United States District Court

EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
	§	
v.	§	CASE NO. 4:16-CV-350
	§	Judge Mazzant
PROPEL ORTHODONTICS, LLC	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is OrthoAccel's Motion for Preliminary Injunction and Permanent Injunction (Dkt. #57). Based on the pleadings, the numerous briefs and submissions, the arguments and evidence presented at a hearing on the motion, and the applicable law, the Court enters the findings of fact and conclusions of law set forth below. Based on these findings and conclusions, the Court **GRANTS** OrthoAccel's Motion for Preliminary Injunction.

BACKGROUND

Plaintiff, OrthoAccel Technologies, Inc. ("OrthoAccel"), is a medical device company that manufactures dental appliances. In 2008, OrthoAccel developed a prototype hands-free dental device that uses gentle vibrations to accelerate tooth movement when used with orthodontic treatment. This prototype would eventually become the AcceleDent device, which has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extraoral component that generates a vibrational force of 0.25N at 30 Hz. The Activator connects directly to the Mouthpiece, which the patient lightly bites down on for 20 minutes daily to accelerate tooth movement during orthodontic treatment.

On November 5, 2011, the Food and Drug Administration ("FDA") granted 510(k) clearance for AcceleDent as "an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps

facilitate minor anterior tooth movement." A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective as a legally marketed device (a "predicate device") that is not subject to premarket approval. 510(k) clearance is required for Class II devices, but Class I devices are 510(k) exempt. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss is classified as a Class I device. Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. Dental implants and braces are examples of Class II devices.

In 2012, OrthoAccel launched its Class II AcceleDent device in the United States to be used in conjunction with orthodontic treatment. In 2013, OrthoAccel launched the AcceleDent Aura ("Aura"), the second generation of AcceleDent, which initially was cleared to be used with braces only. On July 8, 2016, the Aura was cleared for use with clear aligners. Orthodontic patients wear a series of these removable aligners, marketed under names such as Invisalign and ClearCorrect, to gradually straighten their teeth.

Defendant Propel Orthodontics, LLC ("Propel") is also a medical device company that manufactures dental appliances. In January 2016, Propel began marketing a vibratory Class I device designed to help seat clear aligners. In March 2016, Propel released the VPro5, which operates at 120 Hz and requires five minutes of daily use to properly seat (i.e., fit better on the teeth) clear aligners. The VPro5 costs significantly less than the OrthoAccel Aura.

Propel primarily markets the VPro5 through its sales force in a consultative setting. Propel sales representatives promote the VPro5 by telling orthodontists that the device offers several clinical benefits ("5 Clinical Benefits"). These 5 Clinical Benefits include: (1) more efficient aligner seating, (2) relieves orthodontic pain, (3) accelerates tooth movement, (4) fast

tracks retention, and (5) stimulates bone growth and remodeling. Propel's sales force markets the VPro5 as a quicker, cheaper alternative to the AcceleDent device.

On July 19, 2016, OrthoAccel filed its Motion for Preliminary Injunction and Permanent Injunction (Dkt. #57), seeking injunctive relief from Propel's alleged false advertising under the Lanham Act. On August 30, 2016, Propel filed its response (Dkt. #73). On September 9, 2016, OrthoAccel filed its reply (Dkts. #95, #96). On September 19, 2016, Propel filed its sur-reply (Dkt. #109). The Court held oral argument at the request of the parties on September 20, 2016. The hearing continued on October 3, 2016, and concluded on October 4, 2016.[1]

LEGAL STANDARD

To obtain a preliminary injunction, it is well established that a movant must show: (1) a substantial likelihood that the movant will ultimately prevail on the merits; (2) a substantial threat that the movant will suffer irreparable injury if the injunction is not granted; (3) that the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) that granting the injunction will not disserve the public interest. *Paulsson Geophysical Servs., Inc. v. Sigmar*, 529 F.3d 303, 309 (5th Cir. 2008); *Speaks v. Kruse*, 445 F.3d 396, 399–400 (5th Cir. 2006); *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985) (citing *Canal Authority of State of Fla. v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974)).

The decision to grant or deny a preliminary injunction is left to the sound discretion of the district court. *Miss. Power & Light*, 760 F.2d at 621. A preliminary injunction is an extraordinary remedy which should only be granted if the movant has clearly carried his burden

[1] On October 14, 2016, OrthoAccel filed a Post-Hearing Brief (Dkt. #126).On October 17, 2016, Propel filed a Motion to Strike the brief (Dkt. #130). On October 21, 2016, OrthoAccel filed its Response in Opposition (Dkt. #141). The Court did not consider the Post-Hearing Brief and will issue a separate order striking the brief.

of persuasion on all four factors. *Id.*; *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (A preliminary injunction is a "drastic remedy" that "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion.") (citation omitted) (emphasis in original); *PCI Trans., Inc. v. Fort Worth & W. RR Co.*, 418 F.3d 535, 546 (5th Cir. 2005) ("[t]he plaintiff has the burden of introducing sufficient evidence to justify the grant of a preliminary injunction."). As a result, "[t]he decision to grant a preliminary injunction is to be treated as the exception rather than the rule." *Miss. Power & Light*, 760 F.2d at 621; *House the Homeless, Inc. v. Widnall*, 94 F.3d 176, 180 (5th Cir. 1996).

ANALYSIS

In a typical preliminary injunction application, the *movant* must clearly meet its burden of persuasion on all four requirements for the Court to grant injunctive relief. *See Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). OrthoAccel, the movant, argues that the burden should shift to Propel under the *Novartis* exception. *See Novartis v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578 (3d Cir. 2002). In *Novartis*, a pharmaceutical company marketed an antacid as "night time strength" without arguing or presenting *any evidence* that the drug was specifically formulated for night time heartburn or that its product actually remedied heartburn at night more effectively than heartburn during the day. *Id.* at 590. The Fifth Circuit noted that it had previously specifically declined to answer "whether *completely unsubstantiated* advertising claims violate the Lanham Act absent proof that consumers are actually misled by this lack of substantiation." *Id.* at 589 (emphasis in original). But the Fifth Circuit decided to answer what it had previously left open and held, "although the plaintiff normally has the burden to demonstrate that the defendant's advertising claim is false, a court may find that a completely

unsubstantiated advertising claim by the defendant is *per se* false without additional evidence from the plaintiff to that effect." *Id.* at 590.

OrthoAccel argues that the Court should apply the *Novartis* exception, but the Fifth Circuit has not adopted the *Novartis* exception. And the *Novartis* exception would not apply regardless because Propel's claims are not *completely unsubstantiated*. *See id.* at 589–90. The Court finds the *Novartis* exception inapplicable because Propel has offered some evidence substantiating its advertising claims. Thus the burden of proof remains with OrthoAccel to show that the advertising is false and misleading.

Substantial Likelihood of Success on the Merits

In order for the Court to grant injunctive relief, OrthoAccel must show a substantial likelihood that it will ultimately prevail on the merits. *See Sigmar*, 529 F.3d at 309. OrthoAccel alleges that Propel engaged in deceptive advertising in violation of the Lanham Act and Texas common law. In the Fifth Circuit, the elements of a false advertising claim under the Lanham Act are: (1) the defendant made a false statement of fact about its product in a commercial advertisement; (2) the statement actually deceived or had a tendency to deceive a substantial segment of its audience; (3) the deception was material or likely to influence the purchasing decision; (4) the defendant caused the false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result. *Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462 (5th Cir. 2001); 15 U.S.C. § 1125. The Court will discuss each element in turn.

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