

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE**

DENTSPLY INTERNATIONAL INC.

Plaintiff,

v.

US ENDODONTICS, LLC

Defendant.

Civil Action No. 2:14-CV-00196
Judge Greer
Magistrate Judge Inman

PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiff Dentsply International Inc. ("Dentsply"), hereby moves this Court to enter an Order preliminarily enjoining Defendant US Endodontics, LLC ("Defendant" or "US Endo") from manufacturing all *post-heat-treated, nickel-titanium endodontic files* ("post-heat-treated files") using a method that is believed to infringe United States Patent Nos. 8,727,773 ("the '773 patent") and 8,562,341 ("the '341 patent") (collectively the "Asserted Patents" or the "Patents-in-suit").

In support of its motion, Dentsply alleges as follows:

1. On May 20, 2014, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,727,773 entitled "Dental and Medical Instruments Comprising Titanium" to Gold Standard Products, Inc. as assignee of the inventor Dr. Neill H. Luebke.
2. On October 22, 2013, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,562,341 entitled "Dental and Medical Instruments Comprising Titanium" to Gold Standard Products, Inc. as assignee of the inventor Dr. Neill H. Luebke.

GOLD STANDARD EXHIBIT 2019
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3. The '773 and '341 patent are generally directed to a method of manufacturing or modifying a superelastic nickel-titanium dental instrument or device where the dental instrument or device having an elongated shank of super-elastic nickel titanium alloy is provided and the entire instrument is then heat-treated at a temperature of 400°C or above but not to the melting temperature, resulting in a device with shape memory characteristics including an angle of greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion.

4. Dentsply is the exclusive licensee of the '773 and '341 patents and has the right to bring suit for infringement and to recover for any current and past damages.

5. Dentsply has for years sold several nickel-titanium endodontic dental files (for use in rotating drills) including the ProFile®, ProTaper®, GT-Series® and WaveOne®. In February 2012, Dentsply introduced its innovative *post-heat-treated, nickel-titanium endodontic file*, the Vortex Blue®. Dentsply also sells other *post-heat-treated, nickel-titanium endodontic files*, such as the ProTaper Gold®. Because it is post-heat-treated, the Vortex Blue® file, when bent by an endodontist, retains a bent shape. This allows the endodontist to pre-shape the file to follow the natural curved passage of the tooth when performing a root canal, thus yielding better canal shaping and a safer experience for the patient.

6. Subsequent to the introduction of Dentsply's Vortex Blue® product, US Endo began manufacturing and selling heat-treated nickel-titanium endodontic files. US Endo sold these files to Edge Endo, LLC ("Edge Endo"), a direct competitor of Dentsply, which sells the files under the name EdgeFile™. Not only was Dentsply's innovative Vortex Blue® product on the market when US Endo began manufacturing its products, but US Endo was aware at that time of the pendency of certain patent applications that had been filed by Dr. Neill Luebke. Dr.

Luebke is the inventor of the two Patents-in-Suit. The Patents-in-Suit claim priority to earlier Luebke applications of which US Endo was aware by May 2012.

7. Dentsply's endodontic dental files directly compete with products manufactured by Defendant, US Endo, which are then provided to US Endo customers, including at least, Edge Endo, LLC ("Edge Endo"). In fact, according to information submitted by US Endo to the United States Food and Drug Administration ("FDA"), US Endo is the "contract manufacturer" of the EdgeFile™ line of products that are sold and marketed by Edge Endo. Edge Endo sells, markets and distributes the EdgeFiles directly to its customers, in particular, dentists and endodontists.

8. In product literature and in promotional videos on its website, Edge Endo markets the EdgeFiles manufactured by Defendant as "effortlessly compatible" with Dentsply's rotary files. Indeed, Edge Endo provides a "compatibility" chart instructing dentists and endodontists who use Dentsply's WaveOne® to use EdgeFile X1; those who use Dentsply's GT® and GT®X to use EdgeFileX5; and those who use Dentsply's Vortex® or Profile® to use EdgeFile X7.

9. Dentsply believes that US Endo is using a process that is protected by the '773 and '341 patents to manufacture at least the EdgeFile X1, EdgeFile X5 and EdgeFile X7 products. As explained in detail in the accompanying Memorandum in Support of Dentsply's Motion for Preliminary Injunction, the results of testing conducted by independent, third-party laboratories on the EdgeFile X1, X5 and X7 manufactured by US Endo, including thermal analysis by differential scanning calorimetry and mechanical testing (a stiffness test in accordance with ISO 3630-1), are consistent with products that are manufactured by a process that infringes the '773 and '341 patents asserted in the Complaint.

10. Additionally, the founder of US Endo, Bobby Bennett, is the named inventor on a patent application filed in February 2012, which claims and describes a process for manufacturing post-heat-treated endodontic files that falls within the scope of the claims of the Patents-in-Suit. This patent application was filed at least 6 years after the Luebke patent applications to which the Patents-in-Suit claim priority, and stands rejected by the Patent Office. Provided that US Endo is practicing the method claimed in Mr. Bennett's own patent application, then that method infringes claims of the '773 and '341 patents.

11. To further confirm infringement and prepare for the hearing on Plaintiff's Motion for a Preliminary Injunction, Plaintiff is seeking expedited discovery narrowly limited to the specific process used by US Endo to manufacture the EdgeFile products, including in particular, the point in in the manufacturing process when heat-treatment occurs (*i.e.* whether the files are post-heat treated as believed) and the specific temperature at which the files are heat-treated.

12. Dentsply has suffered irreparable harm, including market price erosion and loss of market share, as well as damage to its reputation and goodwill with customers as a result of Defendant's actions.

13. Defendant US Endo has caused and will continue to cause irreparable harm to Dentsply, its business and its reputation through their making, using, offering for sale, sale, importation, marketing and/or distribution of at least the EdgeFile X1, X5 X7. Additionally, Defendant is unlikely to be able to pay an award of damages if an injunction is not issued during the time that it takes for the parties to try the case. Plaintiff is seeking limited expedited discovery specifically directed to facts concerning Defendant's inability to pay a damages award.

14. As demonstrated more fully in the accompanying Memorandum of Law in Support of Plaintiff's Motion for a Preliminary Injunction, Dentsply is likely to succeed on the merits of its claims of infringement and on a showing of patent validity.

15. The balance of equities favors Dentsply. The continued harm to Dentsply in the absence of a preliminary injunction greatly outweighs any alleged harm that Defendant might suffer as a result of a preliminary injunction, and the issuance of an injunction is in the interest of the public.

In further support of its motion, Dentsply relies upon and incorporates by reference the accompanying Memorandum of Law in Support of Plaintiff's Motion for a Preliminary Injunction and the declarations of Dr. Robert Sinclair, Dr. Richard Gering, Dr. Neil Luebke, DDS, John Voskuil, and C. Nichole Gifford, Esq. and the supporting exhibits submitted concurrently herewith. Given the urgency of this matter, Dentsply respectfully requests authority to conduct expedited discovery and that the Court hold an expedited hearing on Plaintiff's Motion for a Preliminary Injunction.

Dated: July 9, 2014

Respectfully submitted,

By: *s/Jimmie C. Miller*

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