier

filed disclosures, and the filing of a terminal disclaimer equally does not forestall an obviousness rejection made under 35 U.S.C. § 103, see Quad Envtl., 946 F.2d at 874.

The process by which a terminal disclaimer is prepared and recorded is provided for in the Code of Federal Regulations, see 37 C.F.R. § 1.321 (1999). Any terminal disclaimer filed must "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection." 37 C.F.R. § 1.321(c)(3) (1999).

GumTech argues that United States Patent No. 4,956,385 (the "'385 patent"), a patent that Eby prosecuted at the same time he prosecuted the '465 patent, is in fact an obvious variation of the '465 patent and thus should be subject to obviousness-type double patenting restrictions. GumTech also argues that the '465 patent is an obvious variation of the '385 patent, see Mem. of Law in Opp'n to Mot. for Prelim. Inj. at 34.[9] The '385 patent claims, inter alia, a method for treating the common cold by applying "a pharmaceutically acceptable saliva soluble and ionizable zinc compound other than zinc gluconate to the oral mucosa", Pl.'s Ex. 16 at col. 4, ll. 32-35.

[9]That is, GumTech appears to argue that the obviousness runs both ways.

The concern over double patenting implicates standing because one of the policy considerations for the double patenting prohibition is to prevent multiple lawsuits filed by various licensees against an alleged infringer, each based on a separate patent for essentially the same invention, see, e.g., In re Van Ornum, 686 F.2d 937, 944 (C.C.P.A. 1982) (quoting Chisum on Patents § 9.04[2][b]). Analogously, a patentee cannot split up the claims in one patent among several assignees, partially because to do so would lead to the risk of multiple suits, see Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co., 144 U.S. 248, 252 (1892) (noting concern for suits among the various assignees).

In order to understand the specifics of the double patenting claims, we must rehearse in some detail the interrelated prosecutions of the '465 reissue patent and the '385 patent. Here, the reissue patent was applied for on April 4, 1986 as a reissue of United States Patent No. 4,503,070 ("the '070 patent"), which itself was issued on March 5, 1985.[10] The reissue patent was issued on November 27, 1990. The '385 patent was applied for on November 1, 1984,[11] and issued on September

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[10]As noted in the text, the '070 patent was the original patent grant that was subsequently reissued as the '465 patent. The '070 claims only a method for treating the common cold with zinc gluconate applied to the oral mucosa in lozenge form, while the '465 reissue broadened the claims to include methods of applying zinc gluconate to the oral mucosa not limited to the form of a lozenge.

[11]Initially, Eby filed application number 667,097 on November 1, 1984 and, subsequently, he filed continuation application number 102,750 on September 24, 1987. Because the (continued...)

11, 1990.[12] Thus the '465 and '385 patents were being prosecuted at the same time, and, in fact, were ultimately issued by the same examiner.[13]

The '385 patent application was initially rejected as double patenting with respect to claims 2 and 3 of the '070 patent; the examiner on April 2, 1986 rejected certain claims under statutory ("same invention") double patenting, and all claims under obviousness-type double patenting, see Def.'s Ex. 28 at [28]. Later, following a response by Eby, which included submission of an entirely new set of claims, all pending claims (claims 21-40) were again rejected on April 24, 1987 under obviousness-type double patenting with respect to claims 1-3 of the '070 patent, see Def.'s Ex. 28 at [70].[14]

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[11](...continued)
later application is a continuation, the papers filed under the first application are regarded as part of the same record, and we will not differentiate between papers filed under the different application numbers.

[12]In its pleadings, GumTech argues that Quigley is suing on the "patent that issued first", though it would appear that technically the '465 patent issued after the '385 patent.

[13]The issuing examiner for both patents was Ronald W. Griffin. Another, evidently subordinate, examiner, Fatemah T. Moezie, was also involved in the prosecution of both patents.

[14]It is appropriate to discuss the content of these rejected claims. The only two independent claims were claims 21 and 31. Claim 21 claimed "A method of treating the common cold comprising: a) applying an effective dose of a pharmaceutically acceptable saliva soluble zinc compound other than zinc gluconate to the oral mucosa . . . ; b) permitting the zinc compound to remain in contact with the oral mucosa to provide an antirhinoviral effect; c) repeating the application periodically until the cold has been treated." Def.'s Ex. 28 at [31]. Claim (continued...)

In response to this second obviousness-type double patenting rejection, Eby signed a terminal disclaimer, which the PTO received on June 11, 1987, see Def.'s Ex. 28 at [81]. The disclaimer reads in part[15]:

> I hereby disclaim the terminal part of any patent granted on the above-identified application which would expire beyond the expiration of Patent No. 4,503,070 and hereby agree that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent No. 4,503,070, this agreement to run with any patent granted on the above identified application and to be binding upon the grantee, its successors or assigns.

Def.'s Ex. 28 at [82].

In an office action dated July 30, 1987, the PTO acknowledged the terminal disclaimer as having overcome the obviousness-type double patenting rejection, but it also stated that, "The request for reconsideration has been considered but does not overcome the rejection." Def.'s Ex. 28 at [84]. Subsequently, on September 24, 1987, Eby submitted his request to file a new application 102,750 to continue application 667,097 under the "file wrapper continuing" procedure, see Def.'s Ex. 28

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[14](...continued)
31 claimed a method for treating the symptoms of the common cold comprising the same three steps claimed in claim 21. See Def.'s Ex. 28 at [33].

[15]We note that the terminal disclaimer was produced on a boilerplate form to which the pertinent information about Eby's patent application was added. In particular, the language of the disclaimer quoted in the text appears to be part of the standard form language.

at [88]. This request asked that the papers from 667,097 be used as the "basic papers" for the new application. Def.'s Ex. 28 at [89].

Along with the file wrapper continuation application, Eby filed an amendment of his claims for consideration by the PTO, see Def.'s Ex. 28 at [93]-[96].[16] In a response dated March 1, 1988, the PTO again rejected all pending claims in the application. As before, the claims were rejected for obviousness-type double patenting over claims 1-3 of the '070 patent. Also, however, the claims were provisionally rejected for obviousness-type double patenting over the then-pending claims in the reissue patent application which, as we noted above, was simultaneously pending, see Def.'s Ex. 28 at [101]. The examiner remarked that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to employ other pharmaceutically active zinc compounds in the methods claimed at the time the invention of [the reissue application] was made." Def.'s Ex. 28 at [101]. The examiner also noted that a terminal

[16]The amendments both deleted some claims and made editorial alterations to others. With respect to independent claims 21 and 31, the editorial changes were minimal. Subparagraph (a) in both claims was amended to read in part "a pharmaceutically acceptable saliva soluble and ionizable zinc compound other than zinc gluconate" (emphasis on added language); subparagraph (b) was amended to read in its entirety "permitting the zinc compound to remain in contact with the oral mucosa"; and subparagraph (c) was amended to read "repeating the application until the cold has been treated." Def.'s Ex. 28 at [94].

disclaimer, timely filed, could overcome this provisional rejection, see Def.'s Ex. 28 at [102].

In response to this August 24, 1988 rejection, Eby stated to the PTO, inter alia, that since a terminal disclaimer had already been filed in the parent application, it was his belief that there was no need to file another one, though he would "be happy to resubmit a new Terminal Disclaimer" if needed. Def.'s Ex. 28 at [120]. The PTO's response to this, dated October 4, 1988, stated, inter alia, that "An additional filing of a terminal disclaimer is not required herein." Def.'s Ex. 28 at [149]. Following additional correspondence, in which obviousness-type double patenting was not discussed,[17] the examiner on May 9, 1989 as a final action rejected all pending claims, see Def.'s Ex. 28 at [175]. Eby subsequently appealed that decision to the Board of Patent Appeals on January 8, 1990, see Def.'s Ex. 28 at [185]. The appeal did not contain any contentions regarding the obviousness-type double patenting rejection, as the brief noted that this rejection was "mooted" on the basis of the previously submitted terminal disclaimer, see Def.'s Ex. 28 at [188].

On April 19, 1990, the patent application was allowed on the basis of Eby's brief on appeal and of a phone conversation on April 11, 1990 between Eby's counsel and the examiner, see Def.'s Ex. 28 at [313]. As part of this conversation, Eby

[17]Nor were the claims amended beyond those changes noted above.

authorized an examiner's amendment to the claims, see Def.'s Ex. 28 at [313], which had the effect of deleting all of the previously pending claims and adding new claims 41-70. Following the examiner's amendment, there were still only two independent claims, which ultimately issued as claims 1 and 16, and the language of these claims was not much changed by the examiner's amendment from the previously extant independent claims. Subparagraph (a) of the independent claims remained unchanged except in that the word "dosage" is substituted for "dose"; subparagraph (b) now reads "permitting said zinc compound to remain in contact with the oral mucosa for a period of time necessary for the zinc thereof to saturate the oral mucosa"; and subparagraph (c) now reads "applying additional dosages of such a zinc compound in like fashion until the cold has been treated." Def.'s Ex. 28 at [310]. The examiner stated that "[t]he primary reason for allowance of the claims is the inclusion of the limitations therein that the pharmaceutically acceptable zinc compound other than zinc gluconate is saliva soluble and ionizable and is permitted to remain in contact with the oral mucosa for a period of time necessary for zinc thereof to saturate the oral mucosa." Def.'s Ex. 28 at [314].[18]

Having thus canvassed at length the history of the '385 patent, we may now move to consider its effect on our case, which

[18]We note that all of these limitations were present in the claims prior to the examiner's amendments with the exception of the saturation requirement.

of course alleges infringement of the '465 patent. Recall that the issue of double patenting relates to standing because of the policy concern regarding multiple lawsuits arising from multiple patents for essentially the same invention. GumTech argues that the claims of the '385 patent issued under, and as a result of, the terminal disclaimer that had earlier been filed in the same application, and consequently the '385 patent constitutes obviousness-type double patenting with respect to the '465 patent. Thus, argues GumTech, the '465 and '385 patents ought not to be enforced separately, and so Quigley should not be allowed to maintain suit on the '465 patent.

One significant dispute between the parties with respect to this question regards the exact effect of the terminal disclaimer Eby filed during the prosecution of the '385 patent. GumTech argues that, according to the terms of the disclaimer, it applies to any patent issued from that application, which would naturally include the '385 patent. Quigley notes that the '385 patent as issued contains no annotation suggesting that it is subject to a terminal disclaimer, see Pl.'s Ex. 16, and argues more broadly that a terminal disclaimer only applies to the claims then pending in the application. Quigley further notes that the examiner's amendment deleted all prior claims, which had been subject to the terminal disclaimer, and substituted all new claims, which had some different language than the previous claims. Moreover, Quigley adds, if the '385 patent truly raised a question about prospective obviousness-type double patenting,

then the '465 application then pending should also have required a terminal disclaimer;[19] however, the prosecution history of the '465 patent contains no rejections for obviousness-type double patenting nor any terminal disclaimers.

The parties' patent expert witnesses displayed a similar difference of opinion. Bradley B. Geist, Esq., Quigley's expert, stated that a disclaimer does not apply to claims added to the patent application later. Edward G. Fiorito, Esq., GumTech's expert, stated that a terminal disclaimer applies to any patent issued from the application that is the subject of the disclaimer.

We thus face a conundrum. On the one hand, the language of the terminal disclaimer, which was signed (if indeed not drafted) by Eby, explicitly states that it is to apply to any patent that issues from the application. The document does not even refer to any claim numbers, much less restrict itself to particular claims then pending. Moreover, after the examiner asserted for the first time the prospective obviousness-type

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[19]During cross examination of the defendant's patent expert, Mr. Fiorito, the plaintiff referred to section 804.02 of the Manual for Patent Examining and Procedure (the "MPEP"), which states that, "If an appropriate double patenting rejection of the nonstatutory [obviousness] type is made in two or more pending applications, an appropriate terminal disclaimer must be filed in each application." Def.'s Post-Hearing Mem. Ex. 1, MPEP § 804.02 at 800-26. However, we would read this to require a terminal disclaimer in both pending applications only if the obviousness-type double patenting objection pertains to both, leaving open the possibility that while one of two pending applications was obvious with respect to the other, the obviousness relationship was not reciprocal.

double patenting rejection with respect to the pending reissue application, she told Eby that the previously filed terminal disclaimer was sufficient to moot this rejection. We are also faced with the fact that the "new" claims in the '385 patent that resulted from the examiner's amendment are extremely close to the previously extant claims and are also quite close to the language of the '465 patent.[20] On the other hand, the fact remains that the '385 patent as issued does not contain an annotation reporting that the patentee had disclaimed a terminal portion of the patent, and consequently it would at least facially appear that the PTO believed the terminal disclaimer to be inoperative.[21]

To resolve the standing issue, however, we need not conclusively decide this difficult question, because even if we assume that the '385 patent is an obvious-type double patent of

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[20]That is, it is difficult to see how the examiner could have felt that the changes in his amendments made the claims less subject to an obviousness-type double patenting rejection, and it is therefore difficult to see how the examiner's amendments would have obviated the need for the terminal disclaimer.

[21]We are also handicapped by the fact that, as noted in the text, two witnesses qualified as experts in the area of patent practice adopted irreconcilable positions on this issue. The parties have not directed us to any precedent completely on point. The defendant cites In re Jentoft, 392 F.2d 633, 638 n.4 (C.C.P.A. 1968), but the cited passage merely remarks that during prosecution the examiner had refused to accept a terminal disclaimer that referred only to the rejected claims, and instead required the disclaimer to refer to any patent granted. While this supports GumTech's position here, it falls short of a holding discussing the application of a terminal disclaimer to new claims added by an examiner's amendment.

the '465 patent, the policy concerns regarding standing still do not persuade us that Quigley should be foreclosed from bringing suit. The policy concern that relates standing to double patenting is that alleged infringers should not be subject to harassment from multiple suits. Quigley is suing here on the less general of the two patents: the '465 patent specifies zinc gluconate, while the '385 patent refers to all pharmaceutically acceptable, saliva soluble, and ionizable zinc compounds that are not zinc gluconate. Zicam is a zinc gluconate product, and it thus seems at the least unlikely that GumTech would be subject to suit on the '385 patent.

Also, the concern with obviousness-type double patenting would seem to apply to the enforceability of a patent that is found to be subject to the terminal disclaimer (here, the '385 patent), not to the patent upon which the obviousness is based (here, the '465 patent). Thus, the issues GumTech raises would seem to go to Eby's ability (or that of his licensees or assignees) to sue on the '385 patent, not to Quigley's ability to sue on the '465 patent.

In a related vein, GumTech has argued that because the '385 patent actually issued before the '465 patent, it is the '465 patent that is rendered unenforceable[22] by virtue of the obviousness-type double patenting discussion that appears in the '385 prosecution. We cannot agree. The double patenting

[22]That is, Quigley has no standing now to sue upon it.

concerns the examiner expressed during the '385 prosecution pertain first to the '070 patent and then move to include the '465 patent; it therefore is apparent that the examiner considered these patents to be the "earlier" patents. Moreover, when one patent says "zinc gluconate" and the other patent says "everything but zinc gluconate", there can be no doubt that the "zinc gluconate" patent is logically antecedent to the other patent. Thus, to say that because the whim of PTO practice caused the '385 patent to issue before the '465 patent should now compel us to prevent suit on the '465 patent makes little sense to us.[23]

We thus find that Quigley has standing to sue in this case.

B. Unenforceability Due to Inequitable Conduct by the Patentee

To show a likelihood of success on the merits, Quigley must show that it is likely to withstand challenges to the enforceability of the patent, see Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc., 141 F.3d 1084, 1088 (Fed. Cir. 1998) (citing Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). One reason a patent may be unenforceable is that there was inequitable conduct by the patentee during prosecution,

[23]It is also worth noting that GumTech has not directed us to any case in which a court found lack of standing for a similar cause. While GumTech avers that our situation is a "rarely encountered set of facts", Mem. of Law in Opp'n to Mot. for Prelim. Inj. at 32, we nonetheless find it significant that there is evidently no precedent to guide us.

and it is this sort of conduct that GumTech alleges here. In particular, GumTech claims that during the prosecution of the '070 patent and during the subsequent reissue prosecution that led to the '465 patent, Eby repeatedly represented to the patent examiner that zinc gluconate nasal sprays did not work, despite the fact that he had co-authored an article that stated that nasal sprays "seemed" to work.

"Patent applicants are required to prosecute patent applications with candor, good faith, and honesty." Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., — F.3d —, No. 98-1377, 2000 WL 233253, at *4, (Fed. Cir. Mar. 2, 2000).

> Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Determination of inequitable conduct requires a two-step analysis. First, the trial court must determine whether the withheld reference meets a threshold level of materiality. The trial court must then also determine whether the evidence shows a threshold level of intent to mislead the PTO. . . . Once the threshold levels of materiality and intent have been established, the trial court is required to weigh materiality and intent. The more material the omission, the less evidence of intent will be required in order to find that inequitable conduct has occurred. In light of all the circumstances, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.

Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998) (citations omitted).

The party alleging inequitable conduct must prove the threshold elements of materiality and intent by clear and convincing evidence, see Refac Int'l, Ltd. v. Lotus Devel. Corp., 81 F.3d 1576, 1581 (Fed. Cir. 1996). Moreover, in conducting this examination, a reference is deemed material if "there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Id. While "a patentee need not cite an otherwise material reference [that is, prior art] to the PTO if that reference is merely cumulative or is less material than other references already before the examiner," Baxter, 149 F.3d at 1328, "[a]ffidavits are inherently material, even if only cumulative." Refac, 81 F.3d at 1583. Also, "cancellation or amendment of a claim 'tainted' by inequitable conduct will not excuse the patentee's intentional failure to disclose material references," and "inequitable conduct with respect to one claim renders the entire patent unenforceable." Baxter, 149 F.3d at 1332.

The putative inequitable conduct here revolves around representations Eby made to the PTO first during the prosecution of the '070 patent and thereafter during the prosecution of the reissue patent. After Eby filed the application[24] that ultimately led to the issuance of the '070 patent, the examiner initially rejected all of the claims, partly because they were

[24]This was application number 378,479, filed on May 14, 1982.

unpatentable as obvious over the prior art found in the Modern Drug Encyclopedia (Jacob Gutman ed., 1941) (hereinafter Modern Drug[25]), see Def.'s Ex. 30 at [22]-[26], which disclosed the use of a zinc borate solution applied to the nostril as an astringent and decongestant, see Def.'s Ex. 31 at [353]-[54]. As a result of this, the ensuing dialogue reflected in the patent file between Eby and the examiner involved Eby's efforts to distinguish his invention from this prior art, and part of this discussion was devoted to Eby's assertions that nasal sprays were ineffective but his invention worked.

In the '070 prosecution, Eby submitted to the examiner a draft copy of an article he had co-authored with two scientists[26] that documented a double-blind study that purported to demonstrate the utility of zinc gluconate lozenges in reducing the duration of the common cold, see Def.'s Ex. 30 at 37. This draft, however, did not contain a passage that did appear in the final version of the article, which was published in the January, 1984 edition of Antimicrobial Agents and Chemotherapy. This passage, which appeared near the end of the article, after the

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[25]There have evidently been a number of editions of Modern Drug, several of which are referred to in the records before us. It does not appear that these editions differ substantively for our purposes, see Quigley Corp., 2000 WL 264130, at *5 n.19.

[26]According to Guy Quigley's testimony, Eby was an urban planner by trade who had come across the utility of zinc gluconate lozenges for treating the common cold somewhat by chance in the course of caring for his daughter, who was then sick with leukemia.

discussion of the test results, reads, "Other protocols were briefly explored. . . . Nasal sprays seemed to work, but required very frequent administration (every 10 to 15 min), perhaps because intranasally administered substances are rapidly cleared from the nose." Pl.'s Ex. 36 at 22-23.

Eby did not subsequently notify the examiner about the added passage during the prosecution of the '070 patent. In a February, 1984 response to the PTO's second rejection of his claims as unpatentable as obvious over Modern Drug, Eby stated that "the method taught by Gutman could not result in the maintenance of inhibition of viral replication because intranasally administered substances are rapidly cleared from the nose." Def.'s Ex. 30 at [77]. The prosecution of the reissue patent also included statements that denied the efficacy of nasally administered zinc in curing the cold. Most notably,[27] in a communication to the PTO dated August 24, 1988, which was sent in response to the PTO's rejection of all reissue claims as unpatentable over Modern Drug, Eby[28] stated that "the inventor

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[27]Elsewhere in the prosecution, for example, Eby noted to the PTO that "[e]arly experiments in 1979 with 150 mmol zinc gluconate nasal spray solutions produced extreme nasal pain." Def.'s Ex. 31 at [162]. However, 150 mmol appears to be a substantially greater concentration of zinc gluconate than has ultimately proved necessary for treatment, see United States Patent No. 4,956,385, Pl.'s Ex. 16 at col. 4, ll. 18-22 ("Zinc concentration in saliva by such treatment must be in excess of 0.1 mM and should not be more than 1 molar and preferably in the 1 to 300 mM range although 5 mM to 50 mM by be even more preferable.").

[28]Though Eby prosecuted the '070 patent pro se, he was (continued...)

has on various occasions tested a zinc gluconate spray intranasaly [sic], and it was not found to be effective in cold treatment (see Reference 35)." Def.'s Ex. 31 at [108].

Reference 35 is identified as an "unpublished article by Mr. Eby which shows that zinc orotate lozenges used with zinc gluconate nasal spray is ineffective and inconvenient in treating common colds. The original draft of this article was prepared in 1982 and the final article was completed after the publication of Mr. Eby's zinc gluconate/common cold article of 1984." Def.'s Ex. 31 at [130]. The "article of 1984" was the Antimicrobial Agents and Chemotherapy piece discussed above. It is also important to note that a copy of the final published version of the 1984 piece was indeed sent to the PTO during the reissue prosecution, as an exhibit to Eby's brief on appeal, see Def.'s Ex. 31 at 234.

GumTech contends that Eby's representations about the inefficacy of nasal sprays constitute inequitable conduct. It maintains that the passage in the 1984 article conclusively demonstrates that Eby was aware that nasal sprays would work under some circumstances, and consequently that the statements that nasal sprays did not work must be, at the very least, knowing half-truths. These (mis)representations about nasal sprays are material, GumTech argues, because they helped to persuade the examiner that the invention was not obvious over

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[28](...continued)
represented by counsel for the reissue prosecution.

Modern Drug, a distinction critical to the patentability of the invention, since the examiner repeatedly had focused on Modern Drug as relevant prior art.

We find that Eby's behavior does not amount to "inequitable conduct" that would render his patents unenforceable. As discussed above, to find inequitable conduct we must, as a threshold matter, find by clear and convincing evidence that the alleged misrepresentations are material and that there was intent to mislead the PTO. There are certainly questions about materiality here. For example, Mr. Geist, Quigley's expert witness, testified that Eby's failure to provide a copy of the published version of the article would not have been material to the '070 patent prosecution where Eby had restricted his claims to a lozenge dosage form. But leaving materiality aside, we cannot find, particularly not to a clear and convincing standard, that there was intent to deceive the PTO.[29]

The difficulty with intent begins with the equivocal and passing nature of the statement in the 1984 article. There, Eby's findings on nasal sprays were in the first instance far from conclusive and were immediately qualified: nasal sprays

[29]Admittedly, our data set here is incomplete in an important way: we have not heard from Eby himself. As noted above, Eby has indicated his desire not to be involved in any lawsuits, and has not made himself available for deposition. Naturally, if Eby is subsequently deposed pursuant to this case and makes statements that support the allegation of inequitable conduct, we would revisit our findings here.

only "seemed" to work, and to the extent that they did they required very frequent reapplication. Moreover, the 1984 article did not report any specific experimental findings on nasal sprays, rather it was simply another "protocol" that was "briefly explored". Thus, insofar as Eby's subsequent statements about nasal sprays' inefficacy are inconsistent with these few lines from the 1984 article, the article itself would only appear to be (at most) a conditional finding.

We also note that Eby's unpublished article referred to as "Reference 35" was a report of actual testing, and these tests found that a nasal spray did not work. This unpublished article was finalized after the publication of the 1984 piece, and thus to the extent that the 1984 piece reported provisional findings of success, the later-completed article's findings that nasal sprays are not effective could be said to supersede the earlier report. What this all may point to is a scenario wherein Eby may have thought at one point that nasal sprays had some promise, but subsequently concluded that they did not.

As stated above, GumTech relies wholly on the brief statement in the 1984 piece to support its claim of misrepresentation; there is no direct indication that Eby intended, by later representations about nasal sprays, to mislead the PTO. Also, a final copy of the published version of the piece was in fact provided to the PTO.[30] Whether or not Eby

[30]We recognize that the article was submitted as one of (continued...)

changed his mind,[31] as we have conjectured above, we cannot find on the evidence before us that there is clear and convincing proof of intent to mislead.

We therefore must reject the argument that the patent is unenforceable for inequitable conduct.

C. Validity of the '465 Patent

GumTech has raised a series of challenges to the validity of the '465 patent. In a trial for patent infringement, the patentee enjoys a presumption of validity under 35 U.S.C. § 282. However, "the presumption does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when that issue concerns the patent's validity." New England Braiding, 970 F.2d at 882. Further, we may decline to enter a preliminary injunction where the evidence raises a "substantial question" as to validity, even though the defense "may not be entirely fleshed out". Id. at 883.

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[30](...continued)
several exhibits to an appellate brief, and that the language at issue is but a short passage in a longer article. Nonetheless, we must expect that the PTO reads what it receives.

[31]We appreciate that simply because Eby had changed his mind did not necessarily relieve him of the responsibility to inform the PTO of the protocol findings reported in the paper. However, the possibility that Eby's later research showed nasal sprays to be ineffective does go to the question of whether he had intent to deceive.

Notwithstanding that Quigley carries the burden here,[32] it will ease our analysis to organize our discussion around GumTech's various arguments against validity.

1. Obviousness in Light of Prior Art

GumTech's first set of arguments is that the '465 patent was in fact obvious in light of various examples of prior art. A patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains." 35 U.S.C. § 103(a).

[32]In support of its positive case for the validity of the '465 patent, Quigley produced the expert testimony of Mr. Geist, who testified, among other things, that the '465 patent was valid in light of prior art.

a. Prior Art Associated with the '905 Patent

The first set of prior art references with respect to which the '465 is allegedly invalid are a group of patents about which the PTO raised questions in considering the validity of another of Eby's patents. On April 25, 1995, the PTO issued to George Eby United States Patent No. 5,409,905 (the "'905 patent"), titled "Cure for Commond [sic] Cold", see Pl.'s Ex. 20. The '905 patent claims, inter alia, "1. A flavor-stable, pleasant tasting composition for sustained release of Zn^{2+} ions within the oral cavity of a human comprising a highly ionizable zinc compound in combination with a pharmaceutically acceptable carrier wherein said composition excludes flavor masking amounts of anethole and flavor masking amounts of strong zinc chelators." Pl.'s Ex. 20 at col. 21, ll. 12-18. The '905 patent also claims: "22. A pleasant tasting, flavor-stable, solid composition for sustained release of Zn^{2+} ions within the oral cavity of a human comprising therapeutically effective amounts of zinc gluconate in combination with a pharmaceutically acceptable carrier consisting essentially of fructose and one or more pharmaceutical necessities . . . ." Pl.'s Ex. 20 at col. 22, ll. 39-45.

After the '905 patent's issuance, the Commissioner of Patents and Trademarks sua sponte ordered a reexamination of the '905 patent because "prior art patents . . . raise a substantial new question of patentability" as to its claims. Pl.'s Ex. 21 at GUM002754. The PTO subsequently rejected all of the '905 claims

as either anticipated or obvious over the prior art patents that the Commissioner had identified.[33]

GumTech argues that these same prior art references also render the '465 patent obvious. For reference, the prior art patents at issue are identified in the margin.[34] Quigley's expert, Mr. Geist, testified that it was not clear that these patents represented prior art with respect to the '465 patent in

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[33]We note that our record of the reexamination proceedings ends with the initial rejection action, which evidently occurred on September 15, 1997, and we therefore do not have the benefit of any further filings that Eby may have made in response, nor of any subsequent PTO action. Importantly, on the record before us we do not know if the '905 patent's claims were in fact ultimately rejected as obvious over the prior patents.

[34]The following patents were identified as raising a question of obviousness over prior art for the '905 patent. The reexamination action by the PTO cites several others, but the ones listed below are those discussed by GumTech. After each of these, we have briefly identified some of the characteristics of these inventions that related them to the '905 patent.

"Oral Composition for Improving Oral Health", U.S. Patent No. 4,229,430 (Fahim et al.) (disclosing application of the same active ingredients as the '905 patent to the oral tissues);

"Method and Composition for Treating Teeth and Method for Preparing Same", United States Patent No. 4,376,115 (McCrorey) (disclosing composition containing zinc chloride and teaching application of zinc ions to the mouth in the same range as that mentioned in the '905 specification);

"Anticalculus Composition", United States Patent No. 4,022,880 (Vinson) (disclosing application of a composition of zinc acetate or zinc benzoate, both of which are mentioned in '905, to the oral tissue resulting in concentrations of zinc ions that were within the '905 patent's claims);

"Stable Dental Composition Containing Hydrogen Peroxide", United States Patent No. 4,226,851 (Sompayrac) (disclosing a mouthwash with zinc chloride in a flavored mouthwash solution acting as an effective germicidal agent);

"Treatment for Gingivitis", United States Patent No. 4,160,821 (Sipos) (disclosing a composition comprising zinc salts such as zinc chloride or acetate).

that they may post-date the '465 invention date, but also that, even assuming that they are prior art, they do not render the '465 patent obvious. He testified that these other patents either did not teach use for treating the common cold[35], or involved active ingredients other than zinc compounds. He also pointed out that the language of the '905 patent is different in significant ways from that of the '465 patent.

We also observe that the '905 patent differs from the '465 patent in that it seeks to patent a "composition" rather than a "method". The PTO office action that rejected the '905 claims upon reexamination highlights this difference. In several points in the analysis of the '905 patent's obviousness with respect to the prior art patents, the examiner notes that the prior art patents render the '905 obvious in spite of the fact that some of the '905 patent's claims specify use of the composition as a remedy for the cold because "recitations of intended use[] do not impart patentability to the composition claims, where the composition is otherwise anticipated by the prior art." Pl.'s Ex. 21 at GUM002769. As the '465 patent is not a composition claim, it would appear that at least some of these problematic issues identified with respect to the '905 patent would be inapplicable to the '465 patent. Thus, to the extent that the examiner remarks that various of the '905 claims that involve recitation of compositions for curing the common

[35]Most of these prior art patents were for inventions evidently intended for use as dentifrices.

cold are obvious in light of the prior patents' disclosure of the application of similar compositions to the oral cavity, this does not appear to us inevitably to carry over to an obviousness analysis of the '465 patent.

GumTech avers that it has not completed its search for prior art patents that would invalidate the '465 patent as obvious over prior art, and argues that given Quigley's burden to show validity, the prior art patents identified for the '905 patent put the '465 validity into serious question, enough to deny Quigley a likelihood of success on the merits. On balance, we do not agree. While it is true that the other patents involve the use of zinc compounds in conjunction with the mouth, there do not seem here to be enough connections to the '465 patent to raise a strong claim of invalidity. Given (1) the differences between the '465 and '905 patents, (2) the reality that the record before us on the history of the '905 patent reexamination appears incomplete, (3) the fact that none of the prior art patents specifies zinc gluconate, and (4) that none of the prior art patents cited are methods for treating the common cold, we think it unlikely that Quigley will fail to succeed in showing the '465 patent valid on this basis.

b. The "Modern Drug" Reference

The next reference that GumTech argues renders the '465 patent obvious is the Modern Drug reference, discussed above, that disclosed the use of a zinc borate solution applied to the

nostrils as a decongestant or astringent. GumTech's contention is essentially that to the extent that the '465 patent is taken to apply to Zicam, then it must also apply to the method disclosed in Modern Drug, and consequently the claims of the patent must be invalid because of the prior art disclosed in Modern Drug. This is so, GumTech argues, because Eby noted in communications to the examiner, as part of the effort to distinguish Modern Drug, that nasal sprays did not work at least partly because they were rapidly cleared from the nose.[36] GumTech argues that such clearance of the nose must result in the nasally-injected material reaching the throat, just as Quigley alleges that Zicam reaches the throat, and that consequently any application of the '465 patent to Zicam would render it at the least obvious over Modern Drug.

We do not think that this syllogism works to render the '465 patent obvious. We first note that there is nothing before us to show that the zinc solution disclosed in Modern Drug -- or, for that matter, any of the "nasal sprays" referred to during the prosecution of these patents -- is constituted in a way similar to Zicam. Zicam dispenses zinc gluconate in a gel, which arguably may affect the manner in which the substance is cleared

[36]For example, Eby stated that "the method taught by Gutman could not result in the maintenance of inhibition of viral replication because intranasally administered substances are rapidly cleared from the nose." Def.'s Ex. 30 at [77].

from the nose.[37] Thus, simply because Eby rejected nasal sprays because they cleared rapidly from the nose does not logically foreclose application of the patent to a nasal spray that may clear in a different fashion. To put this the other way, just because substances cleared from the nose may reach the throat, they may reach the throat in different ways and with different effects, and the nasal sprays that Eby found to clear rapidly may not have done so in a way similar to Zicam's workings in the human body.

Also, Quigley's expert, Mr. Geist, discussed the Modern Drug reference and concluded that it was not prior art rendering the '465 patent obvious because Modern Drug merely teaches the use of a zinc solution as an astringent or decongestant, not as a cure for the common cold. He stated that it was his opinion that Eby gave in too quickly in prosecuting the '070 patent in that Eby limited his claims to a lozenge partly in the face of the examiner's repeated assertions of Modern Drug as prior art. Mr. Geist felt that had a patent attorney prosecuted that application, instead of Eby acting pro se, the examiner's objection regarding Modern Drug could have been overcome, allowing the patent to issue without the restriction to the lozenge form and the oral mucosa.[38]

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[37]In fact, this was the testimony of Dr. Andrew Goldberg, M.D., plaintiff's medical expert, which we will discuss more below.

[38]Naturally, Mr. Geist's position is supported by the (continued...)

We conclude that the '465 patent is unlikely to be found invalid on as obvious over the Modern Drug reference.

c. Obviousness-Type Double Patenting With Respect to the '385 Patent

GumTech argues that claims 4-31 of the '465 patent[39] are obvious in light of claims 1-32 of the '385 patent, and that therefore those claims, which include those Zicam allegedly infringed, are invalid. In our discussion above of double patenting as it relates to standing, we discussed in detail both the prosecution of the '385 patent and the interrelation between the '465 patent and the '385 patent. We will not cover that ground again.

With respect to the '465 patent's obviousness, we first observe, as noted above, that the filing of a terminal disclaimer is not a concession of obviousness, nor will it necessarily prevent an obviousness rejection. All it does it to prevent a rejection for obviousness-type double patenting. Thus, even to the extent that a terminal disclaimer does in fact still apply to the '385 patent (a question which, as discussed above, is much in dispute), this would not necessarily direct a finding of obviousness invalidity for the '465 patent.

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[38](...continued)
prosecution history of the '465 reissue patent. There, the examiner initially objected to the claims as obvious over Modern Drug but eventually allowed claims to issue that did not restrict zinc gluconate to lozenge form.

[39]These are the claims that were added during the reissue process.

Also, as we noted above, the PTO rejected the claims of the '385 patent for obviousness-type double patenting, not the claims of the '465 patent. Thus, based on the prosecution histories, it would be the '385 patent that is rendered invalid as obvious, not the '465 patent -- there is no indication that obviousness, to the extent its existence can even be inferred from the '385 prosecution history, would be reciprocal.

Finally, also discussed above, there is the fact that the '465 patent, applying to zinc gluconate, must be seen as logically antecedent to the '385 patent, which covers zinc salts other than zinc gluconate. Thus, invalidating the '465 patent on the '385 patent would make little (if any) sense. That the '465 patent issued after the '385 for purely ministerial reasons within the PTO similarly cannot drive our decision here.

We conclude that, on the record at this stage of the proceedings, the '465 patent cannot be said to be obvious with respect to the '385 patent, and thus this argument does not impede Quigley's likelihood of showing validity.

2. The Non-criticality of Application to the Oral Mucosa

GumTech also claims that the '465 patent is invalid because it was issued on a false premise. GumTech argues that during the prosecution of the '070 and '465 patents, Eby made repeated representations[40] to the PTO that nasal sprays were not

[40]As detailed above in our discussion of Eby's alleged (continued...)

effective, and in fact stated that application of zinc gluconate to the oral mucosa was "critical", a representation of which the examiner specifically took note during the reissue prosecution, see Def.'s Ex 31 at [144]. GumTech notes that Eby had information that nasal sprays "seemed" to work under some conditions[41] and thus his claims to the examiner about the "criticality" of application to the oral mucosa served to mislead the examiner and thereby taint the issuance of the patent. Alternatively, GumTech argues that even if Eby had no knowledge of nasal sprays' effectiveness, "the fact remains that the ZICAM nasal spray . . . works" and therefore Eby's representations were inaccurate, similarly tainting the patent. Mem. of Law in Opp'n to Mot. for Prelim. Inj. at 15.[42]

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[40](...continued)
inequitable conduct.

[41]Also as detailed above in our discussion of Eby's alleged inequitable conduct.

[42]In support of this as grounds for invalidity, GumTech cites to Nutrition 21 v. United States, 930 F.2d 867, 870 (Fed. Cir. 1991), in which the Federal Circuit vacated a preliminary injunction. That court noted that the submission of an inaccurate affidavit to the PTO in order to overcome a rejection of patent claims could be part of a finding that the plaintiff did not have a likelihood of success on the merits; similarly, a finding that there exists prior art that the PTO did not consider in granting the patent also militates against a finding of a likelihood of success. The Nutrition 21 opinion, however, falls short of stating that a finding of either of these two things necessarily means that the plaintiff does not have a likelihood of success, not leastly because the court below in Nutrition 21 had wrongly put the burden on the defendant to show invalidity rather than on the plaintiff to show validity, see Nutrition 21, 930 F.2d at 870.

We do not find GumTech's argument persuasive. As canvassed above, Eby's later representations regarding the efficacy of nasal sprays are in the first instance not necessarily inconsistent with Eby's published remark that nasal sprays "seemed" to work. Moreover, it does not seem particularly likely that the examiner was misled by Eby's representations, particularly where a copy of the article in question was in fact provided to the PTO during the reissue prosecution. Thus, we do not find that these events tainted the '465 patent.

Similarly, we cannot find that Zicam's alleged efficacy[43] makes it unlikely that the '465 patent is valid. According to the testimony of Charles B. Hensley, Ph.D., one of Zicam's developers, Zicam works by preventing the rhinovirus from binding to certain cellular receptors located primarily in the nasal cavity.[44] Conversely, Eby's patented invention eschews the nasal mucosa in favor of application to the oral mucosa. These two points are not mutually exclusive. Just because applying Zicam to the nose may work to cure the common cold does not mean that applying zinc gluconate to the oral mucosa doesn't work. As discussed above, it is significant that Zicam is dispensed in a

[43]On the stand, Dr. Hensley discussed two experiments that had allegedly demonstrated Zicam's effectiveness, though Quigley challenges the validity of these studies.

[44]The testimony was not clear on the point of whether the zinc ions are meant to bind with the cellular ICAM receptor or the receptor on the rhinovirus that fits in the ICAM receptor. Either way, the point is that the zinc ion prevents the "key" of the rhinovirus from fitting in the "lock" of the ICAM receptor and thus prevents the virus from infiltrating the cell.

gel rather than in an aerosol spray.[45] While Eby represented to the PTO that nasal sprays did not work, and focused his claimed invention on the oral mucosa, we do not find that this forecloses the possibility that a nasal gel may also serve to deliver zinc gluconate to the oral mucosa. Thus, the nasal sprays Eby referred to during the prosecution and the disputed product Zicam are not sufficiently similar so that Eby's representations about "nasal sprays" are rendered false by Zicam's later alleged efficacy. Thus, Zicam's proffered effectiveness does not render the '465 patent invalid as resulting from a false premise.[46]

3. "New Matter"

During a patent prosecution, no "new matter" can be introduced into to the specification of the proposed patent, see 35 U.S.C. § 132.[47] Additional reference to the "new matter"

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[45]According to the testimony of Walter B. "Brown" Russell, GumTech International Inc.'s Chairman, GumTech International specializes in unique delivery systems of bioactive compounds. Thus, the gel -- the unique delivery system employed here -- is by no means an incidental part of the Zicam product, but instead is a vital component of its novelty.

[46]We recognize that it seems counterintuitive to apply the '465 patent to a product squirted into the nose when the patentee went to lengths to distinguish the claimed invention from nasal sprays. Nonetheless, the elements discussed in the text convince us that Zicam's effectiveness standing alone does not render the '465 patent invalid.

[47]The main policy concern behind the "new matter" prohibition is to prevent inventors from modifying the invention after the filing date, which is the date from which, for example, prior art is determined. Along these lines, if an inventor wishes to introduce "new matter" into his application, his proper course of action is to file a "continuation" application, which

(continued...)

prohibition is made in the administrative rules governing the patent process:

> No amendment shall introduce new matter into the disclosure of an application after the filing date of the application. . . All amendments to the specification, including the claims. . . . filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition to the original disclosure, cannot be added to the application after its filing date . . . .

37 C.F.R. § 1.118 (1986).[48] "'New Matter' is a technical legal term . . . a term of art. Its meaning has never been clearly defined for it cannot be. . . . We have to decide on a case-by-case basis what changes are prohibited as 'new matter' and what changes are not." In re Oda, 443 F.2d 1200, 1203 (C.C.P.A. 1971). "Whether particular technological information is 'new matter' depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1992).

Notwithstanding the absence of a precise definition, we are guided not only by the "departure from or addition to"

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[47](...continued)
receives a new filing date.

[48]We cite here to the rules that were in effect at the time the '465 patent was prosecuted. The current rules also contain the new matter prohibition, see 37 C.F.R. § 1.121(a)(6) (1999) ("No amendment may introduce new matter into the disclosure of an application.").

language in the rule quoted above, but by several other principles. Claims that ultimately issue must find support in the original specification, see Kolmes v. World Fibers Corp., 107 F.3d 1534, 1539 (Fed. Cir. 1997), though "an amendment to a specification does not violate the new matter rule if it merely clarifies or completes the existing disclosure." 4 Donald S. Chisum, Chisum on Patents § 11.04[2], at 11-237 (1999) (internal quotation marks omitted) (hereinafter "Chisum on Patents"). Similarly, both Quigley's and GumTech's experts agreed that mere "editorial" changes in the language of the specification would be permissible. Also, the PTO's allowing an amendment without interposing a "new matter" objection is entitled to "an especially weighty presumption of correctness." Brooktree, 977 F.2d at 1574-75 (internal quotation marks omitted).

GumTech contends that during the prosecution of the '070 and '465 patents, Eby impermissibly introduced two items of "new matter" which are crucial to the allegation of infringement before us here. These two items are (1) the definition of the "oral mucosa" to include the lining of the throat, and (2) the requirement that the zinc gluconate "saturate" the oral mucosa. We will consider these in turn.

a. The Definition of "Oral Mucosa" as "New Matter"

In our earlier opinion, we interpreted the term "oral mucosa" as used in the claims of the '465 patent to mean "the lining of the mouth, tongue, and throat". Quigley Corp., 2000 WL

264130, at *5. We assigned this definition based on the definition's appearance in the specification.[49] This definition is of great significance to the outcome here because, as will be discussed more below, it appears from expert testimony that while Zicam may reach the throat when used as directed, it does not reach the mouth to as great an extent, and also that the term "oral mucosa" as used by one skilled in the art may refer only to the mucosa of the oral cavity excluding the throat. Thus, the inclusion of the throat in the definition of "oral mucosa" is highly relevant to the fundamental question of whether Zicam infringes.[50]

The first step, then, in assessing the "new matter" question before us is to look at the initial documents sent from Eby to the PTO for the application that later became the '070 patent. That initial application,[51] which Ely submitted pro se in May, 1982, contains a "detailed description of the invention"

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[49]This was founded on the well-settled principle in patent jurisprudence that "[t]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[50]Thus, because the inclusion of the throat is of significance, we cannot simply set the alleged “new matter” aside as having no impact on the scope of the patent.

[51]This application, number 378,479, was a continuation in part of a previous application, number 228,750, that Eby had filed on July 31, 1988. This application summarized the invention as involving application of zinc to the "oral, pharyngeal and/or nasal mucosal membranes", Pl.'s Ex. 6 at [7], and referred to application to various mucosal membranes in the respiratory tract, including, inter alia, the nose, sinuses, mouth, and throat, see Pl.'s Ex. 6 at [8].

which includes the following language: "Such method involves the administration of pharmaceutically acceptable zinc compounds topically applied to the oral, pharyngeal and/or nasal mucosal membranes." Def.'s Ex. 30 at [8]. Eby's initial patent claims did not specify any particular location for application, instead referring to "virally infected tissues". Def.'s Ex. 30 at [12].

The examiner rejected all of Eby's claims in April, 1983, see Def.'s Ex. 30 at [22]. In response, Eby filed an amendment in August of 1983 which included both alterations to his earlier application and a set of new claims. One of the new independent claims included the restriction that the zinc compound be applied to the "upper respiratory tract", and another new dependent claim limited application to the "oral mucosa". Def.'s Ex. 30 at 33. The language from the specification quoted above was not altered.

The PTO again rejected these amended and added claims in November of 1983, see Def.'s Ex. 30 at [64].[52] In response, in February of 1984, Eby amended the independent claim mentioned above to delete reference to the "upper respiratory tract" and to add "oral mucosa", see Def.'s Ex. 30 at [74].[53] Also in this

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[52]In the same office action, the examiner rejected some changes that Eby had proposed for the specification -- changes unrelated to the issues before us -- on the ground that they constituted "new matter", see Def.'s Ex. 30 at [65]. While this rejection does not impact our outcome here, it does go to show that the examiner was, as we would expect her to be, sensitive to “new matter” issues.

[53]Naturally, these changes to the claims, rather than (continued...)

communication, Eby included a "remark" in which he stated that his "best mode" for applying zinc gluconate to the oral mucosa is to apply it to the "lining of the mouth, tongue, and throat", Def.'s Ex. 30 at [78], though of course this remark did not go to amend the specification. In May, 1984, the examiner again rejected all pending claims, and notified Eby that the rejection was "final", see Def.'s Ex. 30 at [79].

There then ensued a number of telephone conversations between the examiner and Eby during which Eby agreed to various of the examiner's proposals regarding alterations to the patent application, see Def.'s Ex. 30 at [89] (memorializing telephone conversation of June 5, 1984); Def.'s Ex. 30 at [99] (memorializing telephone conversation of August 21, 1984). These conversations spawned additional correspondence between Eby and the PTO. On September 4, 1984, Eby sent to the PTO a copy of the application, annotated by hand to reflect both "previous changes" and changes made in response to an office action dated August 29, 1984,[54] see Def.'s Ex. 30 at [102]. One of the handwritten annotations on this copy of the patent application included, for

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[53](...continued)
to the specification, would not attract a "new matter" objection. The claims must be supported by the specification, and, as we quoted above, the specification then extant did mention the "oral mucosa", so there was nothing per se objectionable about introducing that limitation in the claim. Again, the concern here is not with the use of the term "oral mucosa" but rather with the definition it is given in the specification.

[54]This was an advisory action recommending two changes to the application's language, see Def.'s Ex. 30 at [101].

the first time, the direction, under "Treatment Instructions" that the patient dissolve the zinc gluconate lozenge "so as to saturate the oral mucosa (lining of the mouth, tongue, and throat)".[55] Ex. A, Pl.'s Mem. of Law on "New Matter" at GUM003482.[56] Several weeks later, Eby sent the PTO a typed version of the application, including all of the annotations, see Def.'s Ex. 30 at [103], and the patent subsequently issued on this version of the application.[57]

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[55]We should note that the analysis here was impeded by the organization of the record. GumTech's version of the '070 prosecution history, Def.'s Ex. 30, omitted this annotated version of the patent application, though this document was part of the discovery that GumTech turned over to Quigley. The document appears in Quigley's version of the prosecution history, Pl.'s Ex. 3, but it is placed at the beginning of the record, far out of chronological order. For convenience, we have cited to this document as it is annexed to Quigley's memorandum of law on the "new matter" issue.

[56]Because GumTech raised the "new matter" concern for the first time at the hearing, we afforded the parties an opportunity to brief this issue separately following the hearing.

[57]The existence of the pen-annotated version of the application was discussed at the hearing on the motion for preliminary injunction. This notwithstanding, GumTech continues, in its memorandum of law filed after the hearing, to aver that the typed version of the annotated version was the first time the "so as to saturate the oral mucosa (lining of the mouth, tongue, and throat)" language had appeared. This is naturally of some significance, since part of GumTech's claim here is essentially that this language was slipped past the examiner, who would have had a hard time picking it out of the new typed version since Eby did not specifically flag it in the typed version. Of course, the presence of the language as a hand-written annotation on the earlier copy makes it less likely that the examiner was not alerted to it. On the other hand, the presence of the annotation doesn't effect the broader claim that the "new" definition of "oral mucosa" is in fact “new matter”.

GumTech argues that by defining "oral mucosa" to include "the lining of the mouth, tongue, and throat", Eby changed the scope of the patent claim in that this definition of "oral mucosa" was different than that previously pertaining. Quigley's medical expert, Dr. Goldberg, testified that one skilled in the art would define "oral mucosa" to include the mucosa of the oral cavity, but not the throat. Thus, argues GumTech, this is the definition that applied to "oral mucosa" as used in the '070 application specification prior to the addition of the "lining of the mouth, tongue, and throat" language, and consequently the "new" definition of "oral mucosa" constitutes "new matter", since it expands the definition to include the lining of the throat.

We do not find that the definition of "oral mucosa" presented in the revised patent application documents is "new matter". First, it cannot be argued that the specification does not contemplate the involvement of the throat, since the specification mentions the pharyngeal mucosa as one of the areas to which the zinc gluconate will be targeted.[58] Thus, the focus

[58]In our previous opinion, we had observed in a footnote that the pharyngeal mucosa was not part of the '465 patent claims and that it was distinct from the oral mucosa, see Quigley Corp., 2000 WL 264130, at *5 n.18. We therefore, in that opinion, had excluded the pharyngeal mucosa from the construction of the claims. At the same time, however, we embraced the definition of the oral mucosa as the "lining of the mouth, tongue, and throat". After receiving the benefit of the testimony of the parties' medical experts, we recognize that these two positions are somewhat inconsistent in that the throat is part of the pharynx and thus the pharyngeal mucosa includes
(continued...)

here must be on the fact that Eby originally distinguished between the oral mucosa and the pharyngeal mucosa and then subsequently altered the definition so as to blur that distinction. As noted above, a change to the specification does not amount to "new matter" if it clarifies or completes the existing disclosure, and the alteration of the definition of "oral mucosa" to include the throat -- a part of the body already explicitly discussed in the specification -- would certainly seem to be a mere clarification of the use of that term, rather than an addition of new material into the specification. Moreover, while Eby had initially distinguished between "oral" and "pharyngeal" mucosa, we do not think that the subsequent definition's expansion to include the throat is inconsistent[59]

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[58](...continued)
the lining of the throat. However, as our finding as to the meaning of "oral mucosa" was clearly a holding of our prior opinion, while our position regarding the pharynx was set forth only in a footnote, there can be no question that it is the definition of "oral mucosa" as including the lining of the mouth, tongue, and throat that governs here. To the extent that GumTech seeks to limit the definition of "oral mucosa" on the basis of our prior opinion's discussion of the pharyngeal mucosa, we reject such an argument.

We also note that plaintiff's medical expert, Dr. Goldberg, testified that if the throat were excluded from the definition of "oral mucosa", it would be harder, but not impossible, to say that Zicam saturates the oral mucosa. He testified that the use of Zicam "involves" the mucosa of the oral cavity, and so if the throat were excluded from the "oral mucosa" whether or not Zicam could be said to "saturate" the "oral mucosa" would turn on the definition of "saturate". Thus, even granting GumTech its desired definition of the oral mucosa would not necessarily be dispositive.

[59]The parties debate the applicability here of two cases involving "new matter" allegations that GumTech cited in
(continued...)

with the first "definition", particularly where Eby did not himself attach a specific definition to the terms.[60]

Furthermore, we have every reason to believe here that the examiner approved the definition of "oral mucosa" that ultimately appears in the specification. The first document in which "oral mucosa" is defined as "the lining of the mouth, tongue, and throat" in the specification[61] was in the annotated copy of the patent application that was sent to the PTO in September, 1984. This document itself was the result of several telephone conversations between Eby and the PTO, as well of at least one written PTO office action. Thus, it seems quite likely that this language was the result of an agreement between Eby and

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[59](...continued)
support of its position: Twin Disc, Inc. v. United States, 10 Cl. Ct. 713 (Cl. Ct. 1986) and Dresser Indus., Inc. v. United States, 432 F.2d 787 (Ct. Cl. 1970). Both these cases involve instances where the patentee was alleged to have improperly expanded the definition of a key term in the specification, and the court in both cases found that such expansion indeed constituted "new matter", see Twin Disc, 10 Cl. Ct. at 744; Dresser Indus., 432 F.2d at 793. However, these cases involved circumstances where the definition the patentee sought to employ was radically at odds with prior representations in the specification and during the patent prosecution, and thus they do not greatly inform our decision here, where the distinction, if any, created by the revised definition of "oral mucosa" is not nearly so clear.

[60]That is, to the extent that, as GumTech avers, the original definition of "oral mucosa" was "the lining of the oral cavity only", such a definition was implicit.

[61]We recognize that this definition was used by Eby in the remarks portion of a submission to the PTO in February 1984, and so the examiner at least had an indication that this is how Eby viewed the oral mucosa, but as far as "new matter" is concerned we are properly concerned with the specification and changes thereto.

the PTO.[62] Also, as discussed above in the margin, that this language appeared in a handwritten annotation makes it quite unlikely that the examiner would have failed to notice it, and so we must conclude that the examiner did not believe it to constitute “new matter”. At the outset, we noted that an examiner's failure to identify a change as “new matter” is entitled to a strong presumption of propriety.

For these reasons, then, we find that the definition of "oral mucosa" as "the lining of the mouth, tongue, and throat" did not likely constitute “new matter” in the '070 patent application and therefore the '465 reissue patent is not likely to be invalidated on those grounds.

b. "Saturate" as “New Matter”

GumTech argues that the '465 patent is rendered invalid because the requirement that the zinc gluconate "saturate" the mucosa, which appears in the pertinent claims of the '465

[62]These discussions and agreement concerned changes both to the specification and to the claims. Thus we do not have here a situation where the claims had been approved and Eby changed the "oral mucosa" definition after the fact, since the changes appear to have been contemporaneous. As Quigley has noted, examiners are directed to assist pro se applicants such as Eby in drafting patentable claims, and such an effort may well have been part of the give-and-take represented in the phone conferences and the subsequent changes to the application, see Pl.'s Mem. of Law on "New Matter" at 12 (citing MPEP § 707.07(j)).

patent,[63] was introduced into the precursor '070 patent as impermissible “new matter”.

The initial application Eby filed that led to the '070 patent stated in the "summary of the invention" that zinc compounds should be "applied in such a manner and at such a frequency so as to cause the concentration of zinc ions in the virally infected tissues to be raised to antiviral concentrations, such concentrations being in excess of 10^{-4}M concentrations of zinc ions, and being maintained at antiviral concentrations . . . ." Def.'s Ex. 30 at [7]-[8]. The PTO's April, 1983 response rejected all the claims, and stated that the disclosure of the antiviral amount of zinc was "in question" since that amount could not be determined. Def.'s Ex. 30 at [23]. Eby, in August, 1983, responded to this by deleting the reference to 10^{-4}M concentrations and inserting the following language: "a manner and at a frequency so as to cause a sustained, above normal concentration of zinc ions in the virally infected tissues." Def.'s Ex. 30 at [31].

In November, 1983, the PTO again rejected all claims, and also objected to the specification on the grounds that Eby had added "new matter". Notably, however, in raising the "new matter" objection, the examiner did not mention the new language regarding zinc concentration quoted above, see Def.'s Ex. 30 at

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[63]As GumTech notes, the requirement for saturation was evidently important in the examiner's eventual allowance of the new reissue claims, see, e.g., Def.'s Ex. 31 at [144]; Def.'s Ex. 31 at [256]-[58].

[65]. Subsequently, after a response from Eby, the examiner evidently withdrew her objection as to “new matter”, see Def.'s Ex. 30 at [65].[64] The term "saturate" then appeared in the pen-annotated copy of the application submitted to the PTO in September, 1984.

GumTech argues that the concept of "saturation" that is now contained in the specification was not present in the application as filed. In order to examine this allegation, we must first engage in some language interpretation, since we need first to know the content of the concept of "saturation" in order to evaluate whether it was present in the specification at the outset. The '070 patent specification includes “saturate” in the following context, under “Treatment Instructions”: “The patient dissolves the first tablet in the mouth so as to saturate the oral mucosa (lining of the mouth, tongue and throat) and then a second tablet immediately thereafter.” Pl.’s Ex. 2 at col. 3, lines 30-34.

In interpreting the meaning of this term, we are guided by the legal rules governing claim interpretation, particularly

[64]The examiner had cited 35 U.S.C. § 112, rather than 32 U.S.C. § 132, as her statutory basis for the "new matter" objection, see Def.'s Ex. 31 at [65]. Subsequently, the examiner withdrew her rejection "under 35 U.S.C. 112"; it would thus appear that the “new matter” objection is removed. It is certainly the case that Eby did not alter the new "concentration" language in the specification, and the "final" rejection did not cite the "new matter" objection, see Def.'s Ex. 30 at [80].

as “saturate” later appears in the claims of the '465 patent[65] and the word should have consistent meaning in both. As "saturate" is not defined in the specification of either the '070 or '465 patents,[66] we look to "its ordinary and customary meaning", Vitronics, 90 F.3d at 1576. For such a definition of "saturate", GumTech turns to Stedman's Medical Dictionary, which defines "saturate" as "to impregnate to the greatest possible extent", Mem. of Law in Opp'n to Mot. for Prelim. Inj. at 4. We note that the applicable standard dictionary definition is "to impregnate, soak thoroughly, imbue with", XIV The Oxford English Dictionary 506 (2d ed. 1989) (def. I(2)). On the other hand, we may also look to extrinsic evidence in understanding the true meaning of terms used, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995),[67] and Quigley’s medical expert, Dr. Goldberg, testified under our questioning that "saturate" is not helpful in the "impregnate" sense in that impregnation is not the

[65]The inclusion of the term in the '465 patent is of course why we are concerned with its use in the '070 patent in the first place.

[66]That is, there is nothing to suggest that Eby intended a special definition for "saturate".

[67]Reference may also be had to the prosecution history to determine the meaning of words used in the claims, see Vitronics, 90 F.3d at 1582. In our context here, this would seem a bit circular, since the very reason we're looking for the definition of "saturate" is to evaluate if its meaning was captured in the application prior to the inventor's actual use of that particular word.

process ongoing at the cellular level.[68] He said that it was probably more helpful in the colloquial sense, and added that he was more comfortable, to use the terms "bathe" or "diffuse" in the context of use of a lozenge (e.g., Quigley's product).[69]

On the basis of all this evidence, we conclude that the proper definition of "saturate" as used in the '070 patent and '465 patent is "to bathe or soak", a definition which combines the normal usage with Dr. Goldberg's expert testimony of how one skilled in the art would understand that word used in the context of a lozenge, which is the sole delivery means contemplated by the '070 patent.[70]

Having so defined "saturate", we now turn to see if this meaning was originally present in the '070 application. As

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[68]GumTech argues that the Stedman's definition of "impregnate" is "to diffuse or permeate with another substance", Stedman's Medical Dictionary 859 (26th ed. 1995) (def. 2), and that consequently "impregnate" does have meaning with respect to the use of zinc gluconate insofar as Dr. Goldberg testified that zinc, as any metal, is diffused by the body. If we insert this meaning into the "saturate" definition from Stedman's we get "to diffuse to the greatest possible extent." We do not understand the prosecution history or the testimony before us to show that this is an appropriate meaning for "saturate" as used in the claims, particularly as it is a concentration of zinc ions that is supposedly therapeutic.

[69]The defendant's medical expert, Dr. Riley, endorsed the Stedman's definition for "saturate" as that used by those skilled in the art, see Def.'s Ex. 85 at 5, but on balance we favor (and therefore credit) Dr. Goldberg's more nuanced treatment.

[70]In so defining "saturate", we are cognizant that our reference to extrinsic evidence is properly only directed toward aiding our understanding of the patent, "not for the purpose of varying or contradicting the terms of the claims." Markman, 52 F.3d at 981.

discussed above, the application originally called for application of zinc to a specific concentration, and that subsequent to the examiner's objection to this, Eby amended the specification to state that enough zinc compound should be applied to cause a "sustained, above normal concentration of zinc ions in the virally infected tissues." Def.'s Ex. 30 at [31].[71] It is not immediately clear that "to bathe or soak" necessarily is included in this description, though surely we may expect that bathing or soaking mucosal tissue with or in the zinc compound will result in an elevated concentration of zinc ions.

Thus, if we were considering this question de novo it might present a close case. However, we here have the benefit, as we did in our analysis of the "oral mucosa" definition above, of the examiner's implicit opinion on the use of "saturate". The term "saturate" was added to the specification at the same time as the "new" definition of "oral mucosa". It was thus added in a handwritten annotation to a copy of the application, and the annotations were a result of various communications between Eby and the PTO that included two phone conversations. As such, the addition of “saturate” can be expected to at the least have been noticed by the examiner, if it was not in fact a result of PTO input into the process. The examiner raised no "new matter"

[71]As noted above, we may conclude this new description is not itself “new matter” because the examiner raised a “new matter” objection to other language contemporaneously added to the specification, but did not object to this language. In any event, that “new matter” objection was ultimately withdrawn.

objection to the term "saturate", and given the strong presumption of an examiner's determination that no “new matter” was introduced, we find that it is not likely that the '465 patent will be invalidated by the alleged "saturate" “new matter”.

In sum, then, we find that none of GumTech's arguments to show that the '465 patent is invalid have successfully rebutted Quigley's showing that the '465 patent is valid. Therefore, we find that it is likely that the '465 patent will be found to be valid.

D. Zicam's Infringement of the '465 Patent

In our Memorandum resolving the Rule 56 motion, we discussed at length the law guiding our analysis of direct infringement,[72] and we will not recapitulate the entire discussion here. Briefly, analysis of direct infringement requires two steps: first, we must interpret as a matter of law the meaning and scope of the patent claims at issue, and, second, we must as a matter of fact compare the allegedly infringing invention to the claims to determine if the invention meets every limitation in the asserted claims, see Markman, 52 F.3d at 976;

[72]In our earlier opinion, we also discussed the doctrine of equivalents, under which theory a plaintiff who has failed to show direct infringement may yet prevail over an alleged infringer. On the motion for preliminary injunction, neither party has made explicit arguments based on the doctrine of equivalents, and so we will not discuss it here.

Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999).

1. Claim Interpretation

We explicitly interpreted the meaning of several of the patent claims in the course of our earlier Memorandum, and have continued that process above. We have defined "oral mucosa" in the '465 patent claims to mean "the lining of the mouth, tongue, and throat", and we have just determined that "saturate" as used in the '465 patent means "to bathe or soak". There is one additional term that we have not yet explicitly[73] interpreted in the claims that is disputed by the parties, and that is the term "applying". It will be recalled in this regard that the '465 patent claims, inter alia, "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 . . . " Pl.'s Ex. 1 at col. 4, lines 57-59.

GumTech first argues that we must interpret the claim "applying" narrowly because the prosecution history shows that Eby had foresworn application of zinc gluconate through the nose

[73]Quigley argues that we did interpret the meaning of "applying" in our earlier opinion, and indeed we did state that the claims extended to "any method of delivery" of zinc gluconate to the lining of the mouth, tongue, and throat. Quigley Corp., 2000 WL 264130, at *7. However, we made this statement without the benefit of specific discussion from the parties on the meaning of "applying", and without explicit discussion of our interpretation; we thus find it appropriate to address the term explicitly here. Of course, as discussed below, our interpretation of the term does not change.

as part of the patent. We first note that "[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). GumTech points out that at various points during the prosecution of the '465 patent, and as part of Eby's continuing effort to distinguish his invention from, inter alia, the Modern Drug reference, Eby represented to the examiner that he believed that the nasal "route" was not effective in treating the cold, see, e.g., Def.'s Ex. 31 at [107].

We do not agree that such representations foreclose the enforcement of a patent against a product that is administered to the nostrils. First, as noted above, we cannot take statements in the prosecution history to limit the claims. Thus, to the extent that GumTech would like, on the basis of the prosecution history, to read "applying an effective dosage" as "applying, but not through the nose, an effective dosage", this is not permissible. We also note that, in any event, the language of the prosecution history itself suggests that Eby used the term "route" to refer to the mucosa or membrane on which the zinc was to act, rather than the location at which the substance is first applied to the body, see, e.g., Def.'s Ex. 31 at [109]. Thus, to the extent that Eby stated that the nasal "route" was inoperative, this reinforces the notion that the zinc must work on the oral mucosa.

This brings us to GumTech's second argument on the meaning of "applying". GumTech argues that the term "apply" should properly be interpreted to mean the mucosa to which the substance is first administered. That is, GumTech avers, Zicam is "applied" to the nasal mucosa, not the oral mucosa, and in order to find that Zicam is encompassed by the '465 patent, we would have to interpret the claim to actually mean "applying an effective dosage of zinc gluconate so that it somehow reaches the oral mucosa". Def.'s Post-Hearing Mem. at 8 (emphasis in original). In support, GumTech offers the expert testimony of Dr. David Riley, who states that the ordinary and customary meaning of "applying" to one skilled in the art of treating the common cold via homeopathic means is to refer to the route of administration or introduction, rather than any resultant location, see Def.'s Ex. 85 at 3.

In assessing this argument, we also look to the ordinary meaning of "apply": "To put a thing into practical contact with another," I The Oxford English Dictionary 576 (2d ed. 1989) (def. I), or "To place (a plaster, unguent, or the like) in effective contact with the body; hence, to administer a remedy of any kind," id. at 577 (def. I(3)).[74] We see from these definitions that the focus is on "effective" or "practical" contact. The expert medical testimony before us showed that substances taken into the nose may be expected rather soon to

[74]We note that Stedman's Medical Dictionary does not contain an entry for "apply" or "applying".

pass to the throat as a normal result of bodily processes, and therefore squirting a substance into the nose, we find, has the practical effect of passing that substance to the throat and thus too the oral mucosa.

Thus, we find a tension between the "ordinary" dictionary meaning and Dr. Riley's testimony regarding the meaning of "applying" to homeopathic practitioners. However, after examination we find that GumTech's desired definition of "applying" as the "route" does not really make sense here on the terms of the patent claims. The '465 patent claims application of zinc gluconate to the oral mucosa, which includes the lining of the throat, and "applying" as it appears in the patent was first used in conjunction with a zinc gluconate lozenge. A lozenge is introduced into the mouth, and is intended to remain there -- it is not introduced directly to the throat. To the extent that any of the zinc gluconate from the lozenge gets from the mouth to the throat, it is a result of the same sorts of physical processes that would take zinc gluconate gel from the nose to the throat.[75] Thus, to take "apply" to mean only the point of introduction or "route" of the substance would be to render nonsensical the claims of the '070 patent and the "lozenge" claims of the '465 patent, since "oral mucosa" refers also to the throat. Obviously, we cannot accept such a

[75]That is, the expert testimony on anatomy went to show that the nasal passages and the mouth converge at the throat. Just as substances flow from the mouth to the throat, so too do they move from the nose to the throat.

definition. Thus, we cannot limit "applying" to mean only the situs of the initial introduction of the substance to the body, and instead must take it to allow any means by which the zinc gluconate gets to the mucosa in question.

Having thus completed our interpretation of the claims,[76] we may now look to the evidence relating Zicam to the '465 claims.

2. Infringement

Having above construed the '465 claims, we are left with essentially the same questions about infringement as we had in resolving the earlier motion for summary judgment. Zicam infringes the '465 patent if administering it into the nose via the nasal pump causes an effective dosage of zinc gluconate to bathe or soak the throat. In considering whether Zicam infringes on the '465 patent, we have the benefit of the testimony of Quigley's medical expert, Dr. Goldberg, GumTech's medical expert,

[76]GumTech raises one additional claim interpretation argument that we here address briefly. It argues that the patent claim calling for zinc to "saturate the oral mucosa" must mean that the zinc must saturate the entire oral mucosa. This interpretation would of course help Zicam's position, since there is no evidence that the nasally-introduced Zicam reaches the entire lining of the mouth, tongue, and throat. However, we cannot accept this as the proper interpretation of the claim. Testimony showed that the oral mucosa is quite extensive, as it covers all the interior surfaces of the mouth and the throat. There is no evidence either in the prosecution histories or in testimony before us that the patented invention required zinc to cover each and every square millimeter of these surfaces. We therefore find that it would not be reasonable to import an "entire" restriction to the use of "oral mucosa" in the claims.

Dr. David S. Riley, M.D., and one of Zicam's developers, Dr. Hensley.

Dr. Goldberg testified that the nasal cavity communicates with the throat[77] and that the mucosa in the nose is moved back toward the throat at a rate of about one inch every five minutes, though the rate is slowed when one has a cold because of congestion. Dr. Goldberg testified that he had performed an experiment[78] in which a healthy twenty-nine year old male had used Zicam according to the directions on the package and Dr. Goldberg then observed the subject's nose and throat. Immediately after use, Dr. Goldberg could see the Zicam in the subject's nose, and as time passed the subject reported feeling it in the back of his nose. At eleven minutes after use, the subject could still feel the Zicam in the back of his nose and Dr. Goldberg was able to see some Zicam, which has a white-like color, on the back of the palate at the uvula and at the very back of the mouth. At twelve minutes after use, Zicam was visible on the oropharynx -- that is, in the throat.

Dr. Goldberg testified that if Zicam were used as directed, to include reapplication every two to four hours, this would result in an increase of zinc ions in the throat. In

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[77]The "throat" is composed of the oropharnyx and the hypopharnyx. The nasopharnyx, which is located behind the nasal cavity, is located above the oropharynx and is not part of the throat.

[78]Dr. Goldberg admitted that this was essentially an informal experiment in that there was no approved protocol and it involved only one subject's one-time use of Zicam.

particular, in his opinion Zicam would saturate the oral mucosa specifically in those places where he had observed the Zicam in his test subject following the subject's use of Zicam. Dr. Goldberg also stated that he expected that Zicam would remain the longest in the upper part of the oropharynx -- again, part of the throat -- and that while a liquid spray into the nose might tend to be quickly absorbed, a gel such as Zicam would tend to resist absorption and would instead be passed back towards the throat on the mucosal flow.

On the other hand, Dr. Goldberg stated that some of the Zicam gel would remain in the nose, and that the highest initial concentration of Zicam was in the nose. He also testified that his test subject stated that the substance had no taste, and that given the position of the Zicam in the subject, once it had moved towards the throat, he would have expected the subject to taste the material if indeed it had any taste.[79]

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[79]The testimony about taste may be quite material. If there is one fact upon which the parties agree in this case, it is that zinc gluconate, however effective it may be as a cold treatment, has an utterly disagreeable taste. Guy Quigley, president and CEO of the Quigley Corporation, testified that only approximately seven percent of the population can tolerate its taste. Naturally, when one seeks to provide a medicine in lozenge form, the objectionable taste of the active ingredient is a major roadblock. In fact, Quigley's great accomplishment in developing its Cold-Eeze line of products was marrying Eby's patent for a zinc gluconate cold treatment with a patented sweetener that allowed the zinc gluconate to ionize (since it is the zinc ions that affect viral replication).

On the other hand, we heard testimony that the gel base carrier that is used in Zicam has no taste whatever. Thus, one might expect that if Zicam has no taste when it reaches the back of the mouth and the throat, there is no longer any zinc

(continued...)

For the defense, Dr. Riley[80] offered his opinion that Zicam is designed and intended to remain in the nose, for it is in the nasal cavity that the main antiviral effect is accomplished. He noted that the lining of the nasopharynx, located behind the nasal cavity and above the throat, is physically distinct from the lining of the throat and is most susceptible to the rhinovirus; thus Zicam is made to attack the rhinovirus in the area where it is most likely to infect a human. He also testified that while Zicam's gel base may travel past the nose and down the throat, the zinc is given up in the nose. Moreover, Dr. Riley stated that while the studies undertaken by Quigley to prove the utility of zinc gluconate lozenges involved lozenges containing 25 or 13.3 milligrams each of zinc gluconate, a dose[81] of Zicam contains but 0.2 milligrams of zinc gluconate.

We also received testimony from Dr. Hensley, one of Zicam's developers. He testified that the gel in which the zinc gluconate is contained is intended to keep the zinc gluconate in the nose, and that to the extent the packaging of Zicam states

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[79](...continued)
gluconate present in it. If this, in turn, is the case, then it becomes much less likely that Zicam is applying an effective dosage of zinc to the oral mucosa, as required in the patent claims.

[80]Dr. Riley is board certified in internal medicine, and is a board member of the Homeopathic Pharmacopoeia Convention of the United States, a technical advisory board recognized by the FDA.

[81]That is, per the instructions, one squirt per nostril.

that it is "long-lasting" it refers to the duration in the nose.[82] He also testified that the nasal pump by which Zicam is administered is intended to "splatter" the Zicam within the nose[83], but that in fact a quantity of the gel manually smeared on the inside of the nostril has an equally beneficial effect in fighting the common cold.

On this evidence, and although it is a close case, we find that Quigley has demonstrated a likelihood of success in proving infringement. It would seem clear from Dr. Goldberg's testimony that when Zicam is used as directed, at least some of the product reaches the throat. This is based not only on the brief empirical trial Dr. Goldberg testified to,[84] but also on the basic bodily functions, such as the movement of mucosa, to which he also testified. Thus, on the basis of our interpretation of the '465 claims, it would appear almost certain that Quigley will prove that Zicam is applied to the oral mucosa.

There are two other claim elements that are not as clearly in Quigley's favor: it must show that Zicam "saturates" the mucosa, and also that Zicam applies an "effective dose" of

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[82]This in response to Quigley's point that if the gel is long-lasting in that it slowly releases the zinc, the gel that reaches the throat will still contain zinc.

[83]Indeed. A demonstration in the courtroom showed that the pump was capable of propelling the Zicam about ten feet.

[84]We recognize that GumTech has several quite valid concerns about this test, including that the test subject was not suffering from a cold and that the test admittedly did not include many typical experimental safeguards, such as the use of multiple subjects.

zinc gluconate. As noted above, we found saturate to mean "to bathe or soak" and Dr. Goldberg testified that there was a portion of the throat covered with the Zicam to as to produce this effect. On the other hand, as noted in the margin above, these test results are hardly conclusive. Even more problematic is the question of the effective dosage. As discussed above, it appears that Zicam contains much less zinc gluconate than the tested lozenges; thus, to the extent that the lozenges were effective, this does not mean that the portion of a Zicam dose that reaches the throat is necessarily effective. It is therefore far from certain, as a matter of fact, that Zicam delivers an "effective dosage" of zinc gluconate, even given that it is applied to the throat.[85] However, we cannot find that

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[85]We have seen no argument before us about what exactly is an "effective dose" of zinc gluconate. This may indeed be a thorny problem in that while Eby's original '070 patent application contained a specification regarding the necessary concentration of zinc ions, this was rejected by the examiner who stated that "it is impossible to determine what the antiviral amount would be", see Def.'s Ex. 30 at [23]. The "effective dosage" language is not present in the '070 patent or in claim 1 of the '465 patent. Neither was "effective dosage" present in the initial version of the new claims of the '465 patent application.

Our preliminary review of the '465 patent prosecution history suggests that the term "effective dosage" first appeared as part of the PTO's April 23, 1990 office action in which the PTO gave Eby notice that his appeal from the examiner's final rejection was defective, but also proposed a series of new claims that would be acceptable to the PTO, see Def.'s Ex. 31 at [257]. Thus it seems that "effective dosage" may have come from the PTO, not from Eby. While various of the '465 claims specify dosage amounts of between 2 and 200 milligrams (claim 6) or 2 and 50 milligrams (claim 7), see Pl.'s Ex. 1 at col. 4-5, there is no definition or indication of what dosage is to be considered "effective". To the extent that the dosage numbers in the claims

(continued...)

these concerns foreclose our finding that Quigley has a likelihood, though not a strong likelihood,[86] of success on the merits, based on the fact that Zicam reaches the throat.

IV. Irreparability of Harm to Quigley Absent an Injunction

The most persuasive evidence weighing against the issuance of a preliminary injunction against GumTech comes from the testimony of Guy Quigley, Chairman and Chief Executive Officer of Quigley Corporation, and the exhibits that were considered during the testimony.

In particular, in colloquy with us on March 31, Mr. Quigley described the explosive and immediate results that intense national publicity can cause to a product. In the winter of 1996-97, CNN carried a story regarding the efficacy of Cold-Eeze in reducing the duration of the common cold. According to Mr. Quigley, this story ran on Headline News every half hour, and thus in one day was repeated twenty-eight times. That winter, the ABC television network program, 20/20, devoted a half hour to the common cold, and half of that time was spent on remedies for it. Cold-Eeze was, again, prominently mentioned.

This media bonanza proved to be a two-edged sword. As one might expect, it brought an avalanche of business to Quigley,

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[85](...continued)
go to show effective doses, of course, it is hard to see how Zicam's 0.2 milligrams could be "effective". But this is a problem for another day.

[86]In light of this finding, irreparable harm is not presumed, see Reebok Int'l, 32 F.3d at 1556.

such that, according to its 1999 SEC Form 10-K (Pl.'s Ex. 37), its 1997 sales were $70,172,563, id. at 11. Success like this in the American economy, however, has an inevitable and almost equally immediate effect: in very little time, about forty products appeared on the market that prominently featured the word "zinc". See, e.g., Def.'s Ex. 74 ("Zinc" lozenges in "Cold Season Plus" product); Def.'s Ex. 78("Cold Vac Ionic Zinc" lozenge); Def.'s Ex. 83 ("Fast Dry Zinc"); Def.'s Ex. 76 ("Dr. Zinc" lozenge, which specifically mentions Cold-Eeze); Def.'s Ex. 81 ("Zinc Gluconate Lozenges").

The same Quigley 10-K shows the effect of these copycats. Sales in 1998 dropped to $36,354,155, and in 1999 sales revenue fell to $24,819,942. In Item 7 of the 1999 10-K, which was filed with the Securities and Exchange Commission on March 20, 2000, in "Management's Discussion and Analysis of Financial Condition and Results of Operations", Quigley told the public and the Securities and Exchange Commission that:

> The decrease in sales in 1999 is attributable to increased competition with the additional of herbal and zinc remedies that have not been clinically proven to counteract the symptoms of the common cold. Some unproven zinc products were discontinued in 1999 resulting in clearance selling at severely discounted prices. This increased activity and incessant marketing resulted in consumer confusion with the distinction between what products claim they can achieve and what they have been proven to achieve becoming unclear.

Id. It does not escape our attention that Quigley in this section of its March 20, 2000 10-K fails to mention Zicam.

Most pertinent to the instant motion, none of this decline could be attributable to Zicam until, at the earliest, October of 1999. While it is certainly true that the record confirms Zicam's quick acceptance in the marketplace -- see, e.g., Pl.'s Exs. 40-A and 53 at 13 (GumTech 10-K, filed March 24, 2000), -- by this time Quigley had long suffered from the market confusion forty new "zinc" products had wrought.

The truth of the matter, at least to date, is that Quigley is the victim of its own explosive success, and not the victim of GumTech's conduct. On the record before us, it would represent the sheerest of conjecture for us to extrapolate, from the thin reeds before us, the kind of irreparable harm to warrant the "dramatic and drastic power of injunctive relief" to which our Court of Appeals referred in Adams and Holiday Inns of America, supra.

V. The Balance of Hardships

We are fortified in our conclusion as to irreparable harm when we consider the Draconian effect such an injunction would have on GumTech and its over-5,000 stockholders, as well as on its many employees. By contrast, Quigley and its stockholders will not have their interests snuffed out if we at this juncture allow GumTech to remain in existence.

We are mindful that the products at least to some degree compete with one another. This point was rather starkly presented in photos from a Walgreen's outside Chicago (Pl.'s Ex.

56) which show how that retailer lined up Zicam dispensers on top of Quigley's proprietary display case. But there was no evidence that these Walgreen photographs gave us a true picture of the competitive landscape. To the contrary, what little we heard on this topic confirmed that retailers typically do not put nasal pumps next to lozenge boxes. There would thus seem to be ample room in this market for these two products to co-exist while we sort out these difficult questions in the more rounded context of a final injunction proceeding.[87]

VI. The Demands of the Public Interest

"Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." Hybritech Inc. v. Abbott Lab., 849 F.2d 1446, 1458 (Fed. Cir. 1988) (footnotes omitted). We cannot identify any such critical public interest here. Not only has the common cold been with humanity for a long time, but it is not a fatal or extremely hazardous condition. We note that Quigley's expert, Dr. Goldberg, testified that he and his fellow physicians tended not to prescribe new over-the-counter remedies, such as the zinc

[87] We hasten to note that this sentence in our view applies if either or both of the parties elect to ask the Federal Circuit to do this sorting out first. See 28 U.S.C. § 1292(a)(1).

remedies at issue in this case, to their patients with colds partially because the condition is not serious and tends to dissipate over time without medical intervention.

Thus, though keeping Zicam off store shelves might inconvenience those who had become accustomed to its use, we cannot find that this amounts to a critical interest sufficient to create a general public interest concern that by itself would militate towards denying this motion.

VII. Conclusion

We conclude that Quigley has shown a likelihood of success on the merits by showing that it is likely that the '465 patent will be found to be valid and that it is also likely, though by no means certain, that GumTech's Zicam product will be found to infringe the '465 patent. Quigley has not, however, shown the requisite irreparable harm related to a denial of preliminary injunctive relief, and we have found that the hardships here would fall disproportionately on GumTech were we to impose such an injunction.

Notwithstanding the merits of Quigley’s contentions regarding the ‘465 patent, we therefore will deny the motion for preliminary injunction.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE QUIGLEY CORPORATION	:	CIVIL ACTION
	:	
v.	:	
	:	
GUMTECH INTERNATIONAL, INC., et al.	:	NO. 99-5577

ORDER

AND NOW, this 19th day of April, 2000, upon consideration of plaintiff's motion for preliminary injunction, and defendants' response thereto, and for the reasons stated in the accompanying Memorandum, it is hereby ORDERED that the motion for preliminary injunction is DENIED.

BY THE COURT:

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Stewart Dalzell, J.