UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

DENTSPLY INTERNATIONAL, INC. and TULSA DENTAL PRODUCTS, LLC, d/b/a TULSA DENTAL SPECIALITIES, Plaintiffs,	)	
v.	)	No. 2:14-CV-196
U S ENDODONTICS, LLC, Defendant.	)	

ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION

This patent infringement case is before the Court on Dentsply International, Inc.'s ("Dentsply") motion for a preliminary injunction, [Docs. 26, 27, 59], prohibiting the defendant, US Endodontics, LLC ("US Endo") "from manufacturing all *post-heat-treated nickel-titanium endodontic files*" using a method that infringes two patents (United States Patent Nos. 8,727,773 [the "773 patent"] and 8,562,341 [the "341 patent"]) to which Dentsply asserts exclusive license.[1] US Endo has responded in opposition, [Doc. 65], and Dentsply has replied, [Doc. 77]. An evidentiary hearing was conducted on November 25-26, 2014, [Docs. 161, 162]. The parties have filed both pre-hearing, [Docs. 102, 103, 113, 114], and post-hearing briefs, [Docs. 177, 179]. The matter is now ripe for disposition. For the reasons which follow, the motion for a preliminary injunction is DENIED.

I. Background

On October 22, 2013, the United States Patent and Trademark Office ("USPTO") issued the '341 patent to Gold Standard Products, Inc. ("Gold Standard") as assignee of the inventor, Dr. Neill H. Luebke ("Dr. Luebke"), a board certified endodontist. The USPTO issued the '773

[1] Dentsply has now limited its request for a preliminary injunction to the '773 patent, [Doc. 77, at 2 fn. 1].

patent to Gold Standard as the assignee of Dr. Luebke on May 20, 2014. The '341 and '773 patents generally relate to a method of manufacturing or modifying heat-treated dental or orthodontic instruments used to perform root canals. Dentsply, a manufacturer of dental products, is the exclusive licensee for both the '341 and the '773 patents. The claims of these patents cover a process for post-heat-treating endodontic nickel-titanium files at 400° C or higher. US Endo also manufactures and sells post-heat-treated endodontic files.

Dr. Luebke has decades of experience in root canal therapy and researching and developing endodontic files in both academic and industrial settings. Stainless steel files, traditionally used by dentists, were replaced by nickel-titanium files in the 1990's. These nickel-titanium files were used by dentists to evacuate a tooth canal and were prone to fracture inside a patient's tooth. In 1995, Dr. Luebke began to research a way to address the fracture problem with the nickel-titanium endodontic files. His research led to the invention of post-machining heat-treated files which were more flexible but just as strong as the nickel-titanium files being used in the industry. This heat treatment process was the foundation for the '341 and '773 patents.

US Endo, a New Mexico, LLC, is registered to do business in Tennessee and manufactures nickel-titanium endodontic files marketed and sold by non-party Edge Endo to end users, i.e., dental practitioners. Edge Endo began offering the files for sale in April, 2013. Dentsply alleges that US Endo has been unlawfully manufacturing and selling endodontic files which infringe the '773 patent. Specifically Dentsply asserts that US Endo infringes claim 1 of the '773 patent, which reads:

> 1. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:
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> (a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature from 400° C. up to but not equal to the melting point of the superelastic nickel titanium alloy,

wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

II. Legal Standard

Rule 65 of the Federal Rules of Civil Procedure permits a party to seek injunctive relief if he believes he will suffer irreparable harm or injury during the pendency of the action. Fed. R. Civ. P. 65. Similarly, 35 U.S.C. § 283 permits courts to issue "injunctions in accordance with the principles of equity to prevent the violation of any rights secured by patent, on such terms as the court deems reasonable." The patentee's entitlement to any injunction is a matter largely within the discretion of the trial court. *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

"A preliminary injunction is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *LifeScan Scotland, Ltd. v. Shasta Techs.*, 734 F.3d 1361, 1366 (Fed. Cir. 2013) (quoting *Winter v. Natural Resources Defense Counsel, Inc.*, 555 U.S. 7, 22 (2008)). In determining whether to exercise its discretionary authority to enter injunctive relief the court must consider four universally applicable factors: (1) Whether plaintiff is likely to succeed on the merits; (2) whether plaintiff is likely to suffer irreparable harm in the absence of preliminary relief; (3) whether the balance of equities tips in plaintiff's favor; and (4) whether an injunction is in the public interest. *Winter*, 555 U.S. at 20.

"These factors, taken individually, are not dispositive; rather the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (quoting *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1998)). It is the

movant's burden to prove each of the four elements, *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994). A preliminary injunction should not be granted "if the alleged infringer raises a substantial question regarding either infringement or validity" of the patent. *AstraZeneca, LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010).

III. Analysis and Discussion

In its post-hearing brief, Dentsply argues that the "evidence establishes that US Endo infringes claims 1, 2, 4 and 5 of the '773 patent"[2] and that US Endo failed to present any evidence of non-infringement. US Endo, on the other hand asks the Court to limit its non-infringement analysis to claim 1 and, claims non-infringement on the basis that claim 1 of the '773 patent "should be construed to require the heat-treating occurs in an atmosphere consisting of a gas essentially unreactive with nickel titanium," and, *"[u]nder this construction*, US Endo indisputably does not infringe." [3]

US Endo further argues that the '773 patent is invalid if construed broadly as Dentsply contends because the '773 patent is not entitled to a priority date earlier than April 25, 2012, based on the prior art published before April, 2012. Alternatively, US Endo argues that, even if the '773 patent has a priority date of 2004, it is invalid over pre-2004 art. More specifically, US Endo asserts that the '773 patent is invalid as anticipated by and/or rendered obvious over the prior art, and for lacking an adequate written description. Dentsply responds that US Endo offered no proof of anticipation at the evidentiary hearing and disputes that US Endo has raised a substantial question that claim 1 is invalid under § 103 for obviousness.

A. Likelihood of Success on the Merits

In order to demonstrate a likelihood of success on the merits of its case, a plaintiff

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[2] See Doc. 81-1 at 15

[3] US Endo initially raised two non-infringement arguments but appears to have abandoned its second argument.

in an infringement suit is required to show that (1) the plaintiff will likely prove that defendant is infringing its patent; and (2) that the plaintiff's infringement claim will likely withstand challenges to validity and enforceability of the patent. *Amazon.com*, 239 F.3d at 1350 (citing *Genentec,* 108 F.3d at 1364). If a defendant "raises a substantial question concerning either infringement or validity, i.e., asserts an infringement or invalidity defense that the [plaintiff] cannot prove 'lacks substantial merit,'" plaintiff is not entitled to the requested relief. *Id.*

The standard for assessing likelihood of success on the merits has engendered some confusion over the meaning of the terms "raises a substantial question" and "lacks substantial merit." *See Avery Dennison Corp. v. Alien Technology Corp.*, 626 F. Supp. 2d 693 (N.D. Ohio 2009) (discussing *Enrico Int'l Corp. V. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008) (holding that a substantial question with respect to the validity of the patent is sufficient to support a denial of a motion for preliminary injunction) and *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008) (appearing to reject the "substantial question" formulation of the alleged infringer's burden)). The Federal Circuit, however, clarified the requirements for a preliminary injunction in *Titan Tire Corp. v. Case New Holland, Inc.,* and it may be useful to quote the Federal Circuit verbatim on the standard:

> In assessing whether the patentee is entitled to the injunction, the court views the matter in light of the burdens and presumptions that will inhere at trial. *See Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418, 429, 126 S.Ct. 1211, 163 L.Ed.2d 1017 (2006) ("[T]he burdens at the preliminary injunction stage track the burdens at trial.").
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> *At trial,* as we explained in our recent case of *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed.Cir.2008), an issued patent comes with a statutory presumption of validity under 35 U.S.C. § 282. Because of this presumption, an alleged infringer who raises invalidity as an affirmative defense has the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial

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