

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO  
Judge Robert E. Blackburn**

Civil Action No. 13-cv-01210-REB

STERISIL, INC., a Colorado Corporation,

Plaintiff,

v.

PROEDGE DENTAL PRODUCTS, INC, a Colorado Corporation, and  
MARK A. FRAMPTON, an individual,

Defendants.

---

**ORDER GRANTING MOTION FOR SUMMARY JUDGMENT**

---

**Blackburn, J.**

This matter is before me on the following: (1) the **Motion for Summary Judgment** [#90]<sup>1</sup> filed April 14, 2018; and (2) **Plaintiff, Sterisil, Inc.’s Corrected Motion for Summary Judgment of Infringement** [#98] filed April 20, 2018. The parties filed responses [#102, #106] and replies [#109, #114]. I grant the motion of the defendants and deny the motion of the plaintiff.

**I. JURISDICTION**

I have jurisdiction over the parties and subject matter of this case. My jurisdiction arises under 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1338(a) (patent infringement).

---

<sup>1</sup> “[#90]” is an example of the convention I use to identify the docket number assigned to a specific paper by the court’s case management and electronic case filing system (CM/ECF). I use this convention throughout this order.

## II. STANDARD OF REVIEW

Summary judgment is proper when there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); **Celotex Corp. v. Catrett**, 477 U.S. 317, 322 (1986). A dispute is “genuine” if the issue could be resolved in favor of either party. **Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.**, 475 U.S. 574, 586 (1986); **Farthing v. City of Shawnee**, 39 F.3d 1131, 1135 (10<sup>th</sup> Cir. 1994). A fact is “material” if it might reasonably affect the outcome of the case. **Anderson v. Liberty Lobby, Inc.**, 477 U.S. 242, 248 (1986); **Farthing**, 39 F.3d at 1134.<sup>2</sup>

A party who does not have the burden of proof at trial must show the absence of a genuine issue of fact. **Concrete Works, Inc. v. City & County of Denver**, 36 F.3d 1513, 1517 (10<sup>th</sup> Cir. 1994), **cert. denied**, 514 U.S. 1004 (1995). By contrast, a movant who bears the burden of proof must submit evidence to establish every essential element of its claim or affirmative defense. **See In re Ribozyme Pharmaceuticals, Inc. Securities Litigation**, 209 F.Supp.2d 1106, 1111 (D. Colo. 2002).

In either case, once the motion has been properly supported, the burden shifts to the nonmovant to show by tendering depositions, affidavits, and other competent evidence that summary judgment is not proper. **Concrete Works**, 36 F.3d at 1518. All evidence must be viewed in the light most favorable to the party opposing the motion. **Simms v. Oklahoma ex rel Department of Mental Health and Substance Abuse**

---

<sup>2</sup> The issues raised by and inherent to the motion for summary judgment are fully briefed, obviating the necessity for evidentiary hearing or oral argument. Thus, the motion stands submitted on the papers. Cf. **FED. R. CIV. P. 56(a). Gear v. Boulder Cmty. Hosp.**, 844 F.2d 764, 766 (10th Cir.1988) (holding that any hearing requirement for summary judgment motions is satisfied by court's review of documents submitted by parties).

**Services**, 165 F.3d 1321, 1326 (10<sup>th</sup> Cir.), **cert. denied**, 528 U.S. 815 (1999) (abrogated on other grounds, **Martinez v. Potter**, 347 F.3d 1208, 1210 - 1211 (10th Cir. 2003); **Eisenhour v. Weber Cnty.**, 744 F.3d 1220, 1227 (10th Cir. 2014)). However, conclusory statements and testimony based merely on conjecture or subjective belief are not competent summary judgment evidence. **Rice v. United States**, 166 F.3d 1088, 1092 (10<sup>th</sup> Cir.), **cert. denied**, 120 S.Ct. 334 (1999).

### III. FACTS

In its complaint [#1], the plaintiff, Sterisil, Inc., alleges that the defendants, ProEdge Dental Products, Inc. and Mark A. Frampton, are infringing a patent owned by Sterisil.<sup>3</sup> The patent in suit is attached to an earlier motion for summary judgment as Exhibit A [#51-1]. The patent is titled “Structure and Process for Continuously Treating Dental Unit Water.” Like the parties, I refer to the patent as the ‘736 patent. The ‘736 patent is dated January 31, 2006. The summary of the invention in the ‘736 patent describes the invention as follows:

The present invention pertains to methods for purifying dental water from heterotrophic bacteria. These methods involve the administration of a microbiocidally or bacteriostatically effective amount of metal ions and/or metal ion salt(s) to the source water. The administration of these metal ions and/or metal ion salt(s) to the source water causes microorganisms that are present to be killed or maintained in a non-growth status.

*‘736 Patent*, 2:38 - 45. According to the specification of the ‘736 patent, the “(c)ontinuous disinfection of a” dental water line “will prevent additional biofilm growth and eventually dead bacteria will slough and the biofilm formation will be reversed.” *‘736 patent*, 2:51 - 60.

---

<sup>3</sup> Hereafter, I refer to the defendants collectively as “ProEdge.”

The '736 Patent discloses seven claims. Claims 1, 3, and 7 are independent claims. All other claims in the patent are dependent on Claims 1, 3, or 7. Claim 3 involves "mixing a disinfectant consisting essentially of silver nitrate or silver citrate in powder or tablet form with source water, thereby releasing microbiocidally effective amounts of silver ions into source water to provide residual disinfection properties in the source water. . . ." '736 Patent, 8:44 - 48. Claim 7 involves "admixing, in an independent water reservoir, source water and at least one tablet consisting essentially of silver nitrate or silver citrate to provide a concentration of silver ions sufficient to impart residual disinfection properties to the source water . . . ." '736 Patent, 9:5 - 10. Both Claim 3 and Claim 7 provide for delivering the treated water to dental instruments.

The accused ProEdge product is called BluTab. Like the product addressed in the '736 patent, BluTab is a dental waterline treatment which is intended to inhibit the growth of microbial contamination in dental unit waterlines. *Motion for summary judgment* [#90], Collard Declaration [#90-1], Exhibit 9 [#90-10] (BluTab product label). BluTab is a tablet that can be dropped into a water reservoir of a dental water unit. *Id.* According to the label on the BluTab product, silver is the active ingredient in BluTab. *Id.*

According to Sterisil, when BluTab is placed in a container with water, and the container is connected to dental waterlines, the BluTab product will dissolve in the container and deliver silver ions to the water in the container. Sterisil says this process forms treated dental water, as in the patent claims asserted by Sterisil. The treated dental water then is delivered to the dental waterlines so the disinfection properties of the treated dental water kill existing biofilm in the dental waterlines and in any dental instrument connected to the dental waterlines. Sterisil claims this use of BluTab meets

all of the elements of Claims 3 and 7 of the '736 patent. *Motion for summary judgment* [#98], pp. 9 - 10. Thus, Sterisil claims BluTab infringes Claims 3 and 7 of the '736 patent.

Under Fed. R. Civ. P. 53, I appointed a master to recommend a construction of the disputed terms of the '736 patent. The master filed a detailed recommendation [#45] in which he recommends constructions for all of the ten disputed claim terms. The defendants filed objections [#46] to some of the term constructions recommended by the master. The plaintiff did not file objections to the recommendation of the master. In a separate order [#55], I overruled the objections of the defendants and approved and adopted the constructions recommended by the master.

After the disputed terms of the '736 patent were construed, the parties engaged in discovery. With discovery complete, the parties filed the present motions for summary judgment. Sterisil seeks entry of judgment declaring that BluTab infringes Claims 3 and 7 of the '736 patent. ProEdge seeks entry of judgment declaring that BluTab does not infringe the '736 patent. In addition, ProEdge seeks entry of judgment declaring that the '736 patent is invalid as obvious and invalid because it seeks to patent a natural phenomenon.

#### **IV. PATENT VALIDITY - OBVIOUSNESS**

##### **A. STANDARD OF REVIEW**

ProEdge argues Claims 3 and 7 of the '736 patent are invalid because the elements of these claims were disclosed in prior art and, at the time the '736 patent was issued, it would have been obvious to one of ordinary skill in the art to combine those elements. A claimed invention may not be patented "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) (2006).<sup>4</sup> The “test for obviousness is what the combined teachings of the references would have suggested to those having ordinary skill in the art.” *In re Mouttet*, 686 F.3d 1322, 1333 (C.A. Fed. 2012) (citation omitted). “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int’l Co. v Teleflex Inc.*, 550 U.S. 398, 417 (2007) (internal quotation and citation omitted).

Under § 282 of the Patent Act of 1952, “[a] patent shall be presumed valid” and “[t]he burden of establishing in-validity of a patent or any claim thereof shall rest on the party asserting such invalidity.” *Microsoft Corp. v. I4I Ltd. Partnership*, 564 U.S. 91, 95 (2011). A party asserting a patent is invalid must prove invalidity by clear and convincing evidence. *Id.* The Supreme Court of the United States defined clear and convincing evidence as evidence which supports “an abiding conviction” that a factual contention is “highly probable.” *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (internal quotation omitted); *see also J. Strong, McCormick on Evidence* (4th Ed.), § 340 (1992).

A court must consider four factors to determine whether an asserted patent claim would have been obvious at the time the invention was made: (A) the level of ordinary

---

<sup>4</sup> The America Invents Act amended § 103. America Invents Act (AIA), Pub.L. No. 112–29. The amended § 103 applies to patent applications with claims having an effective filing date on or after March 16, 2013. The application for the ‘736 patent was filed prior to that date. As a result, the pre-AIA version of § 103 applies. *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 858 (C.A. Fed. 2015).

skill in the art; (B) the scope and content of prior art; (C) the differences between the prior art and asserted claims; and (D) objective indicia of non-obviousness. **KSR International Co. v. Teleflex Inc.**, 550 U.S. 398, 406 (2007) (citing **Graham v. John Deere Co.**, 383 U.S. 1, 17–18 (1966)). “(T)he sequence of these questions might be reordered in any particular case.” **KSR**, 550 U.S. at 407.

A *prima facie* case of obviousness is established if references in the prior art “[i]n combination ... teach all of the limitations of the claims” and a person of ordinary skill in the art would combine the elements to create the invention. **Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.**, 617 F.3d 1296, 1303 (Fed. Cir. 2010). If the prior art combines to support a *prima facie* case of obviousness, then the court also must consider any objective evidence of non-obviousness. **Id.** at 1305. Objective indicia of non-obviousness include commercial success, long-felt but unmet needs, failure of others, and unexpected results. **Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc.**, 805 F.3d 1092, 1097 (C.A. Fed. 2015). Some courts refer to these objective indicia as “secondary considerations.” **Id.** at 1096 - 1097.

Assessing obviousness is a legal determination based on underlying findings of fact. When “the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate.” **KSR**, 550 U.S. at 427.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

\* \* \* \*

As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

*Id.* at 418. The KSR Court cautioned against “the distortion caused by hindsight bias” and “arguments reliant upon ex post reasoning.” *Id.* at 421.

ProEdge cites patents referred to as Layton, Engelhard, and Welsh to support its invalidity argument. According to ProEdge, the combination of Layton and Welsh or the combination of Engelhard and Welsh, considered by one of ordinary skill in the art, render Claim 3 and Claim 7 of the ‘736 patent obvious and, therefore, invalid. Dr. Shannon Mills provided a detailed report analyzing this prior art and the ‘736 patent. *ProEdge motion for summary judgment* [#90], Collard Declaration [#90-1], Exhibit 6 [#90-7] (Mills report).<sup>5</sup> Dr. Mills concludes, *inter alia*, that the patents referred to as Layton and Welsh, considered together, disclose all requirements of Claim 3 and Claim 7 of the ‘736 patent. *Mills Report* [#90-7], ¶¶ 115, 133. In addition, Dr. Mills concludes that a person of ordinary skill in the art would have thought to combine the teachings of Layton and Welsh. *Id.* Thus, ProEdge contends Claims 3 and 7 arrange old elements disclosed in Layton and Welsh, with each performing the same function it had been known to perform, and yields no more than one would expect from such an arrangement, in view of the prior art. On this basis, ProEdge contends Claims 3 and 7

---

<sup>5</sup> In its response [#106], Sterisil includes brief statements in which it contends Dr. Mills has provided improper legal opinion. *Response* [#106], pp. 1, 5. I have considered the report of Dr. Mills as evidence of (1) how a person of ordinary skill in the art would view the prior art; (2) the scope and content of prior art; (3) the differences (and similarities) between the prior art and asserted claims; and (4) objective indicia of non-obviousness. To the extent Dr. Mills may express legal opinions in his report, any such opinions are not the basis for my analysis.



are invalid because they are obvious.

## B. LEVEL OF ORDINARY SKILL IN THE ART

Sterisil filed the expert report of Karl Linden, PhD, in support of its opposition to the motion for summary judgment of ProEdge. *Sterisil motion for summary judgment* [#98], Exhibit B [#98-3] (Linden report). Dr. Linden defines someone with ordinary skill in the art to which the '746 patent pertains is someone "with a bachelors degree in bacteriology or Biological Engineering, or at least a college level education in chemistry and experience in disinfection and treatment of water." *Linden report* [#98-3], p. 3.

Dr. Mills, an expert for ProEdge, defines a person of ordinary skill in the art is a person "with over 2-3 years' experience in an industry that involves disinfecting water (including the dental industry, though not necessarily a dentist) or a person in academia (student with 2-3 years' experience or a professor) with familiarity with the antimicrobial activity of silver, copper and other metals and metal ions on free floating bacteria and bacterial biofilms." *Mills report*, ¶ 22. Dr. Mills describes also the state of the art in 2001. *Id.*, ¶¶ 23 - 26.

The standard stated by Dr. Mills is narrower and stricter than the standard stated by Dr. Linden. Dr. Mills satisfies the standard stated by Dr. Linden, and Dr. Linden satisfies the standard stated by Dr. Mills. Viewing this evidence defining the relevant level of ordinary skill in the art in the light most favorable to Sterisil, I conclude that the narrower and stricter standard of Dr. Mills is applicable. In the end, however, application of either standard does not alter the analysis.

## C. SCOPE & CONTENT OF PRIOR ART

In his report, Dr. Mills discusses patents referred to as Layton, Engelhard, and

Welsh. He concludes (A) that Claims 3 and 7 of the '736 patent are obvious in light of Engelhard and ordinary skill in the art as of 2001; (B) that Claims 3 and 7 of the '736 patent are obvious in light of Welsh and ordinary skill in the art and/or combined with Engelhard; and (C) that Claims 3 and 7 of the '736 patent are obvious in light of Layton and Welsh and ordinary skill in the art. *Mills report* [#90-7], pp. 24 - 44. These are three independent bases for the conclusion of Dr. Mills that the subject matter of Claims 3 and 7 of the '736 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. I address obviousness in view of the Layton & Welsh analysis of Dr. Mills. I do not, because I need not, address the additional combinations discussed by Dr. Mills.

Layton is a reference to U.S. Patent No. 6,544,427. *Motion for summary judgment* [#90], Collard Declaration [#90-1], Exhibit 4 [#90-5] (Layton patent). The Layton patent is dated April 8, 2003. The Layton patent "pertains to the employment of colloidal silver as a bactericide for water storage and delivery equipment used in dental offices." *Layton patent*, 1:7 - 10. The invention claimed is said to be "particularly useful for safely preventing microbial growth in dental delivery unit water lines . . . ." *Id.*, 1:11 - 13. The Layton patent notes that development of microbial biofilms in the water lines of dental equipment is the primary problem addressed by the patent. *Id.*, 1:41 - 59. The patent discloses that concentrations of colloidal silver of 0.5 ppm, and as low as 0.25 ppm, are sufficient to eliminate "all microbial growth in dental equipment . . . ." *Id.*, 4:20 - 22. The patent discloses other concentrations sufficient to keep water sterile under certain conditions. *Id.*, 3:66 - 4:17. The preferred embodiment in the Layton patent includes adding silver treated water to the water bottle of the dental water system. *Id.*, 4:57 - 58. The water bottle supplies water to the attached dental devices. *Id.*, 4:57 - 58.

Describing the preferred embodiment, the patent notes that most of the particles of metallic silver used in the method are coated with various silver oxides. *Id.*, 4:35 - 39. The silver oxides, the patent says, allow formation of silver ions which are effective at killing microbes. *Id.*, 4:40 - 43. The solution described is to be used with a “closed (bottle type) dental water delivery system.” *Id.*, 50 - 51.

Welsh is a reference to U.S. Patent No. 3,518,343. *Motion for summary judgment* [#90], Collard Declaration [#90-1], Exhibit 8 [#90-9] (Welsh patent). The Welsh patent is dated June 30, 1970. The Welsh patent concerns an effervescent tablet containing an antimicrobial substance. *Welsh patent*, 1:14 - 16. When the tablet is dissolved, the solution created “is useful for cleaning solid surfaces, particularly, the teeth and periodontal gum areas of the oral cavity.” *Id.*, 1:23 - 25. The Welsh patent notes that, when dissolved in water, the tablets produce a solution which could be used to clean solid surfaces “such as the surfaces of dental appliances . . . .” *Id.*, 8:25 - 26.

#### D. DIFFERENCES BETWEEN PRIOR ART & ASSERTED CLAIMS

##### 1. Evidence Presented by Pro Edge

###### a. ‘736 Patent - Claim 3

Dr. Mills properly sees Claim 3 of the ‘736 patent as having two steps. He analyzes the two steps separately in view of the prior art.

**Step one:** “mixing a disinfectant consisting essentially of silver nitrate or silver citrate in powder or tablet form with source water, thereby releasing microbiocidally effective amounts of silver ions into source water to provide residual disinfection properties in the source water, thereby changing the source water to a treated dental unit water.”

*‘736 patent*, 8:44 - 50.

Dr. Mills cites the Layton patent as disclosing: (a) the creation of a disinfectant by mixing silver with water; and (b) the purpose of the mixing is to release silver ions to kill

microbes. *Mills report* [#90-7], ¶ 110. “While Layton teaches releasing silver ions from silver colloid, one skilled in the art reading Layton in 2001 would have appreciated that silver ions could be obtained from silver nitrate or silver citrate, both of which were available in powder or tablet form.” *Id.* More than 30 years prior to Layton, Dr. Mills notes, Welsh “specifically disclosed making a tablet using either silver citrate or silver nitrate.” *Id.*, ¶ 111. Welsh says the “antimicrobial substance of the water soluble tablet of this invention can be any of the wide range of microbiostatic or microbial compounds or substances.” *Welsh patent*, 4:64 - 66. Welsh provides a long list of such substances, including silver nitrate and silver citrate. *Id.*, 5:28 - 29.

Addressing Claim 3, step one in view of Welsh and Layton, Dr. Mills concludes:

It would have been obvious to combine Welsh and Layton. Both deal with using silver to treat water to disinfect surfaces of dental equipment or appliances. For the skilled artisan looking to continuously disinfect internal surfaces of dental appliances, it would have been obvious that Layton could continuously treat such surfaces but with the drawback of needing a continuous supply of silver colloid. The tablets described in Welsh were a well-understood, and more readily available, source of silver ions and it would have been obvious to a skilled artisan to try them in a system similar to that described in Layton. The combination of the two items would provide the expected results. Therefore, step one was obvious in view of Layton and Welsh.

*Mills report*, ¶ 111.

**Step two:** “supplying the treated dental unit water to at least one dental instrument via at least one dental unit waterline, whereby the residual disinfection properties of the treated dental unit water are sufficient to kill existing biofilm established in the dental unit and reduce additional biofilm growth therein.”

*'736 patent*, 8:51 - 56.

Layton says its method can “sanitize the water supply of dental water delivery units.” *Layton patent*, Abstract. The object of Layton is to “discourage the growth of microbial colonies” and “reduce bacterial growth” within the water supply of dental

delivery units. *Layton patent*, 2:13 - 15, 31 - 32. Layton provides that the silver solution is added, in a specified amount, to “water in dental office water reservoirs.” *Id.*, 5:9 - 10. That water then is supplied to “the illustrated devices,” which include a dental drill and syringe. *Id.*, 4:56 - 57, fig. 1. Layton teaches that silver at various levels kills or reduces established biofilm and reduces additional biofilm growth. *Id.*, 3:66 - 4:21. Dr. Mills concludes that “Layton discloses all requirements of [Claim 3,] step two.” *Mills report*, ¶ 114.

Addressing Claim 3, steps one and two, in view of Welsh and Layton, Dr. Mills concludes:

In sum, Layton discloses all requirements of Claim 3, except the use of a tablet made from silver nitrate or silver citrate. Welsh supplies this limitation, and one skilled in the art would have thought to combine the teachings of Layton and Welsh.

*Mills report*, ¶ 115.

b. ‘736 Patent - Claim 7

Dr. Mills properly sees Claim 7 has having two steps. He analyzes the two steps separately in view of the prior art.

**Step one:** “admixing, in an independent water reservoir, source water and at least one tablet consisting essentially of silver nitrate or silver citrate to provide a concentration of silver ions sufficient to impart residual disinfection properties to the source water without having a negative effect on dental enamel or dentin bonding agents; thereby changing the source water to treated dental water.”

*‘736 patent*, 9:4 - 10:2.

Dr. Mills cites the Layton patent as disclosing: (a) water treated with silver ions; and (b) adding the treated water to a water bottle or independent reservoir of a dental unit. *Layton patent*, 4:35 - 58. Dr. Mills says “one of skill in the art in 2001 would

recognize that silver ions could be obtained from tablets of silver nitrate or silver citrate, which were well known at the time.” *Mills report*, ¶ 127. Dr. Mills notes that Welsh describes such a tablet and using such a tablet “would have been obvious to one of skill in the art in 2001.” *Id.* Dr. Mills also opines that one “of ordinary skill in the art would also recognize that rather than mixing silver outside the water bottle and adding the mixture to a water bottle,” as described in Layton, “that mixture could occur in the water bottle.” *Id.*, ¶ 128. On this basis, Dr. Mills concludes that “Layton and Welsh disclose admixing, in an independent water reservoir, source water and at least one table[t] consisting essentially of silver nitrate or silver citrate to provide a concentration fo silver ions.” *Id.*

As noted previously in regard to Claim 3, step one, Dr. Mills observes again that the stated purpose of Layton is to “sanitize the water supply of dental water delivery units” to “discourage the growth of microbial colonies” and “reduce bacterial growth” within the water supply of dental delivery units. *Layton patent*, Abstract, 2:13-15, 2:31-32. Dr. Mills concludes that Layton discloses admixing. *Mills report*, ¶ 129.

**Step two:** “supplying the treated dental unit water to at least one dental instrument via at least one dental unit waterline, whereby the residual disinfection properties of the treated dental unit water are sufficient to kill existing biofilm established in the dental unit and reduce additional biofilm growth therein.”

*’736 patent*, 10:3 - 10:8.

The language of Claim 7, step two is identical to the language of Claim 3, step two. As a result, the analysis of Dr. Mills concerning Claim 7, step two is identical to his analysis of Claim 3, step two. Addressing Claim 7, step two, Dr. Mills concludes that “Layton discloses all requirements of [Claim 7,] step two.” *Mills report*, ¶ 132.

Addressing Claim 7, steps one and two, in view of Welsh and Layton, Dr. Mills concludes:

In sum, Layton discloses all requirements of Claim 7, except the use of a tablet made from silver nitrate or silver citrate. Welsh supplies this limitation, and one skilled in the art would have thought to combine the teachings of Layton and Welsh.

*Mills report*, ¶ 133.

In sum, Dr. Mills concludes that, considered together, Layton and Welsh disclose all of the requirements of Claim 3 and Claim 7. He concludes also that one of ordinary skill in the art would have thought to combine the teachings of Layton and Welsh as they are combined in Claim 3 and Claim 7 of the '736 patent.

## 2. Evidence Presented by Sterisil

In its response [#106] to the ProEdge motion for summary judgment [#90], Sterisil notes the argument of ProEdge claiming invalidity due to obviousness. *Response* [#106], pp. 2 - 3, 4 - 5. Sterisil acknowledges Welsh, but contends Welsh “does not discuss or recognize any of the problems associated with dental waterlines, and accordingly offers no solutions to such problems.” *Id.*, p. 2. Sterisil argues Welsh provides nothing more than acknowledgment that silver citrate and silver nitrate were known before the '736 patent. *Id.* As noted previously, Welsh discloses a tablet containing an antimicrobial substance, which may include, *inter alia*, silver nitrate or silver citrate. The Welsh tablet can be dissolved in water. Welsh notes also that the solution created by dissolving the tablet could be used to clean “dental appliances.” *Welsh patent*, 8:26. The solution described in Welsh has “antimicrobial properties.” *Id.*, 1:32.

Sterisil notes also that Dr. Mills, the expert for ProEdge, does not discuss the

reasons of the patent examiner for allowance of the '736 patent. In a document titled Examiner's Amendment, the examiner amended the application for the '736 patent. *Motion for leave* [#103], Exhibit A-2 [#103-3] (*Examiner's Amendment*).<sup>6</sup> In the amendment, the examiner discusses some of the relevant prior art and the application for the '736 patent. *Id.* The examiner concludes that none of the prior art specified in the Examiner's Amendment teaches "the method for treating water consisting essentially of silver nitrate or silver citrate powder or tablets as the disinfectant and supplying to a dental unit." *Examiner's Amendment* [#103-3], p. 3. The examiner observes that "it would not be obvious to arrive at the applicant's invention from these references in any combination because there is no suggestion in any of these references that silver nitrate or silver citrate alone would work as an appropriate disinfectant and can be delivered in appropriate concentration from powder or tablets to a dental water supply system." *Id.*, pp. 3 - 4.

In the Examiner's Amendment [#103-3], the examiner does not mention or discuss Layton or Layton in combination with Welsh. The analysis in the Examiner's Amendment does little if anything to undermine the conclusion of Dr. Mills that Claims 3 and 7 of the '736 patent are obvious in light of Layton and Welsh and ordinary skill in the art. "(A) party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the U.S. Patent and Trademark Office." ***Tokai Corp. v. Easton Enterprises, Inc.***, 632 F.3d 1358,

---

<sup>6</sup> It is apparent that Sterisil intended the Examiner's Amendment to be an exhibit to its response [#106]. An error of unknown source caused the Examiner's Amendment not to be included with the response when docketed as [#106]. However, the Examiner's Amendment is readily accessible as an exhibit to an earlier version of the response [#103-1].



1367 (C.A. Fed. 2011). “An added burden of deference to the PTO is not required, however, with respect to invalidity arguments based on evidence that the PTO did not consider.” *Id.* (citation omitted). Here, because the examiner did not consider or discuss Layton, added deference to the PTO is not required.

Attached to the Sterisil motion for summary judgment [#98] is the expert report of Karl Linden, PhD, in support of its opposition to the motion for summary judgment of ProEdge. *Sterisil motion for summary judgment* [#98], Exhibit B [#98-3] (Linden report). In his report [#98-3], Dr. Linden does not discuss prior art and invalidity due to obviousness.

Attached to the ProEdge motion for summary judgment [#90] is the rebuttal expert report of Dr. Linden, which was prepared on behalf of Sterisil. This report is titled “Rebuttal Expert Report of Karl Linden, PhD, Re. Certain Observations of Dr. Shannon Mills in Support of Defendants’ Invalidity Contentions.” *ProEdge motion for summary judgment* [#90], Exhibit 23 [#90-24] (Linden rebuttal report). In his rebuttal report, Dr. Linden notes that Engelhard, a patent discussed in the report of Dr. Mills, is listed on the face of the ‘736 patent and was considered by the patent office when making the decision to grant the ‘736 patent. *Linden rebuttal report* [#90-24], ¶ 2. He does not analyze these facts further. Dr. Linden observes that Welsh does not recognize the problem of biofilm in dental office waterlines and does not offer any solution to the associated problems. *Id.*, ¶ 3. In his rebuttal report, Dr. Linden does not mention or discuss Layton.

In his rebuttal report, Dr. Linden notes also that Welsh does not include sodium Laurel sulfate (SLS) and concludes that Welsh is consistent with the conclusion of Dr.

Linden that SLS is not a disinfectant. *Linden rebuttal report* [#90-24], ¶ 3. At the end of his rebuttal report, Dr. Linden cites additional reasons to support his conclusion that SLS is not a disinfectant. *Id.*, ¶¶ 4 - 6. This issue is not relevant to the contention of invalidity of ProEdge.

In its response [#106], Sterisil argues that Dr. Mills did not recognize that the '736 patent eliminates steps or components used in the Engelhard patent. Engelhard is U.S. Patent No. 6,267,895. *Motion for summary judgment* [#90], Collard Declaration [#90-1], Exhibit 3 [#90-4] (Engelhard patent). The Engelhard patent "relates to purification of dental water lines, to destroying biofilm that may be present and to preventing biofilm buildup . . . ." *Engelhard patent*, 1:16 - 19. The invention involves enriching water with oxygen and/or ozone and then conveying the water past a silver catalyst cartridge. *Id.*, 2:42 - 49. The silver acts as a catalyst which contributes to disinfection. *Id.*, 1:18 - 24. This combination is claimed to destroy biofilm in a dental water system. *Id.*, 2:58 - 59. Sterisil notes that the '736 patent eliminates the oxygen and/or ozone enrichment step of Engelhard but retains the function of reducing or eliminating biofilm. It "may also be unobvious to omit an element while retaining its function." ***Application of Edge***, 359 F.2d 896, 899 (Cust. & Pat.App. 1966) (citation omitted).

The analysis of Sterisil and Dr. Linden as summarized above cites discrete differences between the '736 patent and Welsh and discrete differences between the '736 patent and Engelhard. Nowhere do Sterisil or Dr. Linden address Layton or the combination of Layton and Welsh, a combination detailed in the analysis of Dr. Mills. Nowhere do Sterisil or Dr. Linden address how one of ordinary skill in the art would consider the combined teachings of Layton and Welsh. Among other things, the

analysis of obviousness concerns the “interrelated teachings of multiple patents.” **KSR International Co. v. Teleflex Inc.**, 550 U.S. 398, 418 (2007). Sterisil and Dr. Linden do not engage in this analysis. As a result, Sterisil fails to rebut the conclusion of Dr. Mills that Claims 3 and 7 of the ‘736 patent are obvious in light of Layton, Welsh, and ordinary skill in the art.<sup>7</sup>

### 3. Conclusion - Prior Art, Ordinary Skill in the Art, & Asserted Claims

The detailed examination and analysis of Dr. Mills provides strong evidence that Claims 3 and 7 of the ‘736 patent are obvious in light of Layton, Welsh, and ordinary skill in the art. The evidence and argument cited by Sterisil do not significantly undermine the evidence and analysis of Dr. Mills and ProEdge. Viewing the evidence in the record in the light most favorable to Sterisil, I find that the evidence in the record shows clearly and convincingly that the references in the prior art, in combination, teach all of the limitations of the Claims 3 and 7 of the ‘736 patent. Further, the evidence shows clearly that a person of ordinary skill in the art would combine those elements to create the invention reflected in Claims 3 and 7 of the ‘736 patent. Thus, ProEdge has established a *prima facie* case that Claims 3 and 7 of the ‘736 patent are invalid because they are obvious. **Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.**, 617 F.3d 1296, 1303–04 (Fed. Cir. 2010).

#### E. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

If the prior art combines to support a *prima facie* case of obviousness, then the court must consider also any objective evidence of non-obviousness. **Id.** at 1305.

---

<sup>7</sup> Sterisil also fails to rebut the conclusion of Dr. Mills that Claims 3 and 7 of the ‘736 patent are obvious in light of Welsh and ordinary skill in the art and/or combined with Engelhard. I do not address in this order this analysis and conclusion of Dr. Mills.

Objective indicia of non-obviousness include commercial success, long-felt but unmet needs, failure of others, and unexpected results. ***Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc.***, 805 F.3d 1092, 1097 (C.A. Fed. 2015).

Dr. Mills, on behalf of ProEdge, opines that the presence of biofilm in dental units has been known since the late 1960s. *Mills report* [#90-7], ¶ 135. In the early 1990s, concerns about the risks of bacteria became heightened due to the increasing numbers of patients with compromised immune systems. *Id.* The 1996 American Dental Association (ADA) statement on dental unit waterlines challenged the dental manufacturing industry to develop methods to control biofilm in dental unit water systems. '736 patent, 1:22 - 28. Dr. Mills says many treatment methods quickly emerged, particularly after the 1996 ADA statement. *Mills report* [#90-7], ¶ 135.

A review of dental waterline treatment products published by the U.S. Air Force Dental Evaluation and Consultation Service (DECS) in 2012 described 20 currently marketed products from seven different manufacturers which used chemical agents to improve dental water quality. *Mills report* [#90-7], ¶ 43. Seven of these products, including four made by Sterisil, employed ionic silver as an active ingredient. *Id.* An internet search for additional products outside the United States identified two additional waterline treatment agents, Oxygenal 6, Kavo Dental GMBH, Hamburg, Germany and Planosil, Planmeca, Finland, which use silver and an oxidizing agent that also attacks the biofilm matrix. *Id.* Dr. Mills says use of silver as a germicide is practiced by many without, as far as he knows, copying the claims of the '736 patent or requiring a license of the '736 patent. *Id.*, ¶ 136.

Dr. Mills says the '736 Patent has not resulted in any unexpected, superior, or

praiseworthy results. *Id.*, ¶ 137. In the view of Dr. Mills, the fact that silver ions can be used to create a disinfectant is unremarkable. *Id.* He says silver has been used to treat water since antiquity, when soldiers of the Roman Empire would place silver coins in their water vessels to purify their drinking water. *Id.* According to Dr. Mills, use of silver ions to treat bacteria in dental plumbing is merely what would be expected based on the known properties of silver. *Id.*

In its response [#106], Sterisil does not address the objective factors. The report and rebuttal report of Dr. Linden [#98-3 & #90-24] do not address the objective factors. Thus, Sterisil fails to rebut the analysis and conclusions of Dr. Mills concerning the objective factors.

Viewing the evidence in the record in the light most favorable to Sterisil, I find that the objective factors do not undermine the *prima facie* case that Claims 3 and 7 of the '736 patent are obvious. It is apparent that Sterisil has some degree of commercial success with its dental water line products. However, there is no evidence in the record to show the level of commercial success of these Sterisil products. The report of Dr. Mills shows there is a long-felt need for products to control biofilm in dental lines. However, the report of Dr. Mills tends to show that this need is being met by a variety of products. There is no evidence of a long-felt but unmet need. There is no evidence that Claims 3 and 7 of the '736 patent have led to unexpected results. Individually or in combination, none of the objective factors undermines the *prima facie* case of invalidity established by ProEdge.

#### F. CONCLUSION - INVALIDITY BASED ON OBVIOUSNESS

Considering all of the evidence submitted by the parties, and viewing that evidence in the light most favorable to Sterisil, I find and conclude that ProEdge has

established by clear and convincing evidence a *prima facie* case that Claims 3 and 7 of the '736 patent are invalid because they are obvious. Viewing the evidence in the record in the light most favorable to Sterisil, I find that the objective factors do not vitiate the *prima facie* case that Claims 3 and 7 of the '736 patent are obvious. Thus, I find and conclude that the defendants, ProEdge Dental Products, Inc. And Mark A. Frampton, are entitled to summary judgment on their contention that Claims 3 and 7 of the '736 patent of the plaintiff, Sterisil, Inc., are invalid because they are obvious.

#### **V. STERISIL MOTION FOR SUMMARY JUDGMENT**

In its motion for summary judgment [#98], Sterisil seeks summary judgment on its claim that the BluTab product of the defendants infringes Claims 3 and 7 of the '736 patent. However, I have conclude that Claims 3 and 7 of the '736 patent are invalid because they are obvious. Therefore, by definition, Sterisil is not entitled to summary judgment on its infringement claims.

#### **VI. CONCLUSION & ORDERS**

Viewing the evidence in the record in the light most favorable to Sterisil, the defendants are entitled to summary judgment on their contention that Claims 3 and 7 of the '736 patent of the plaintiff, Sterisil, Inc., are invalid because they are obvious. For that same reason the motion of Sterisil for summary judgment on its claim that the BluTab product of the defendants infringes Claims 3 and 7 of the '736 patent is denied.

**THEREFORE, IT IS ORDERED** as follows:

1. That the **Motion for Summary Judgment** [#90] of defendants, ProEdge

Dental Products, Inc. and Mark A. Frampton, is granted to the extent the defendants seek summary judgment declaring that Claims 3 and 7 of the '736 patent are invalid because they are obvious;

2. That otherwise, the **Motion for Summary Judgment** [#90] of defendants, ProEdge Dental Products, Inc. and Mark A. Frampton, is denied as moot;

3. That **Plaintiff, Sterisil, Inc.'s Corrected Motion for Summary Judgment of Infringement** [#98] is denied;

4. That **Defendants' Motion to Exclude Testimony of Plaintiff's Damages Expert Armando Chavez at Trial** [#107] and **Motion to Strike Expert Testimony of Bradley J. Downs** [#112] are denied as moot;

5. That judgment shall enter in favor of the defendants, ProEdge Dental Products, Inc. and Mark A. Frampton, and against the plaintiff, Sterisil, Inc., on the first affirmative defense of invalidity and the second counterclaim asserting invalidity, as pled in the answer [#11], to the extent the affirmative defense and counterclaim allege invalidity based on obviousness;

6. That based on this order and the earlier **Order on Motion for Summary Judgment** [#56], judgment shall enter in favor of the defendants, ProEdge Dental Products, Inc. and Mark A. Frampton, and against the plaintiff, Sterisil, Inc., on the patent infringement claims asserted by the plaintiff in the complaint [#1];

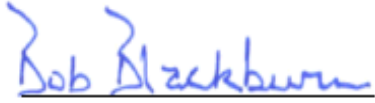
7. That the jury trial set to begin May 21, 2018, is vacated;

8. That the defendants are awarded their costs to be taxed by the clerk of the court in the time and manner prescribed in Fed. R. Civ. P. 54(d)(1) and D.C.COLO.LCivR 54.1; and

9. That the court retains jurisdiction to resolve the pending motion for leave to restrict [#108] and motion for sanctions [#110].

Dated May 11, 2018, at Denver, Colorado.

**BY THE COURT:**



Robert E. Blackburn  
United States District Judge