

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

PROCTER & GAMBLE COMPANY,

Plaintiff,

v.

MCNEIL-PPC, INC.,

Defendant.

OPINION and ORDER

08-cv-251-bbc

This is a civil action for infringement of a patent for tooth whitening strips. Plaintiff Procter & Gamble Company is the owner of U.S. Patents Nos. 6,551,579 (“the ‘579 patent”) and 6,949,240 (“the ‘240 patent”) that cover plaintiff’s products such as Crest Whitestrips® Premium, Crest Whitestrips® Premium Plus, Crest® Healthy Radiance, Crest Whitestrips® Renewal and Crest Whitestrips® Supreme. On May 1, 2008, plaintiff filed a complaint against Johnson & Johnson and defendant McNeil, alleging that their Listerine Whitening Quick Dissolving Strips infringe the ‘579 and ‘240 patents and that the infringement is willful and wanton. This court has jurisdiction to hear this dispute under 28 U.S.C. §§ 1331 and 1338.

On July 14, 2008, plaintiff’s claims against Johnson & Johnson were dismissed from

this case without prejudice. Dkt. #30. On March 24, 2009, I granted plaintiff's motion to dismiss with prejudice its claims of infringement of the '579 patent and I dismissed without prejudice defendant's counterclaims regarding the same patent. Dkt. #316. Thus, the only remaining claims are plaintiff's claims of infringement of the '240 patent and defendant's counterclaim of inequitable conduct.

Now before the court are the parties' cross motions for summary judgment on the issues of infringement, invalidity and inequitable conduct; two preliminary motions by defendant: one for sanctions under Rule 37 and one to strike evidence, expert reports and sections of plaintiff's reply brief on inequitable conduct; plaintiff's motion to clarify the court's claims construction order; and plaintiff's Rule 56(f) motion to deny defendant's motion for summary judgment on plaintiff's claim of willful infringement.

The issues will be decided as follows. First as for the preliminary motions:

1. Plaintiff's motion for clarifications of this court's claim construction order, dkt. #326, will be granted;
2. Defendant's motion for Rule 37(b) sanctions, dkt. #288, requesting that the court strike rebuttal and supplemental expert reports by Harold Heymann and Robert E. Cohen and additional proposed findings of facts will be granted because plaintiff failed to comply with the deadline for expert reports;
3. Defendant's motion, dkt #298, to strike new material, exhibits and facts raised in

plaintiff's reply brief will be denied as unnecessary; and

4. Plaintiff's Rule 56(f) motion, dkt. #328, to deny defendant's motion for summary judgment on plaintiff's claim of willful infringement, dkt. #192, will be denied.

As to the dispositive motions:

1. Defendant's motion for summary judgment, dkt. #192, that the claims of the '240 patent are invalid for obviousness will be denied;

2. Defendant's motion for summary judgment, dkt. #192, that the accused products do not directly infringe the '240 patent because they do not consist of a "strip of material" with "low flexural stiffness" will be denied;

3. Defendant's motion for summary judgment, dkt. #192, that it did not willfully infringe will be granted because plaintiff has failed to offer sufficient evidence that defendant's actions were objectively reckless; and

4. Plaintiff's motion for summary judgment of no inequitable conduct, dkt. #187, will be granted because defendant has failed to meet its burden of showing the necessary intent to deceive.

In addition, defendant has moved for summary judgment on obviousness and non-infringement on the '579 patent, dkt. #192, and asked in its reply brief for entry of judgment in its favor. With the dismissal of defendant's counterclaims regarding the '579 patent on March 24, 2009, this request is moot. These rulings leave the following issue for

trial: whether defendant's Listerine strips infringe claims 1-7, 9, 12-14 and 17-19 of the '240 patent.

I. PRELIMINARY MOTIONS

A. Clarification of Court's Claim Construction Order

On January 26, 2009, the court issued a claims construction order on several disputed terms in the '240 and '579 patents. Dkt. #169. Two of the constructions appear to have caused confusion, leading to a new round of tests on defendant's allegedly infringing product and a series of expert opinions on the meaning of the construction, which caused defendant to file a motion for sanctions regarding plaintiff's supplemental expert reports. As a result, plaintiff filed a motion to clarify this court's order. Dkt. #326. Defendant opposes this motion, arguing that plaintiff is asking the court to reconsider its claims construction decision. I disagree with defendant's characterization of the motion. Because the meaning of the terms of the '240 patent is relevant to disputed issues of infringement and has caused the parties some consternation, I will address the issues raised in plaintiff's motion to clarify.

Plaintiff contends that defendant has misconstrued this court's construction of the terms "layer of tooth whitening composition" and "strip of material" found in claims 1 and 14 of the '240 patent. In the January 26, 2009 order, I concluded that those terms meant the following:

- the “layer of tooth whitening composition” disclosed in claims 1 and 14 is separate from the “strip of material” disclosed in claims 1 and 14;
- the “strip of material” disclosed in claims 1 and 14 has a low flexural stiffness, but the “strip of material” disclosed in claims 1 and 14 is not indefinite and does not contain the following limitations: (1) it cannot dissolve or disintegrate in the mouth; (2) it is conformable to the countered surfaces of the teeth; (3) it serves as a substantially water impermeable barrier during use; (4) it is easily removable and intact after use and (5) it has structural integrity

Order, dkt. #169, at 32. Defendant’s experts argue that what this court meant by (1) “low flexural stiffness” is not an object that is stiff and brittle and (2) “separate” means that the layer of tooth whitening composition is “separable” from the strip of material. As an initial matter, the court did not construe the terms “low flexural stiffness” or “separate.” Because those terms were not construed, any argument regarding their meaning would require the parties to support their construction of the disputed term with language from the claim, specification, prosecution history or other extrinsic evidence typically used in construing claim terms.

Although defendant has not expressly asked this court to construe the disputed terms in its current summary judgment motion, it does so implicitly by asking the court to consider whether “low flexural stiffness” has the meaning offered by defendant’s experts; I will address what is meant by this term in the section dealing with defendant’s argument regarding non-infringement. With respect to the term “separate,” this term is not addressed in either

party's motion for summary judgment. Therefore, it is not necessary to construe the meaning of the term at this time. However, this court did not hold that "separate" means "separable." It held only that these two objects were separate from each other. I will not decide at this time whether "separate" means "separable" because the parties did not brief the issue. If they wish to address the point prior to trial in their motions in limine, they may do so but they should brief the issue as though it were a motion for claims construction, identifying the language in the claim language, specification or prosecution history that supports their proposed construction.

B. Motions for Sanctions and to Strike

1. Defendant's Rule 37(B) motion for sanctions

Defendant's first motion to strike involves expert reports filed by plaintiff. Defendant contends that these expert reports address for the first time a new theory of infringement based on the doctrine of equivalents, new opinions about the meaning of the claim terms of the '240 patent and new validity opinions regarding the '240 patent. Defendant argues that this is an improper third round of expert reports in violation of this court's preliminary pretrial conference order and in violation of Rule 26. Defendant's motion for sanctions will be granted. Plaintiff's supplemental reports add new expert opinions without permission from the court as opposed to merely supplementing the subjects addressed in plaintiff's

initial expert report.

In this court's preliminary pretrial conference order, dkt. #25, issued on June 20, 2008, the magistrate judge explained to the parties that:

[a]ll disclosures mandated by this paragraph must comply with the requirements of Rule 26(a)(2)(A), (B) and (C). There shall be no third round of rebuttal expert reports. *Supplementation pursuant to Rule 26(e)(1) is limited to matters raised in an expert's first report*, must be in writing and must be served not later than five calendar days before the expert's deposition, or before the general discovery cutoff if no one deposes the expert. . . . Failure to comply with these deadlines and procedures could result in the court striking the testimony of a party's experts pursuant to Rule 37. The parties may modify these deadlines and procedures only by unanimous agreement or by court order.

Dkt. #25, at 2-3 (emphasis added). By court order, initial expert reports were due December 8, 2008 and responsive reports were due February 4, 2009. Responsive reports are limited to "evidence intended solely to contradict or rebut evidence on the same subject matter identified by another party" in an expert report. Fed. R. Civ. P. 26(a)(2)(C)(ii).

On December 8, 2008, plaintiff submitted opening expert reports on infringement and defendant submitted expert reports on invalidity and inequitable conduct. When plaintiff's experts, Heymann and Cohen, submitted their initial opinions, both experts had reviewed and read defendant's claims construction filings and were aware of defendant's positions regarding the meaning of the disputed claim terms of the '240 patent. The court issued its claims construction order on January 26, 2009. Both parties submitted rebuttal

expert reports on February 4, 2009 in accordance with the court's scheduling order. Now defendant takes issue with ¶¶ 631-37 of the Heymann rebuttal report, dkt. #256, as improperly adding a new infringement opinion.

On February 27, 2009, plaintiff submitted a third round of expert reports from Heymann and Cohen, entitled "Supplemental Expert Reports," dkt. ##253 and 257, without filing a motion for leave to file additional expert reports. As the title suggests, these reports supplemented the opinions submitted by the experts in December to include (1) opinions regarding the meaning of the term "low flexural stiffness" and tests conducted on the accused product, Supp. Exp. Reports, dkt. # 253, ¶¶ 32-73, and dkt. #257, ¶¶ 31-68; (2) opinions regarding whether "separate" meant "separable"; and (3) an additional opinion regarding the Gerlach Abstract that defendant contends is undisclosed prior art demonstrating both invalidity and inequitable conduct on plaintiff's part.

Plaintiff responds that the rebuttal report and supplemental reports are proper because they are "limited to matters raised in their first report" and are necessary to address this court's claims construction order and defendant's "novel interpretation" of that construction. I disagree with plaintiff on both grounds.

First, ¶¶ 631-37 in Heymann's rebuttal report are not proper "rebuttal" of defendant's expert reports on inequitable conduct and validity. The paragraphs are identified unequivocally as "Supplementation of My Opinion on Infringement." Because rebuttal

reports are limited to responding to the issues raised by the opposing parties' experts, I will dismiss these paragraphs because they are improper supplementation and fail to comply with Fed. R. Civ. P. 26(a)(2)(C)(ii).

Second, under Fed. R. Civ. P. 26(e)(1), a party may supplement or correct its Rule 26(a) disclosures "if the party learns that in some material respect disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1). That is not the case here. The supplemental expert reports raise entirely new matters regarding infringement not raised in the experts' initial reports. The initial reports did not discuss any of the limitations defendant proposed in its claims construction order, including the meaning of the terms "low flexural stiffness," and did not contain opinions regarding the doctrine of equivalents.

The experts had the benefit of defendant's claims construction briefs and knew what limitations could be found in the disputed claim terms. Although they did not believe that any of these limitations were present, they were not precluded from offering their opinions on the proposed constructions in the alternative. In addition, if plaintiff's experts believed in December that the accused product infringed under the doctrine of equivalents, they should have said so at that time. The failure to address these issues in the initial expert reports was plaintiff's choice. It was not dictated by defendant or this court. Plaintiff

cannot now seek to alter its strategy without a showing of good cause, which it has failed to make.

Plaintiff adds that its experts expressly reserved the right to provide limited supplementation in their initial expert reports. The fact that they did so does not mean they have such a right. In this case, their right was limited to matters addressed in their initial report.

Third, plaintiff argues that it will be prejudiced if it cannot submit expert reports regarding defendant's argument on "low flexural stiffness" and "separate." As discussed in this opinion, plaintiff will not be prejudiced in either respect because the court is not adopting either of defendant's experts' proposed constructions. To be specific, the court is not adopting defendant's construction of the disputed term "separate" or defendant's proposed construction of the term "low flexural stiffness." Defendant's motion for Rule 37 sanctions to strike plaintiff's supplemental and rebuttal expert reports will be granted.

2. Defendant's motion to strike new facts and arguments raised in plaintiff's reply brief

Defendant has requested that the court strike portions of plaintiff's reply brief, responses to defendant's additional proposed findings of fact and new exhibits, the Feit and Lippert Declarations, dkt. ## 260, 261 and 280, on the ground that plaintiff should have raised these arguments, proposed these facts and presented these exhibits with its initial brief

for summary judgment. In the alternative, defendant requests an opportunity to file a sur-reply brief to respond to these “new arguments.”

As an initial matter, defendant bears the burden of proving a claim of inequitable conduct. Larson Manufacturing Co. of South Dakota, Inc. v. Aluminart Products Ltd., 559 F.3d 1317, 1327 (Fed. Cir. 2009) (“To successfully prove inequitable conduct, ‘the accused infringer must present evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO].’”)(citation omitted). Defendant alleges that plaintiff failed to present any evidence to refute defendant’s accusation of intent to deceive the patent examiner. Defendant fails to consider that it was not plaintiff’s burden to prove a negative.

Plaintiff took the position that defendant had no evidence of plaintiff’s alleged intent to deceive. Defendant cited a number of withheld references but it failed to adduce sufficient evidence that any of the references were material or, more important, that either plaintiff or any its employees withheld these references with the specific intent to mislead the patent examiner. Even taken in the light most favorable to defendant, the evidence failed to establish a claim of inequitable conduct. Therefore, it was not necessary to consider plaintiff’s reply brief or its response to defendant’s additional proposed findings of fact. Accordingly, defendant’s request to strike plaintiff’s reply or file a sur-reply will be denied

as unnecessary.

C. Rule 56(f) Motion

On May 3, 2009, plaintiff filed a Rule 56(f) motion requesting the court to deny defendant's motion for summary judgment on willful infringement because defendant had failed to reveal to plaintiff whether it had relied on an opinion of counsel to determine infringement of the '240 patent. Under Rule 56(f) a court may deny a summary judgment motion if the nonmoving party has not had a fair opportunity to engage in full discovery of a disputed issue. "Rule 56(f) requires a party to state the reasons why it cannot adequately respond to the summary judgment motion without further discovery and must support those reasons by affidavit." Waterloo Furniture Components, Ltd. v. Haworth, Inc., 467 F.3d 641, 648 (7th Cir. 2006). "When a party fails to secure discoverable evidence due to his own lack of diligence, the necessary justification is lacking, and 'it is not an abuse of discretion for the trial court to refuse to grant a continuance to obtain such information.'" Kalis v. Colgate-Palmolive Co., 231 F.3d 1049, 1057 n.5 (7th Cir. 2000) (citing Pfeil v. Rogers, 757 F.2d 850, 857 (7th Cir. 1985)); see also Farmer v. Brennan, 81 F.3d 1444, 1449 (7th Cir. 1996) ("This Court has noted that the party seeking further time to respond to a summary judgment motion must give an adequate explanation to the court of the reasons why the extension is necessary.").

According to plaintiff, defendant repeatedly asserted the attorney-client privilege and work product objections to block plaintiff's discovery efforts. Plaintiff identifies three instances of defendant's dilatory efforts. In June 2008, defendant asserted the attorney-client privilege in responding to plaintiff's interrogatories. In October and again in November 2208, defendant allegedly instructed its Rule 30(b)(6) witnesses not to answer certain question during depositions. In February 2009, defendant filed a motion for summary judgment, contending that plaintiff had failed to adduce any evidence that defendant had engaged in the objectively reckless behavior necessary to prove willful infringement as a matter of law. On March 20, 2009, defendant waived the attorney-client privilege and disclosed 90 pages of detailed opinion letters of counsel on validity and infringement.

Although plaintiff asserts that defendant engaged in repeated efforts to railroad its discovery efforts, plaintiff had sufficient time and notice to secure the discovery it needed on its willful infringement claim. Because plaintiff asserted a claim of willful infringement, it was aware that it would bear the burden of proving this claim at trial. In re Seagate Technology, LLC, 497 F.3d 1360, 1373 (Fed. Cir. 2007) ("when a complaint is filed, a patentee must have a good faith basis for alleging willful infringement[;] . . . [s]o a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct"). If plaintiff believed that it lacked the evidence it

needed to prove this claim because of defendant's discovery machinations, it was plaintiff's responsibility to file a motion to compel discovery on this issue with the court. It did not. In the court's preliminary pre-trial conference order, parties are instructed to file motions with the court when discovery disputes arise:

This court also expects the parties to file discovery motions promptly if self-help fails. Parties who fail to do so may not seek to change the schedule on the ground that discovery proceeded too slowly to meet the deadlines set in this order.

Order, dkt. #25. Thus, plaintiff has notice of its duty to bring this issue to the court but choose not to do so until too late.

Moreover, when defendant filed its motion for summary judgment on February 8, 2009, arguing that plaintiff had failed to produce enough evidence of willfulness, plaintiff was aware that it might need additional discovery on the issue of willful infringement. Again, plaintiff chose not to raise the discovery issue to this court. Plaintiff has not identified any efforts by defendant to purposefully conceal information or hide relevant discovery. Plaintiff knew why defendant was withholding certain information and could have brought this issue to the fore sooner. Its decision to wait undermines its claim of injustice. Because plaintiff was not diligent in pursuing discovery on the issue of willful infringement, its Rule 56(f) motion will be denied.

II. SUMMARY JUDGMENT

From the parties' proposed findings of fact, I find the following facts to be material and undisputed.

UNDISPUTED FACTS

A. Parties

Plaintiff Procter & Gamble is a corporation organized and existing under the laws of the State of Ohio having its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, Ohio. Plaintiff is the owner of the '240 patent. It sells the Crest Whitestrips® Premium, Crest Whitestrips® Premium Plus, Crest® Healthy Radiance, Crest Whitestrips® Renewal, and Crest Whitestrips® Supreme, all of which are covered by the claims of the '240 patent.

Defendant McNeil-PPC, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. Defendant sells the Listerine Quick Dissolving Strips.

B. Claims of the '240 patent

The '240 patent discloses a strip-based tooth whitening product. Before the development of strip-based whitening products, the consumer tooth whitening industry

consisted mostly of tray-based systems that individuals wore for multiple hours. The whitening strips patented by plaintiff and covered by the '240 patent provide a less bulky and cumbersome solution for tooth whitening. Plaintiff has asserted the following claims of the '240 patent against defendant: Claims 1-7, 9, 12-14, and 17-19. The only independent claims asserted are claims 1 and 14.

Claim 1 of the '240 patent recites:

A tooth whitening product, comprising:

a strip of material sized to cover the front surface of one or more teeth and soft tissue adjacent the front surface of the one or more teeth;

a layer of a tooth whitening composition disposed on said strip of material, wherein said whitening composition comprises a peroxide active having concentration greater than about 7.5% by weight of said tooth whitening composition;

and wherein said tooth whitening composition has a peroxide density less than about 1.3 mg/cm².

Claim 14 of the '240 patent recites:

a package having a headspace; a strip of material sized to cover the front surface of one or more teeth and soft tissue adjacent said front surface, wherein said strip of material is disposed within said package;

a layer of a tooth whitening composition disposed on said strip of material, wherein said tooth whitening composition comprises a peroxide active having a concentration between about 7.5% and about 40% by weight of said tooth whitening composition;

and wherein said tooth whitening composition has a peroxide density between about 0.01 mg/cm² and about 1.3 mg/cm².

Some of the dependent claims add further limitations to high peroxide concentrations, including ranges from 8% to about 40% and from 10% to about 20%. Claims 2-6, 9, 12 and 13 are dependent on claim 1 and claims 17 through 19 are dependent on claim 14. Dependent claims 2, 13 and 17 disclose a peroxide concentration range greater than 7.5%. Claims 4 and 5 disclose a peroxide density range between .01 and .5 mg/cm² and 1.3 mg/cm². Claims 12, 13 and 18 are directed at the thickness of the tooth whitening layer. Claims 6 and 7 contain a tooth whitening composition that contains water. Claims 9 and 19 add a gelling agent to claims 1 and 14.

As defined in the '240 patent, peroxide density is "the ratio of the amount of peroxide active (mg) or peroxide dose to the surface area (cm²) of the thin layer that is applied to the tooth surfaces and adjacent soft tissue of the oral cavity." '240 Pat., col. 5, lns. 52-55.

C. Prosecution History of the '240 Patent

The patent application for the '240 patent was filed by Paul Albert Sagel and Robert Woodrow Gerlach on May 23, 2002. The application was filed more than a year after the introduction of the first Crest Whitestrip product. The inventors disclosed more than 40 prior publications to the Patent Office, including scientific articles and declarations.

On August 11, 2004, the patent examiner issued an office action, rejecting the pending claims of the '240 patent as being anticipated by U.S. Patent No. 6, 582,708 (the '708 patent) and obviousness-type double patenting. The examiner stated, in relevant part,

the prior art is seeking to optimize the same parameters of surface area to volume as [plaintiff], using strips having the same physical dimensions as [plaintiff], which are coated with a thin layer of whitening agent made from the same components in the same percentages as [plaintiff]. It is readily apparent, given these facts, that the prior art whitening strips must also inevitably and inherently have peroxide densities which are substantially the same as those claimed instantly, i.e., less than about 1.3 mg/cm², more preferably 0.1 to 1.3, and most preferably 0.5 to 1.3 [], even though patentees did not specifically measure that parameter.

Kopelman Decl., Exh. II, dkt. #199-20, at 55.

On February 11, 2005, inventor Sagel discussed the patent application with the patent examiner. In his interview summary, the patent examiner noted that the '240 patent teaches that “by increasing the peroxide concentration of the gel, while decreasing its thinness, soft tissue compatibility is unexpectedly increased without sacrificing bleaching activity.” Id. at 66. The patent examiner observed that the allegedly anticipating '708 patent “provides no motivation for picking and choosing [individual parameters of peroxide concentration and gel layer thinness], and judiciously balancing them to provide improved soft tissue compatibility while maintaining bleaching activity as [plaintiff] has done. (In other words, it would at best only have been ‘obvious to try’).” Id.

In addition, plaintiff provided the examiner with information about peroxide density

and concentration values of Crest Whitestrips products. Plaintiff submitted the following table that highlighted plaintiff's commercialized products having peroxide densities between 1.2 mg/cm² and 1.3 mg/cm² and peroxide concentrations between 6% and 6.5% :

	Hydrogen Peroxide Concentration	Gel Loading (g) per cm ²	Thickness (cm)	HP Dose (mg) per cm ²
Crest Whitestrips Original	6	.02	.02	1.2
Crest Whitestrips Professional	6.5	.02	.02	1.3
Double Whitestrips concentration	12	.02	.02	2.4
Double conc / half gel amount	12	.01	.01	1.2
Crest Whitestrips Premium	10	.012	.012	1.2
Very high concentration	20	.005	.005	1.0

Kopelman Decl., Exh. II, dkt. #199-20, at 117. The table was intended to explain the concept of peroxide density to the examiner. The first two lines list the peroxide density of 1.2 mg/cm² and concentration of 6% for the Crest Whitestrips Original product and the density of 1.3 mg/cm² and concentration of 6.5% for Crest Whitestrips Professional

product. Plaintiff discussed these values with the examiner.

In response to the Office Action dated August 11, 2004, plaintiff submitted “Amendment After 1st Office Action Under 37 CFR 1.111(c).” In this amendment, plaintiff stated that

the claimed invention is not mere optimization because the claimed invention is not taught by [the ‘708 patent], as the reference fails to direct the use of the combination of the claimed peroxide concentration level at the claimed peroxide density, which can achieve increased whitening efficacy and soft tissue tolerability. Additionally,[the ‘708 patent] does not teach peroxide density values, or how to calculate peroxide density. The values disclosed in [the ‘708 patent] include load/area and peroxide amount by weight of the substance. It is submitted that the values included in these ranges do not result in the claimed peroxide density, nor do these values alone disclose the claimed peroxide density. One would have to pick and choose a variety of numbers from multiple ranges including, size of the strip, amount of peroxide, and amount of the gel to calculate the claimed peroxide density. Additionally, no teaching in [the ‘708 patent] directs one to choose a particular value from any of these ranges to achieve the claimed peroxide density.

Kopelman Decl., Exh. II, dkt. #199-20, at 147-48. In his “Reasons For Allowance,” the patent examiner stated that:

The prior art of record does not fairly suggest, teach or disclose the instantly claimed combinations of peroxide concentration and peroxide density, as previously discussed. This not only permits higher concentrations of peroxide to be used, but it also quite unexpectedly does so without increasing soft tissue irritation, as would be expected from the state of the art. Accordingly, this permits the use of whitening strips which contact the soft tissue (gums). This is a major step forward in the art, because it eliminates the (inconvenient) need for the consumer to carefully place the strips on the teeth only, while providing increased bleaching activity.

Id. at 115.

D. Prior Art to the '240 Patent

The disclosed prior art to the '240 patent taught that increasing peroxide concentration, among other factors, can increase soft tissue irritation in tray-based systems. Other factors included patient sensitivity and irritation with wearing a tray. No clinical trials or studies disclosed in the prosecution of the '240 patent expressly addressed the correlation between peroxide concentration and soft-tissue irritation phenomenon in strips. (Defendant contends that the Gerlach Abstract teaches this correlation). At the time of the invention, the prior art contained no suggestion that using the same peroxide density at higher concentrations would result in a thinner product.

The patent issued on September 27, 2005. The '240 patent does not claim priority to any earlier application.

1. Disclosed prior art

a. Crest Whitestrips

Crest Whitestrips were first marketed to the public in May 2000. The first Crest Whitestrips were known as Crest Whitestrips Retail and had a peroxide concentration of 5.3%. A later version of the Whitestrips increased the peroxide concentration to 6%. In

May 2001, plaintiff began marketing Crest Whitestrips Professional with a peroxide concentration of 6.5%. Some previous versions of the Crest Whitestrips had a peroxide density of 1.1 mg/cm².

b. The '708 patent

U.S. Patent No. 6,582,708 to Sagel et al. (the '708 patent) was filed on June 28, 2000. The '708 patent discloses a tooth whitening product comprising a "strip of material" and a "tooth whitening substance." The '708 patent states that the peroxide concentration in the tooth whitening substance can be from about 0.1 % to about 20%. The '708 patent discloses a range of tooth whitening substance per unit area from about .005g/cm² to about 0.1 g/cm². (The parties dispute whether this measurement is a "peroxide density" as defined by the '240 patent.) The '708 patent discloses a "strip of material" that has a low flexural stiffness within the same preferred range of flexural stiffness as the '240 patent.

2. Undisclosed prior art

a. The Sagel-Gerlach article

In July 2000, Paul Sagel and Robert Gerlach co-authored and published an article entitled "Vital Tooth Whitening With a Novel Hydrogen Peroxide Strips System: Design, Kinetics, and Clinical Response." The inventors did not disclose this article to the patent

office during prosecution of the '240 patent.

The Sagel-Gerlach article describes a Crest Whitestrip product consisting of a thin, flexible strip coated with an adhesive hydrogen peroxide whitening gel. The article states:

For many years, at-home whitening has been used with great success and produces some of the most satisfying results of all dental procedures. Historically, the most common procedure used was a custom-fabricated tray loaded with a 10% carbamide peroxide gel that was worn overnight. Today, many manufacturers offer higher concentrations (15% and 20% carbamide peroxide) for faster results.

Kopelman Decl., Exh. ZZ, dkt. #201-5, at 10. The Crest Whitestrips discussed in the Sagel-Gerlach article have two different strip designs, one for the upper teeth and one for the lower teeth. Both strips delivers approximately 1.1 mg hydrogen peroxide per square centimeter of contact.

The Sagel-Gerlach article discusses two trials comparing the efficacy of a tray-based whitener to a strip-based whitener. The tray-based whitening systems and Crest Whitestrips had similar efficacy. Both systems deliver the same amount of peroxide per tooth area. In the trial conducted by Gerlach, he found “no reports of tooth sensitivity among participants,” *id.* at 14, despite an increase from 10% carbamide peroxide to 16% carbamide peroxide (equivalent to 5.3% hydrogen peroxide). He reported that “the whitening strips provided a benefit similar to the 10% carbamide peroxide tray-based product with half the total wear time, . . . [t]he time-efficiency advantage of the strip is likely a result of faster delivery of

peroxide due to the large concentration gradient established when the strip is applied.” Id.

b. The Gerlach article

In July 2000, Robert Gerlach published an article entitled “Shifting Paradigms in Whitening: Introduction of a Novel System for Vital Tooth Bleaching.” Gerlach discussed numerous developments in tray-based systems, including “increases in peroxide concentration, to address perceived needs for faster and faster whitening.” Kopelman Decl., Exh. ZZ, dkt. #201-5, at 5. The article also noted the “uniform, low absolute peroxide dose, ranging from 8 mg to 11 mg of hydrogen peroxide per exposure.” Id. at 7.

The Gerlach article was prior art to the ‘240 patent. None of plaintiff’s employees or the patent inventors disclosed the article to the patent office during prosecution of the ‘240 patent.

c. The Gerlach Abstract

In March of 2001, D.A. McMillan, R.D. Gibb, and Robert W. Gerlach gave a poster presentation entitled “Impact of Increasing Hydrogen Peroxide Concentration on Bleaching Strip Efficacy and Tolerability.” The presentation was referred to as the Gerlach Abstract and was published in the Journal of Dental Research in 2001. The abstract is prior art to the ‘240 patent. Neither of the inventors nor any of plaintiff’s employees disclosed the

Gerlach Abstract to the patent office during prosecution of the '240 patent.

Gerlach described a 22-person clinical trial conducted to determine whether any correlation existed between increased peroxide concentration and increased soft tissue irritation in tooth-whitening strips. The study involved two separate groups who wore strips containing peroxide concentrations of 5.3% and 6.5%. The abstract states:

With the professionally-administered tray systems, increasing peroxide concentration increases whitening efficacy, but decreases tolerability. Since this relationship has not been established for polyethylene strip-based bleaching systems, a double-blind clinical trial was conducted among 22 adults to assess the impact of increasing peroxide concentration on clinical response.

Fiet Decl., Exh. #12, dkt. #260-13. Table 1 of the Gerlach Abstract shows that the 5.3% strip group had seven reported instances of oral soft tissue irritation and the 6.5% group had three reported instances of oral soft tissue irritation. The 6.5% group had one subject “drop out for cause.” There were no dropouts “for cause” in the 5.3% hydrogen peroxide group. Gerlach concluded that “a modest increase in peroxide concentration on a flexible bleaching strip results in increased whitening effectiveness, without adversely impacting on overall tolerability.” Id.

E. Accused Product: Listerine Quick Dissolving Strips

The Listerine strip is a tooth whitening product. These strips are small and cover a portion of the front surface of one or more teeth. The strip contains a hydrogen peroxide

concentration greater than 7.5% by weight of the tooth-whitening composition. The tooth whitening composition has a peroxide density less than about 1.3 mg/cm². The Listerine strip is composed of two layers, a thin and a thick layer. (Plaintiff contends that the thin layer is the “strip of material” described in claims 1 and 14 the ‘240 patent and the thick layer is the tooth whitening composition.). The strip dissolves in the wearer’s mouth.

Dr. Georgiades, defendant’s Rule 30(b)(6) witness, testified that “[t]he thick layer is coated onto the thin layer,” and agreed that the thick layer with the hydrogen peroxide is put onto the thin layer. Dr. Georgiades also stated that when the Listerine Strip is put on the teeth, it is designed to contour to the nooks and crannies of the teeth. In his deposition testimony, Dr. Georgiades was asked about the difference between the thin layer in the final product and the thin layer in the intermediate stage:

Q. When did you realize this fact that the thin layer in the final product when used breaks and is brittle and all the things you just said; when did you first figure that out?

A. I was talking about thin layer on the raw material. On the intermediate material very thin, very brittle and flaky and falls apart.

Q. So in the intermediate stage of the thin layer, it is your belief it is brittle and flaky?

A. It’s the truth, it is brittle and flaky, it is a fact.

Q. It is intermediate stage?

A. Yes.

Georgiades Dep., dkt. #244, at 55.

F. Low Flexural Stiffness

On January, 2009, the court construed the “strip of material” disclosed in claims 1 and 14 of the ‘240 patent as having a low flexural stiffness. The ‘240 patent refers to “low flexural stiffness” as follows:

The strip of material should have a relatively low flexural stiffness so as to enable it to drape over the contoured surfaces of the teeth with very little force being exerted; that is, conformity to the curvature of the wearer’s mouth, teeth, and gaps between teeth is maintained because there is little residual force within the strip of material to cause it to return to its substantially flat shape.

‘240 pat., col. 11, lns. 10-16. (Defendant disputes whether this language defines the phrase “low flexural stiffness.”)

The ‘240 patent discloses a means for measuring the flexural stiffness of a sample strip called the “Handle-O-Meter.” The ‘240 patent states in relevant part:

Flexural stiffness is a material property that is a function of a combination of strip thickness, width, and material modulus of elasticity. This test is a method for measuring the rigidity of polyolefin film and sheeting. It determines the resistance to flexure of a sample by using a strain gauge affixed to the end of a horizontal beam. The opposite end of the beam presses across a strip of the sample to force a portion of the strip into a vertical groove in a horizontal platform upon which the sample rests. A microammeter, wired to the strain gauge is calibrated in grams of deflection force. The rigidity of the sample is read directly from the microammeter and expressed as grams per centimeter of sample strip width. In a preferred embodiment but not required for the present invention, the flexible strip of material has a flexural stiffness

of less than about 5 grams/cm as measured on a Handle-O-Meter, model #211-300, available from Thwing-Albert Instrument Co. of Philadelphia, Pa., as per test method ASTM D2923-95. Preferably, the strip of material has a flexural stiffness less than about 4 grams/cm, more preferably less than about 3 grams/cm, and most preferably from about 0.1 grams/cm to about 1 grams/cm.

'240 pat., col. 11, lns. 23-40.

The "thin layer" of the Listerine strip is made primarily of shellac and silica. SEM images of the shellac coating were created by Materials Evaluation and Engineering, Inc. in Plymouth, Minnesota. (The parties does not explain "SEM images.") The SEM images reveal cracks in the shellac coating when it is stretched across a 50 mm disc. Additional SEM images show that the coating is subject to cutting stress, that it fractures into flakes and that it is brittle.

G. Willful Infringement

Defendant served an interrogatory on June 9, 2008, asking plaintiff to "[s]tate all facts supporting plaintiff's contention that defendant's alleged infringement has been willful and wanton" Plaintiff responded to the interrogatory with the following response:

[Plaintiff] contends that [defendant] infringes both the '240 and '579 Patents. [Plaintiff] also believes and contends that [defendant] was aware of each of the asserted patents prior to the commencement of this litigation. At the very least, [defendant] has been aware of [plaintiff's] patents since at least October 2007. [Defendant] has presented no basis for contending that its infringement of the asserted patents has been based on a good faith belief that the '240 and

'579 Patents are not infringed or not valid.

On July 15 and July 23, 2008, defendant sent letters stating that it believed plaintiff's response regarding willful infringement was "legally insufficient." As of February 6, 2009, plaintiff had not supplemented its interrogatory response on willful infringement.

Dr. Georgiades learned about the '240 patent before the lawsuit and during the development of the Listerine strips. He testified that the peroxide concentration in the Listerine strip was increased as a result of clinical trials:

Q. At some point you decided, though, to increase the hydrogen peroxide concentration in your multilayered strip?

A. Yes.

Q. When was that?

A. It was after the first clinical. We actually put two 6 percent products in the first clinical. One was, it was the same formula, we just changed the weight so one would deliver more milligrams than the other. It was the same formula. I believe it was after that first clinical study we said that, we looked at the tolerance of the subjects and patients and made a decision to increase the peroxide concentration.

Georgiades Dep., dkt. #171, at 49. Defendant's employees knew about the "Crest Whitening Strips" as of January 7, 2004. They compared prototypes of Listerine strips to the Crest Whitestrips on the market.

G. Inequitable Conduct

According to Sagel, the study reported in the Gerlach Abstract was “a scientifically valid study” but it was not statistically sized to show a difference in the safety effects of increasing concentration of hydrogen peroxide.

The following exchange occurred at Sagel’s Deposition:

Q. If someone were trying to determine whether there was a relationship between increase in peroxide concentration and decreasing tolerability for a polyethylene strip-based bleaching system, would they find this study useful?

A. Yes.

Q. Would they find it important?

A. Yes.

Sagel signed a form indicating that he had reviewed a compilation of abstracts for the American Association of Dental Research Meeting in March of 2001, one of which was the Gerlach Abstract. Defendant asked Sagel why the Gerlach Abstract was not disclosed to the patent office; Segal answered that he was not aware whether it had been disclosed or not. Gerlach stated that he did not know why the Gerlach Abstract was not disclosed. Sagel was not aware of any information published before the Gerlach Abstract that addressed the existence of a relationship between increased peroxide concentration and increased soft tissue irritation for strip-based systems.

OPINION

Defendant has moved for summary judgment on three grounds: (1) the claims of the '240 patent are invalid for obviousness; (2) defendant's accused product does not directly infringe the '240 patent because it is not a "strip of material"; and (3) defendant cannot be found to have willfully infringed because plaintiff has failed to offer evidence that defendant's actions were objectively reckless. Plaintiff has moved for summary judgment on the ground that it did not engage in inequitable conduct during the prosecution of the '240 patent by withholding three publications written by the inventors of the patent.

A. Obviousness

A patent approved by the patent examiner is presumed valid. 35 U.S.C. § 282. When a party alleges that a patent is invalid, the accusing party bears the burden of proving invalidity by clear and convincing evidence. Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319 (Fed Cir. 2003). A court may invalidate a patent for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The "obviousness" analysis is an objective one and requires a district court to consider: (1) the scope and content of the prior art; (2) differences between the prior art and

the claims at issue; and (3) the level of ordinary skill in the pertinent art. KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)). “[S]econdary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” KSR, 550 U.S. at 406. The main question under § 103 is “whether the combined teachings of the prior art, taken as a whole, would have rendered the claimed invention obvious to one of ordinary skill in the art.” In re Napier, 55 F.3d 610, 613 (1995). Defendant contends that all the claims of the ‘240 patent are invalid for obviousness.

The ‘240 patent discloses a tooth whitening product that contains a tooth whitening composition that is delivered by a strip of material. The strip is quite small, ranging in size from 6.5 cm long by 1.5 cm wide to 5 cm long by 2 cm wide, ‘240 pat., col. 3, lns. 55-59, and composed of flexible material that allows it to conform to the tooth surface. Id., col. 11, lns. 10-22. The strip contains a tooth whitening composition that includes peroxide, which is a crucial ingredient in whitening. “[I]ncreasing the concentration of peroxide . . . generally results in faster whitening per time of use,” id., col. 1, lns. 45-47, but increasing peroxide can lead to increased soft tissue irritation.

The ‘240 patent is not the first patent relating to tooth whitening strips or the first patent that discusses peroxide dose relative to the size of the strip. The novelty of the ‘240

3patent is that it achieves an increase in “peroxide concentration,” which increases whitening, without increasing soft tissue irritation. It accomplishes this by both reducing the thickness of the layer of tooth whitening and keeping the “peroxide density” low. Plt.’s Opp. Br., dkt. #259, at 21.

Before proceeding any further, it is necessary to define what the inventors of the ‘240 patent meant by “peroxide concentration” and “peroxide density.” “Peroxide concentration” is the percentage of hydrogen peroxide active relative to other ingredients in the tooth whitening composition. ‘240 pat., col. 1, lns. 63-66, col. 7, lns. 31-62. “Peroxide density” is “the ratio of the amount of peroxide active (mg) or peroxide dose to the surface area (cm²) of the thin layer that is applied to the tooth surfaces and adjacent soft tissues fo the oral cavity.” Id., col. 5, lns. 52-55.

According to plaintiff, the decision to increase peroxide concentration while simultaneously reducing thickness of the tooth whitening substance and maintaining a constant peroxide density was not obvious to a person of skill in the art. Defendant disagrees, arguing that increasing peroxide concentration while maintaining peroxide density was a “predictable use of the prior art.” KSR, 550 U.S. at 418. Defendant contends that the ‘708 patent and two publications by the inventors of the ‘240 patent are relevant prior art that teach or suggest the innovation claimed by the ‘240 patent. Id. at 417-18 (“it will be necessary for a court to look to interrelated teachings of multiple patents . . . in order to

determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). Specifically, defendant contends that (1) the ‘708 patent disclosed the claimed peroxide concentration; (2) the Sagel-Gerlach article taught the concept of keeping peroxide density low; and (3) the Gerlach Abstract disclosed the discovery that increasing peroxide concentration did not lead to increase irritation. Further, defendant argues, the decision to increase peroxide concentration to increase whitening was driven by market demands and not scientific literature.

Plaintiff does not deny that the market demanded products with increased whitening efficiency but argues that the market did not demand an increase in “peroxide concentration.” This is not a particularly persuasive argument. It is mostly irrelevant whether consumers know what is required for particular product improvement. The relevant question is whether the particular improvement is an obvious “next step” or a truly innovative development. KSR, 550 U.S. at 416 (“[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.”); see also Ritchie v. Vast Resources, Inc., — F. 3d — , 2009 WL 1098802, *2 (Fed. Cir. Apr. 24, 2009) (“Among the inventions that the law deems obvious are those modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value (otherwise they would not be undertaken) but do not involve sufficient inventiveness to merit patent protection.”); Ball Aerosol and Specialty Container, Inc. v. Limited Brands,

Inc., 555 F.3d 984, 992-93 (Fed. Cir. 2009). If the innovation of the ‘240 patent involved simply increasing the peroxide concentration without any other variation to the strip, this would be a prime example of the type of “innovation” that is not protected by patent law. However, the ‘240 patent is not so limited. Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, 1352 (Fed. Cir. 2008) (“knowledge of the goal does not render its achievement obvious”). The patent balances increasing whitening efficiency by reducing the thickness of the whitening substance, increasing peroxide concentration while maintaining low peroxide density. It is not readily apparent that accomplishing this is a modest, routine, everyday or incremental improvement.

Plaintiff disputes defendant’s contention that the prior art ‘708 patent, the Sagel-Gerlach article and the Gerlach Abstract make the ‘240 patent obvious. It argues that whether the prior art references are considered individually or in combination, they do not teach or suggest increasing peroxide concentration while maintaining low peroxide density and decreasing thickness. Although plaintiff concedes that the prior art contains overlapping elements, it denies that these factors of the tooth whitening substance suggest the key innovation. I agree with plaintiff that none of the prior art references teach the improvements found in the ‘240 patent and that defendant has failed to show by clear and convincing evidence that it was obvious to combine these elements as plaintiff did in the ‘240 patent.

With respect to the '708 patent, defendant contends that it claims a peroxide concentration and peroxide density range that substantially overlaps with the '240 patent. "Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006). However, this presumption can be rebutted if plaintiff can show that the "the claimed range produces new and unexpected results." First Years, Inc. v. Munchkin, Inc., 575 F. Supp. 2d 1002, 1026 (W.D. Wis. 2008) (citing Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004)).

The undisputed facts show that the '240 patent claims a peroxide concentration range from 7.5% to 40%, '240 pat., col. 17, lns. 26-33, and the '708 patent has a range "from about 0.1% to about 20% peroxide." '708 pat., col. 13, lns. 47-51; col. 14, lns. 46-50. Therefore, there is no question that the ranges overlap. However, the peroxide concentration claimed by the '240 patent produced a new and unexpected result: increased whitening without increased irritation. In responding to the initial rejection of the '240 patent application, the inventors argued that "the claimed invention is not a mere optimization because the claimed invention is not taught by [the '708 patent], as the reference fails to direct the use of the combination of the claimed peroxide concentration level at the claimed peroxide density, which can achieve increased whitening efficacy and soft tissue tolerability." Kopelman Decl., Exh. II, dkt. #199-20, at 147-48. In his reasons for allowance, the patent

examiner agreed with the inventors, finding that “[t]he prior art of record does not fairly suggest, teach or disclose the instantly claimed combinations of peroxide concentration and peroxide density.” Id.

Defendant argues that this “result” is not unexpected given the conclusions of the undisclosed Gerlach Abstract that indicate no correlation between increased peroxide concentration and increased soft tissue irritation. However, the abstract is the *only* prior art reference defendant identifies as teaching the lack of a correlation between increased peroxide and increased irritation, and it described a clinical study of only 22 patients divided into two separate groups. It is hard to believe that this single trial would necessarily be sufficient scientific evidence to rebut the general understanding in the field of whitening that increasing the peroxide content would increase irritation. Although the studies supporting this understanding in the art had been conducted only on tray-based whitening systems, it would not be an illogical or unconventional leap to believe the same principle would translate to strips.

With respect to defendant’s contention regarding overlapping peroxide densities, the ‘708 patent does not discuss peroxide density at all. The ‘708 patent discloses a range of tooth whitening substance per unit area from about .005g/cm² to about 0.1 g/cm². ‘708 pat., col. 14, lns. 31-35. However, peroxide density as defined by the ‘240 patent is the ratio of peroxide active to the surface area of the strip of material. Peroxide active is merely one

component of the tooth whitening substance. Perhaps it is simply a matter of multiplying the claimed peroxide concentration of the '708 patent to the tooth whitening substance per unit area in order to calculate peroxide density. (If peroxide concentration is a percentage of the amount of peroxide in a tooth whitening substance ($pc = \text{peroxide/tooth whitening substance}$) and the '708 patent claims a ratio of tooth whitening substance to surface area (tws/sa), then multiplying the peroxide concentration by the ratio of tooth whitening substance to surface area ($pc \times (tws/sa)$) could give one the peroxide density.) However, it is not readily apparent from either patent that this is a proper equation for peroxide density and defendant has not demonstrated by clear and convincing evidence that it is. Therefore, I conclude that the '708 and '240 patent do not have overlapping peroxide densities.

Defendant argues that the Sagel-Gerlach article teaches the need to keep peroxide density low when increasing peroxide concentration or dose. According to defendant, the article suggests that peroxide density is the amount of peroxide, or peroxide dose, delivered over the surface area of a strip and that peroxide dose is not affected by the peroxide concentration. However, the article never discusses that peroxide dose is not affected by peroxide concentration.

First, defendant does not explain the difference between peroxide dose and peroxide concentration or how they interrelate. This is a key point because the innovation of the '240 patent involves increasing peroxide concentration but does not discuss increasing or

decreasing peroxide dose. The relationship between peroxide dose and concentration is not obvious from the patent. Perhaps one increases concentration by reducing the quantity of non-peroxide materials in the tooth whitening substance and maintaining the total amount of peroxide delivered. However, defendant has not argued this point and neither the '240 patent nor the prior art suggests it as a possibility. It is defendant's burden to demonstrate this point by clear and convincing evidence. Abbott Laboratories, 544 F.3d at 1351-1352 ("The evaluation of the choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial understanding of how technical advance is achieved in the particular field of science or technology. Such understanding is critical to judicial implementation of the national policy embodied in the patent statute.").

Second, the article makes only passing references to the concept of peroxide density and does not explain its role in the whitening process. The article states in relevant part:

The . . . strip is loaded with .200g of the adhesive whitening gel and contains approximately 11 mg of hydrogen peroxide, providing delivery of approximately *1.1 mg hydrogen peroxide per square centimeter of contact*. The mandibular strip . . . is loaded with .150g of adhesive whitening gel and contains approximately 8.3mg of hydrogen peroxide, providing delivery of approximately *1.1mg hydrogen peroxide per square centimeter of contact*.

Kopelman Decl., exh. ZZ, dkt. #201-5, at 11(emphasis added). Aside from describing a whitening strip that has a peroxide density within the range claimed by the '240 patent, less than 1.3 mg/cm², the article makes no further mention of peroxide density. It does not

explain how to keep density constant while increasing either peroxide concentration or peroxide dose. Moreover, the article says nothing about the possibility that soft tissue irritation can be decreased by reducing peroxide density or altering thickness. I conclude, therefore, that the Sagel-Gerlach article does not teach or suggest the innovations claimed by the '240 patent.

Last, defendant argues generally that altering the different elements of peroxide concentration, peroxide density and thickness are not patentable innovations. In its view, these elements all affect the tooth whitening delivery system. Therefore, it would be obvious to try different permutations. Although KSR suggests that simple experimentation with different variables suggests obviousness,

[t]he Court in KSR did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is “obvious to try,” without considering the nature of the science or technology. The methodology of science and the advance of technology are founded on the investigator's educated application of what is known, to intelligent exploration of what is not known. Each case *must be decided in its particular context*, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, *and the predictability of results in the area of interest*.

Abbott Laboratories, 544 F.3d at 1352 (emphasis added). In this case, defendant has failed to adduce evidence that plaintiff's improvements were obvious to a person of ordinary skill in the art. Moreover, it is not common sense to expect that manipulating the variables of peroxide dose, concentration and density will create the desired results. Although I believe

this is a close case for obviousness in light of the overlapping ranges and the limited variables affecting tooth whitening, I cannot conclude as a matter of law that the combinations proposed in the '240 patent were "obvious to try" given either the prior art references or market demands. Therefore, defendant's motion for summary judgment on obviousness will be denied.

B. Non-Infringement of the '240 Patent

“Summary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents.” U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1374-1375 (Fed. Cir. 2007) (quoting PC Connector Solutions LLC v. SmartDisk Corp., 406 F.3d 1359, 1364 (Fed. Cir. 2005)). Patent infringement analysis involves two steps. First, the patent claims must be interpreted or construed to determine their meaning and scope. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). Second, the properly construed claims are compared to the process or device accused of infringing. Id. To establish infringement, plaintiff must prove that each claim element is present in the accused product, either literally or by equivalence. Dawn Equipment Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1015 (Fed. Cir. 1998). Conversely, defendants can prevail by demonstrating that at least one

element of the asserted claim is absent from their devices.

Defendant contends that its Listerine Quick Dissolving Strips do not directly infringe claims 1-7, 9, 12-14 and 17-19 of the '240 patent. Plaintiff does not agree, but has not filed its own cross motion for summary judgment on infringement at this time. Defendant's sole basis for arguing that its product does not infringe the '240 patent is that the Listerine strips do not contain a "strip of material" with "low flexural stiffness." According to defendant, an object with "low flexural stiffness" means "that something can be flexed easily without breaking or cracking;" Dft.'s Br., dkt. #223, at 16; defendant's strip is allegedly composed of materials with high flexural stiffness that crack and break easily; it follows, therefore, that it does not have the requisite "low flexural stiffness." Defendant's argument is unconvincing.

As previously discussed, the court construed certain disputed terms of the '240 and '579 patent. One of those terms, "strip of material," was the subject of much disagreement. Defendant argued that a number of limitations should be imported into the claim terms and plaintiff argued that no limitations should be imposed. Ultimately, I concluded that the term "strip of material" in the '240 patent contained only one limitation proposed by defendant: "low flexural stiffness." At the time, neither party discussed what the '240 patent meant by the term "low flexural stiffness."

Defendant begins its non-infringement argument on the premise that "low flexural stiffness" means not cracking or breaking. However, this court never construed the term in

that way (or in any other). Plaintiff argues that defendant has improperly defined “low flexural stiffness” by not construing it within the context of the patent but relying on extrinsic evidence, such as the opinion of its experts. Essentially, the parties are inviting the court to construe additional disputed claim terms of the ‘240 patent. Because resolution of the non-infringement question requires determining what the ‘240 patent means by a strip of material with low flexural stiffness, I will accept the parties’ invitation.

I. Construction of “low flexural stiffness”

When construing disputed terms in a claim, a court should generally give the terms their ordinary and customary meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The ordinary and customary meaning of terms “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” Phillips v. AWH Corporation, 415 F. 3d 1303, 1313 (Fed. Cir. 2005). The Court of Appeals for the Federal Circuit has held that the person of ordinary skill in the art would read a term both in the context of the claim in which it appears and “in the context of the entire patent, including the specification.” Id. (citing Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Additionally, a patent's prosecution history can be relevant to construing disputed terms of a patent because it “provides evidence of how the PTO and the inventor understood the patent.” Phillips,

415 F.3d at 1317.

The term “low flexural stiffness” is not defined in either the claim language or the specification. The closest thing to a definition in the patent is the following: “[f]lexural stiffness is a material property that is a function of a combination of strip thickness, width, and material modulus of elasticity.” ‘240 pat., col., 11, lns. 23-25. This is not entirely helpful. It leaves unclear what is required for an object to have low flexural stiffness or its opposite. However, the ‘240 patent discusses “low flexural stiffness” in the following manner:

The strip of material should have a relatively low flexural stiffness so as to enable it to drape over the contoured surfaces of the teeth with very little force being exerted; that is, conformity to the curvature of the wearer’s mouth, teeth, and gaps between teeth is maintained because there is little residual force within the strip of material to cause it to return to its substantially flat shape.

‘240 pat., col. 11, lns. 10-16. Although this is not a definition in the traditional sense, it explains the purpose of the low flexural stiffness limitation: specifically, the strip of material must be sufficiently pliable to conform to the individual’s teeth.

This description is supported by dictionary definitions of these terms. Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F. 3d 1364, 1375 (Fed. Cir. 2005) (“judges may ‘rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent

documents”) (citation omitted). Flexural is defined as “of, pertaining to, or resulting from flexure,” Webster’s New International Dictionary 967 (2d Ed. 1981) and flexure is defined as “[a] flexing or state of being flexed; a turning. . . [c]apability of bending; a turn, bend, fold . . .” Id. Stiffness is “the quality or state of being stiff,” id., at 2475, and stiff is “not easily bent, not flexible or pliant.” Id. Therefore, according to the dictionary, an object with flexural stiffness is one that is pliant up to a point but also has some degree of rigidity. None of the definitions suggest that the term would apply to a material that cracks or breaks when bent.

The only other mention of “flexural stiffness” comes in column 11, where the inventors describe testing flexural strength on a machine designated for that purpose and identify the flexural stiffness of a preferred embodiment of the invention, as measured on the machine. The specification contains no guidance for determining all the possible measurements for flexural stiffness that would fall within the language of the ‘240 patent.

Defendant’s only ground for its proposed construction is the opinion of its experts. Such opinions are given less weight than the intrinsic evidence and viewed within the context of that intrinsic evidence. Phillips, 415 F.3d at 1318-19; see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 595 (1993) (expert evidence can be misleading and difficult to evaluate). In this case, defendant’s experts make no effort to reconcile their opinions with the text of the ‘240 patent. Therefore, I will disregard their opinions. Because

the term “low flexural stiffness” is used primarily to describe a functional use of the strip, I conclude that it means **a combination of strip thickness, width and elasticity that allows a strip to conform readily to the surface of the teeth with little pressure.**

2. Non-infringement analysis

With this construction in mind, defendant’s argument for non-infringement is undermined. All the evidence offered by defendant on the issue of non-infringement relates to tests showing that the allegedly infringing layer of the Listerine strip breaks and cracks when bent or stretched. None of this evidence is relevant to whether defendant’s product infringes. Defendant’s evidence shows that the materials composing the accused layer of the Listerine strip are brittle and flaky at an intermediate stage of development. Whether materials composing the accused layer are brittle and flaky at a certain stage of development does not prove that the layer does not have “low flexural stiffness.” Defendant has offered no evidence showing that the accused layer does not conform readily to the surface of the teeth with little pressure. Therefore, defendant has not shown that one of the elements of the claim term is not present in its Listerine strips.

In its reply brief, defendant argues for the first time that, even if the term “low flexural stiffness” is construed according to its functional use, the court should still granted its motion because plaintiff has failed to produce evidence that the infringing layer has low

flexural stiffness as opposed to the entire Listerine strip. According to defendant, the Listerine strip is composed of two layers, one thin and one thick layer and these layers are inseparable. Plaintiff alleges that the “thin layer” of the Listerine strip is the “strip of material” in the ‘240 patent. Defendant contends that to prove its claim of infringement plaintiff must produce evidence that the accused thin layer of the Listerine strip has low flexural stiffness.

As an initial matter, defendant raises this argument for summary judgment for the first time in its reply brief, giving plaintiff no opportunity to respond to the argument. Third Wave Technologies, Inc. v. Stratagene Corp., 405 F. Supp. 2d 991, 1002 (W.D. Wis. 2005) (“A party cannot bring up new matter in a reply brief to which its opponent has no opportunity to respond.”).

Even if I did consider this argument, defendant’s argument would fail. Defendant concedes in its reply brief that plaintiff has shown that the Listerine product as a whole has low flexural stiffness but it argues that this is insufficient because plaintiff has not provided any evidence about the allegedly infringing thin layer. Dft.’s Reply, dkt. #286, at 5. The distinction defendant attempts to draw is unpersuasive. If the thin and thick layer are inseparable and plaintiff has produced evidence showing that the two layers combined have low flexural stiffness, it follows logically that the “thin layer” could (and likely does) have low flexural stiffness. Defendant has offered no evidence or argument to suggest otherwise.

Because plaintiff has produced sufficient evidence to allow a reasonable jury to find that defendant's product infringes the claims of the '240 patent, defendant's motion for summary judgment on non-infringement will be denied.

C. Willful Infringement

Defendant argues that because plaintiff has failed to produce any evidence that it acted with objective recklessness in creating and selling the Listerine strips and because the court adopted portions of defendant's proposed construction of the disputed terms in the '240 patent, this court should grant summary judgment in its favor. "To establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." In re Seagate Technology, LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). "If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer."

Id.

Plaintiff opposes defendant's motion on three grounds: (1) the claims construction order supports plaintiff's willfulness argument; (2) defendant has prevented plaintiff from obtaining discovery on the issue of willful infringement; and (3) plaintiff has produced

sufficient evidence of defendant's objective recklessness. Plaintiff's first two grounds for opposing defendant's motion do not address the question whether defendant's actions were objectively reckless. The court's claim construction is not evidence showing that defendant's actions constituted willful infringement. The order simply establishes the meaning of disputed terms in the patent in suit; plaintiff still bears the burden of producing evidence of objective recklessness. Second, as discussed at the outset of this opinion, plaintiff will not succeed on its argument that defendant has engaged in improper discovery practices because plaintiff has not been diligent in pursuing this information. Therefore, the only ground plaintiff has for opposing defendant's motion is evidence of objective recklessness.

Because plaintiff is the non-moving party on this issue, I consider the evidence in the light most favorable to it. Plaintiff argues that the following undisputed facts establishes that defendant acted with objective recklessness: (1) defendant knew about the '240 patent before launching the Listerine strips; (2) defendant tested prototypes of the Listerine strips against Crest Whitestrips; and (3) defendant learned the amount of hydrogen peroxide in plaintiff's Crest Whitestrips. None of these facts establish the type of behavior sufficient to find willful infringement, whether they are considered individually or in combination.

Defendant's awareness of the subject matter of the '240 patent before developing the Listerine strips does not suggest that it intended to infringe plaintiff's strips. In fact, unlike plaintiff's strips, the express novelty of defendant's whitening strips is that they dissolve in

the individual's mouth. From an objective perspective, it is unlikely that a reasonable factfinder would conclude that defendant acted in the face of an obvious risk that the Listerine product would infringe the '240 patent when plaintiff's invention did not claim a dissolving strip.

In addition, defendant's use of plaintiff's whitening strips in clinical test simply shows that defendant was comparing the whitening efficiency of its product to plaintiff's. This testing does not indicate that defendant was creating a product that delivered whitening substances in the exact or similar manner of the '240 patent, only that it was comparing the quality of its product to plaintiff's. Further, the undisputed fact that defendant knew the quantity of hydrogen peroxide in the Crest Whitestrips does not suggest infringement. Plaintiff does not have a patent on a quantity of hydrogen peroxide in its strip. (Plaintiff takes contradictory positions on the question of hydrogen peroxide in its strips. In its opposition to defendant's assertions of invalidity, it argues that the novelty of the '240 patent is not the amount of hydrogen peroxide in the strip; here, however, it attempts to argue that this information is relevant to issue of infringement. If the amount of peroxide alone is not part of the claims of the '240 patent, defendant cannot infringe by creating a product that contains the same or similar quantities of peroxide.) The evidence proffered by plaintiff regarding what defendant knew about the '240 patent and the Crest Whitestrips fails to demonstrate "an objectively high likelihood that [defendant's] actions constituted

infringement of a valid patent.” In re Seagate Technology, LLC, 497 F.3d at 1371. Because plaintiff has failed to produce sufficient evidence to carry its burden at summary judgment, defendant’s motion will be granted and plaintiff’s claim of willful infringement of the ‘240 patent against defendant will be dismissed.

D. Inequitable Conduct

Plaintiff has moved for summary judgment on defendant’s counterclaim that plaintiff engaged in inequitable conduct before the patent examiner during the application of the ‘240 patent because it failed to disclose two articles by the inventors of the patent. Although plaintiff has moved for summary judgment on this issues, as the accused infringer, defendant bears the burden of proving inequitable conduct at trial. Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). “To successfully prove inequitable conduct, the accused infringer must present ‘evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO].’” Id. (citing Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007)). Moreover, the accused infringer must prove each of these elements by clear and convincing evidence. Star Scientific, Inc., 537 F.3d at 1365. “If the requirements of materiality and intent are met, ‘[t]he court must then determine whether the questioned conduct amounts to inequitable

conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other.’” Larson Manufacturing Co. of South Dakota, Inc. v. Aluminart Products Ltd., 559 F.3d 1317, 1327 (Fed Cir. 2009) (citation omitted). Therefore, defendant bears a heavy burden in proving a claim of inequitable conduct. Star Scientific, Inc., 537 F.3d at 1365 (“The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability.”).

Defendant contends that by failing to disclose the Gerlach Abstract and the Sagel-Gerlach article, plaintiff and the inventors of the ‘240 patent knowingly withheld information relevant to the patentability of the ‘240 patent. In defendant’s opinion, these two prior art references would create a prima facie case for obviousness or at the very least be relevant to this issue. Therefore, it argues, because these publications bear directly on the issue of patentability they are material. Thus, plaintiff’s failure to disclose them is proof of plaintiff’s intent to deceive.

Although the question whether the undisclosed articles are material is a close one, I conclude that defendant has failed to offer evidence of plaintiff’s “intent to deceive.”

As discussed previously with regards to the question of obviousness, defendant contends that the Gerlach Abstract taught or at least suggested the lack of correlation

between an increase in peroxide concentration and an increase in soft tissue irritation and that the examiner would have found the results of this clinical trial important. According to defendant, this is a material misrepresentation because plaintiff informed the patent examiner that the prior art did not disclose any correlation between an increase in peroxide and an increase in irritation. In addition, defendant argues that the Sagel-Gerlach article specifically taught the need to keep peroxide density at the level claimed by the '240 patent and indicated a market demand for increased whitening efficiency. Dft.'s Opp. Br, dkt. #269, at 12-13.

Whether plaintiff or the inventors engaged in misrepresentation before the patent examiner is a difficult question. The undisputed evidence shows that in its response to the initial rejection of the '240 patent application, plaintiff stated that “[t]raditionally, use of higher levels of peroxide concentration can result in soft tissue irritation.” However, plaintiff goes on to state that “[n]o teaching in the art directs one to combine higher concentrations of peroxide with lower peroxide density.” Although defendant argues that the Gerlach Abstract suggests this innovation, the abstract does not address the issue of peroxide density or strip thickness at all, only peroxide concentration. Even if one were to consider the Sagel-Gerlach article in combination with the Gerlach Abstract, it is not clear that the two articles would teach a person of ordinary skill in the art the idea of maintaining a low peroxide density and reducing thickness of the strip while increasing peroxide concentration. No

discussion in the prior art identified by defendant suggests that keeping density low and reducing thickness will reduce irritation. I cannot conclude that the undisclosed articles are unquestionably material; it was defendant's burden to provide this evidence and it failed to do so. Even if I did find that the articles were material, defendant has failed to adduce any direct evidence of intent.

“With regard to the deceptive intent prong . . . , we have emphasized that ‘materiality does not presume intent, which is a separate and essential component of inequitable conduct.’” Cohesive Technologies, Inc. v. Waters Corp., 543 F.3d 1351, 1366 (Fed. Cir. 2008) (citing Star Scientific, Inc., 537 F.3d at 1366). Therefore, “[t]he accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO.” Id., at 1366.

[T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to . . . mislead[] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.

Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995).

In this case, the only “direct” evidence defendant produces of plaintiff's intent to deceive is that both inventors knew about the Gerlach Abstract and the Sagel-Gerlach article but did not offer any good faith argument for not disclosing it as prior art to the patent

examiner. Defendant maintains that plaintiff's inventors *should have known* the articles were material. For support it cites the following excerpt from Sagel's deposition:

Q. If someone were trying to determine whether there was a relationship between increase in peroxide concentration and decreasing tolerability for a polyethylene strip-based bleaching system, would they find [the Gerlach Abstract] study useful?

A. Yes.

Q. Would they find it important?

A. Yes.

Dft.'s PFOF, dkt. #268, at 13, ¶63. However, none of the evidence proffered by defendant clearly indicates or necessarily suggests an intent to deceive. From the undisputed fact that the inventors of the '240 patent knew about the prior art references but failed to disclose them, one could infer that the inventors were delinquent or negligent in their duties, but one cannot infer purposeful deceit. Because defendant has failed to produce any direct evidence of intent to deceive, I could grant summary judgment in plaintiff's favor on the lack of direct evidence alone. Larson Manufacturing Co. of South Dakota, Inc., 559 F.3d at 1341 ("an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation"); see also Cohesive Technologies, Inc., 543 F.3d at 1366 (finding no inequitable conduct where accused infringer cited no independent evidence of specific intent to deceive).

However, as defendant argues, because of the difficulty of proving intent by direct evidence, intent can be inferred from other indirect and circumstantial evidence. Star Scientific, Inc., 537 F.3d 1366. Nonetheless, as the court held in Star Scientific, Inc.:

such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement. . . . Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but *it must also be the single most reasonable inference* able to be drawn from the evidence to meet the clear and convincing standard.

Id. at 1366 (emphasis added). In this case, the most reasonable inference to be drawn from plaintiff's failure to disclose the two publications is not that plaintiff was intending to deceive the patent examiner. The Sagel-Gerlach article offers little insight into the '240 patent other than information about the growing desire in the market for increased whitening efficiency and a product that contains a peroxide density similar to the '240 patent. The inventors had disclosed information to the patent examiner in other prior art references. Adding the Sagel-Gerlach article would have been cumulative. Larson Manufacturing Co., 559 F.3d at 1327 ("a withheld otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner").

Additionally, although the Gerlach Abstract was relevant to the existence of a correlation between peroxide concentration and irritation, it is as plausible to believe that it was withheld because the trial was small and statistically insignificant as it is to believe

that it was withheld with an intent to deceive. Id. at 1327 (“inequitable conduct requires not intent to withhold, but rather intent to deceive”) (citation omitted). Despite defendant’s best efforts to glean intent from a series of omissions by plaintiff, it has failed to produce sufficient evidence from which a reasonable fact finder could infer intent to deceive. Because defendant has failed to adduce sufficient evidence of either element of its inequitable conduct counterclaim, plaintiff’s motion for summary judgment will be granted.

E. Conclusion

After sifting through the parties’ respective motions for summary judgment, it is helpful to discuss the issues remaining for trial. Because I have denied defendant’s motion for summary judgment on non-infringement of the ‘240 patent but will grant judgment in defendant’s favor on willful infringement, plaintiff’s only remaining claim is that defendant’s Listerine strips infringe claims 1-7, 9, 12-14 and 17-19 of the ‘240 patent.

ORDER

IT IS ORDERED that:

1. Plaintiff Procter & Gamble Company’s motion for clarifications of this court’s claim construction order, dkt. # 326, is GRANTED;
2. Defendant McNeil-PPC, Inc.’s motion for Rule 37 sanctions to strike rebuttal and

supplemental expert reports by Harold Heymann and Robert E. Cohen and additional proposed findings of facts, dkt. #288, is GRANTED because of plaintiff's failure to comply with this court's deadline for expert reports;

3. Defendant's motion to strike new material and facts raised in plaintiff's reply brief, dkt. #298, is DENIED as unnecessary;

4. Plaintiff's Rule 56(f) motion, dkt. # 328, to deny defendant's motion for summary judgment on willful infringement, dkt. #192, is DENIED.

5. Defendant's motion for summary judgment, dkt. #192, of non-infringement, invalidity and willful non-infringement is DENIED with respect to non-infringement and invalidity and GRANTED with respect to no willful infringement;

6. With respect to the disputed term "low flexural stiffness" found in U.S. Patent No. 6,949,240, I construe the terms as follows: "low flexural stiffness" is the quality of the strip of material that allows it to easily conform to the surface of the teeth with little pressure.

7. Plaintiff's motion for summary judgment on defendant's counterclaim of inequitable conduct is GRANTED because defendant has failed to adduce sufficient evidence from which a reasonable jury could find in its favor on its counterclaim.

Entered this 12th day of May, 2009.

BY THE COURT:

/s/

BARBARA B. CRABB
District Judge