IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION NO. 4:16-cv-350**
	§	**JURY TRIAL DEMANDED**
PROPEL ORTHODONTICS, LLC, and PROPEL ORTHODONTICS USA, LLC,	§	
	§	
Defendants.	§	

PLAINTIFF'S ORIGINAL COMPLAINT AND APPLICATION FOR PRELIMINARY AND PERMANENT INJUNCTION AND OTHER RELIEF

Plaintiff, OrthoAccel Technologies, Inc., ("*OrthoAccel*" or "*Plaintiff*") files this Complaint complaining of Defendants Propel Orthodontics LLC and Propel Orthodontics USA LLC.

I. NATURE OF THE SUIT

1. This action seeks damages and injunctive relief arising out of Defendants Propel Orthodontics, LLC ("*Propel LLC*") and Propel Orthodontics USA, LLC's ("*Propel USA*") (together "*Propel*" or "*Defendants*") false, deceptive, and misleading advertising and promotion. OrthoAccel designed, created, tested, and produced an accelerated vibratory orthodontic device that speeds orthodontic treatment and decreases patient discomfort during treatment (the "*AcceleDent*"). Through hard work, creative design, and detailed scientific study, OrthoAccel received regulatory clearance to market AcceleDent—an achievement that changed the orthodontics industry. Defendants have now undertaken an organized campaign to penetrate the accelerated orthodontic marketplace with false and misleading promotions for a competing product (the "*VibraPro5*" or "*VPro5*"). Through its marketing program, sales team, YouTube

videos, sponsored study clubs, and the website of related Propel entities, Defendants have disseminated false and materially misleading information to doctors and patients. Defendants' unfair competition and false advertising has harmed OrthoAccel substantially. By this suit OrthoAccel seeks, among other relief, an injunction to prevent further harm.

II. PARTIES

2. Plaintiff OrthoAccel is a domestic corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 6575 West Loop South, Suite 200, Bellaire, Texas, 77401. OrthoAccel, for itself and through its subsidiaries, does business throughout the State of Texas, the United States, and beyond.

3. Defendant Propel LLC is a domestic limited liability company, organized and existing under the laws of in the State of Delaware, with its principal place of business located at 233 S. Highland Avenue, Ossining, New York, 10562. Propel LLC may be served with Summons and Complaint by serving its registered agent at the foregoing address: 17350 State Highway 249, Suite 220, Houston, Texas 77064.

4. Defendant Propel USA is a domestic limited liability company, organized and existing under the laws of the State of Delaware. Upon information and belief its principal place of business is located at 233 S. Highland Avenue, Ossining, New York, 10562. Propel USA may be served with Summons and Complaint by serving its registered agent at the foregoing address: Delaware Corporate Services, Inc. 901 N. Market Street Suite 705, Wilmington, Delaware, 19801.

JURISDICTION AND VENUE

5. This Court has jurisdiction over OrthoAccel's claims pursuant to 28 U.S.C. §§ 1331, 1338, and supplemental jurisdiction over remaining claims under 28 U.S.C. §1367.

6. This Court has *in personam* jurisdiction over this case. OrthoAccel is a medical device company engaged in the creation, manufacturing, marketing, and sales of innovative solutions that enhance dental care and orthodontic treatment with its principal place of business in Houston, Texas. During the relevant timeframe, OrthoAccel maintained its principal place of business at 6575 West Loop South, Suite 200, Bellaire, Texas 77401.

7. Propel transacts business in the District and has engaged in activities that subject Propel to the jurisdiction of this Court. Propel has previously and continues to purposefully avail itself of the privilege of conducting business in the state of Texas by selling and distributing products to residents of the state of Texas. Propel has marketed and distributed its products, including the VPro5, in Texas, to Texas doctors, with false and misleading representations concerning VPro5 and its comparisons to AcceleDent. For example, on May 10, 2016, Propel engaged in business in Dallas, Texas, by presenting a marketing presentation to a group of Texas dentists, orthodontists, and dental staff. Propel also has sales staff based in Texas and is actively marketing its product to Texas dentists, orthodontists, and dental staff. In addition, Propel has marketed directly to customers within this District and has sold product to customers within this District following Propel's false and misleading advertising. For example, upon information and belief, Propel has falsely promoted VPro5 to one or more doctors in Plano, Texas.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants transact business in the District, and the Defendants made their false and misleading representations within the District. Propel has engaged in its false and misleading business activities in Collin County, Texas. For example, upon information and belief Propel has falsely promoted VPro5 to one or more doctors in Plano, Texas.

III. FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

A. OrthoAccel's Innovative Solution

9. OrthoAccel takes innovation seriously. After securing an existing patent in 2007, OrthoAccel worked hard and quickly and by 2008 had developed a prototype hands-free medical device that uses gentle vibrations (SoftPulse Technology®) to accelerate tooth movement when used with an orthodontic treatment ("*AcceleDent*"). AcceleDent is manufactured in the USA under the Quality Control and Good Manufacturing Processes mandated by the FDA.

10. The technology behind AcceleDent involves pulsatile forces to move teeth faster by accelerating the bone remodeling process. Animal studies beginning in the early 2000's revealed the effect of pulsatile forces on bone remodeling and the biological response at a cellular level.[1] These studies serve as the foundation for the AcceleDent technology; however, OrthoAccel has built upon that foundation with clinical studies of AcceleDent on human patients. The results were dramatic: patients using AcceleDent 20 minutes a day significantly accelerated tooth movement by 38 to 50 percent.[2] Further studies also prove that using AcceleDent decreases patients' pain and discomfort during treatment.[3]

11. AcceleDent has two main functional components: (1) a "Mouthpiece" and (2) an "Activator." The Activator is a small extaoral component that generates a vibrational force of about 30 Hz. The Activator connects directly to the Mouthpiece; while the patient lightly bites

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[1] Kopher et al. "Suture Growth Modulated by the Oscillatory Component of Micromechanical Strain." JOURNAL OF BONE AND MINERAL RESEARCH" 18.3 (2003): 521-28, incorporated herein by reference for all purposes as Exhibit A; Nishimura et al. "Periodontal Tissue Activation by Vibration: Intermittent Stimulation by Resonance Vibration Accelerates Experimental Tooth Movement in Rats." AM J ORTHOD DENTOFACIAL ORTHOP 2008;133:572-83 incorporated herein by reference for all purposes as Exhibit B.

[2] Pavlin et al. "Cyclic loading (vibration) accelerates tooth movement in orthodontic patients: A double-blind, randomized controlled trial." SEMINARS IN ORTHODONTICS, Volume 21, Issue 3, 187 – 194 , incorporated herein by reference for all purposes as Exhibit C, and available at http://www.semortho.com/article/S1073-8746(15)00036-5/pdf.

[3] Lobre, et. al., "Pain Control in Orthodontics Using a Micropulse Vibration Device: A Randomized Clinical Trial" ANGLE ORTHOD. Oct. 23, 2015, incorporated herein by reference for all purposes as Exhibit D and available at http://www.angle.org/doi/pdf/10.2319/072115-492.1

down, vibration transmits through the Mouthpiece and ultimately through the teeth. The design is simple and can be used by patients at home.

12. Supported by clinical, peer-reviewed, double-blind studies that show that AcceleDent is safe and effective, OrthoAccel submitted AcceleDent to rigorous 510(k) review to obtain clearance from the Food and Drug Administration ("*FDA*") to market and sell AcceleDent as a class-two medical device. On November 15, 2011, the 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."[4] In addition to FDA clearance, OrthoAccel has also received regulatory clearance to market AcceleDent in the United Kingdom, the European Union, Korea, Mexico, China, Canada, Singapore, and Australia. Achieving regulatory clearance, and specifically FDA clearance, was a crucial step. Since FDA clearance is essential to any US customer's decision to purchase. OrthoAccel's vision, innovation, hard work, and commitment to supporting AcceleDent with data and clinical studies paved the way, and in 2012, OrthoAccel began marketing AcceleDent in the United States. In line with industry practice, OrthoAccel largely promotes and advertises AcceleDent through direct sales contact between sales representatives and doctors.

13. OrthoAccel continues to support research and studies with scientists and research professionals across the US. In 2013, OrthoAccel launched AcceleDent Aura ("*Aura*"),[5] the second generation of AcceleDent. Although AcceleDent and vibratory therapy is still new to the

[4] *See* Public Health Service Announcement attesting to FDA 510(k) clearance on AcceleDent, incorporated herein by reference for all purposes as Exhibit E.

[5] AcceleDent Aura is a modified version of the predicate FDA-cleared AcceleDent. The fundamental scientific technology of delivering therapeutic vibrations to teeth and the intended use have not changed with the subject AcceleDent Aura device. *See* April 11, 2013 FDA Summary of Special 510(k), incorporated herein by reference for all purposes as Exhibit F. This pleading uses "AcceleDent" throughout to describe both products.

world of dentistry and orthodontics, AcceleDent's safety has been proven time and again. Since launching AcceleDent in 2012 and selling more than 60,000 units worldwide, not a single adverse event has been reported. And, the results of clinical studies—published in a well-respected peer-reviewed publication—show that using AcceleDent in conjunction with orthodontic appliances does not cause any additional root resorption in excess of the standard orthodontic appliance usage.[6] This safety data, reviewed and accepted by the FDA as a part of its 510(k) application process, addresses a major concern in the orthodontic field. Orthodontic treatment, in some cases, may cause the roots of the teeth to shrink. However, OrthoAccel has clinically proven that vibrational force of 0.25 N at 30 Hz applied for 20 minutes a day does not put patients at a higher risk of root resorption. Because of OrthoAccel's innovation, production, and testing of AcceleDent, doctors can offer an improved quality of orthodontic treatment and can now safely accelerate tooth movement while decreasing patient discomfort.

14. Market reports show that vibratory therapy used with orthodontic treatment is the future of orthodontic care.[7] Patients, understandably, want to safely speed uncomfortable orthodontic treatment and decrease their pain during treatment. AcceleDent is the first and only FDA-cleared vibratory medical device designed to facilitate tooth movement with braces. AcceleDent is also the only vibratory device clinically proven to reduce patient pain during treatment.

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[6] *See* Exhibit C, supra note 2; Kau, et. al., "A Radiographic Analysis of Tooth Morphology Following the Use of a Novel Cyclical Force Device in Orthodontics" HEAD & FACE MEDICINE 2011; 7:14, incorporated herein by reference for all purposes as Exhibit G, and available at http://head-face-med.biomedcentral.com/articles/10.1186/1746-160X-7-14.

[7] *See* Steve Beuchaw "Align Technology Inc, Underappreciated Growth Drivers" May 13, 2016, incorporated herein by reference for all purposes as Exhibit H. *See also,* Robert G. Keim, "The Editor's Corner: Accelerating Tooth Movement" JOURNAL OF CLINICAL ORTHODONTICS, XLVII, April 2014, at 213-214, incorporated herein by reference for all purposes as Exhibit I; *See also*, Robert G. Keim, et. al, "2014 JCO Study of Orthodontic Diagnosis and Treatment Procedures: Part 1, Results and Trends" JOURNAL OF CLINICAL ORTHODONTICS, XLVIII: 10, October 2014, at 607-630, incorporated herein by reference for all purposes as Exhibit J.

15. OrthoAccel committed the necessary time, resources, and creativity to produce, test, and gain regulatory clearance for AcceleDent. As a result, patients can achieve their orthodontic goals faster and with less discomfort than offered by previous methods. Consumers of AcceleDent, both doctors and patients, can rely on OrthoAccel to provide a safe and effective, FDA-cleared device.

B. Propel's Launch of VPro5

16. Upon information and belief, Propel is a company started by Dr. Richard Johnson that produces medical devices designed to facilitate accelerated orthodontics. Propel purports to be an "innovator and manufacturer of orthodontic medical devices."

17. Upon information and belief, in January 2016, Propel began marketing the VPro5 device to doctors within the United States and launched sales in March 2016.

18. The VPro5 is very similar in design to AcceleDent and includes an Activator, which Defendants call an "Oscillator," and a mouthpiece. Like AcceleDent, patients are instructed to gently bite the mouthpiece while activating the Oscillator's vibrational force. Defendants claim that the VPro5 delivers 120 Hz[8] vibration and that all clinical benefits can be achieved with use for only five minutes each day.[9]

19. Defendants are currently advertising and promoting the VPro5 primarily and largely through their sales force, which has been assigned to various regions across the country. Defendant's sales team has been emailing and meeting directly with doctors across the country promoting the VPro5. Through its sales force, Defendants have engaged in an active, organized campaign to penetrate the orthodontic marketplace with promotion of the VPro5.

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[8] *See* http://www.youtube.com/watch?v=zE4NPVujcdw. A screenshot of the relevant youtube.com page, as well as a transcript of the Propel video, incorporated herein by reference for all purposes as Exhibit K.
[9] Propel Marketing Brochure, incorporated herein by reference for all purposes as Exhibit L.

20. Upon information and belief, Defendants' sales force directs doctors to the Facebook page for both the Defendants and Propel Ortho Singapore PTE LTD ("*POS*"). POS's Facebook page is easily accessible from the United States.

21. Defendants also promoted the VPro5 at the Association of American Orthodontists ("*AAO*") trade show in Florida in April and May 2016, where they presented the VPro5 to interested doctors in a separate location inaccessible to the public. Defendants also hosted a study club on May 10, 2016, in Dallas, Texas, where they presented the VPro5 to a group of Texas orthodontists, dentists, and staff.

22. Upon information and belief, Defendants hold conference calls with their entire sales force to discuss Defendants' organized campaign to penetrate the marketplace. Upon information and belief, Defendants' sales team is instructed during such calls to promote the VPro5 with false or misleading statements. As a result, the false and misleading promotion of the VPro5 is widespread and has been disseminated to large portions of the relevant purchasing pool of dentists and orthodontists.

C. Propel's False and Misleading Promotion of VPro5

a. Propel's False Claims that VPro5 is FDA Registered or Cleared

23. Upon information and belief, since January 2016, Defendants have mobilized their sales force to falsely and deceptively promote VPro5. Upon information and belief, Defendants' sales team has told doctors that the VPro5 is an FDA-registered or an FDA-cleared medical device. However, according to all available information, including the publically available FDA Device Registration and Device Listing, the VPro5 is niether registered nor cleared.[10]

[10] *See* FDA Establishment Registration & Device Listing for Propel Orthodontics LLC, , incorporated herein by reference for all purposes as Exhibit M, and available at http://www.accessdata.fda.gov/scripts/cdrh/

24. The regulatory clearance of a medical device is a material fact likely to influence the decision of any doctor or patient. Upon information and belief, Defendants' sales representatives did much more than fail to disclose that the VPro5 was not registered or cleared; the Propel sales representatives made affirmative representations that the VPro5 is registered and cleared with the FDA,a nd that the FDA has approved the product for sale in the United States.

25. Upon information and belief, Defendants have held nationwide sales calls to discuss the lack of registration for the VPro5 and have actively instructed their sales force to promote the product as "registered" despite the evident lack of any FDA registration or clearance. Upon information and belief, Defendants are disseminating promotional information that is both false and material though interstate commerce to large amounts of the relevant purchasing population.

26. Defendants' false promotion of the VPro5 as an FDA-registered or cleared device has deceived the marketplace, consuming the time and effort of OrthoAccel's sales team forced to respond to Defendants' false promotion and diminishing the value of OrthoAccel's innovative and FDA-cleared device. FDA authorization is essential to consumers' decisions when purchasing a medical device, and Defendants' promotion of the VPro5 as properly authorized is false and deceptive. Vibrational orthodontic therapy is a new category of medical device. Defendants' false promotion of an unregistered and untested device as an FDA registered or cleared device threatens the credibility and reputation of not only AcceleDent but also vibrational therapy as a method of accelerating orthodontics.

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cfdocs/cfRL/rl.cfm; FDA Establishment Registration & Device Listing for Propel Orthodontics USA LLC, , incorporated herein by reference for all purposes as Exhibit N, and available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm.

b. Propel's False and Misleading Claims Regarding the Benefits of VPro5

27. Through organized direct contact by the sales team and the POS Facebook page, Defendants promote several specific benefits of the VPro5 and claim that the promoted benefits are available for half or a third of the cost of AcceleDent. However, none of these purported benefits is supported by *any* reliable scientific evidence and are, therefore, *per se* false. Defendants' sales representatives point to these unsubstantiated benefits to draw direct comparisons between VPro5 and AcceleDent, thus misleading consumers.

Propel's False Promotion that VPro5 Accelerates Tooth Movement

28. Through their sales team and POS Facebook page, Defendants claim that VPro5 accelerates tooth movement. However, these claims are unsubstantiated by any scientific or other clinical data. OrthoAccel has several studies published in respected medical journals supporting its claims that AcceleDent accelerates tooth movement.[11] By comparison, Defendants have literally no support for their advertisement and promotion of VPro5 for accelerated tooth movement. Upon information and belief, no published studies exist concerning VPro5's claims of accelerated tooth movement.

29. Whether VPro5 is effective for accelerated tooth movement is a material factor for the doctors to whom the device is marketed. However, Defendants' claim is *per se* false, as they lack support for such a claim. Defendants' false promotion of the VPro5 as an effective tool to accelerate tooth movement has deceived the marketplace and harmed OrthoAccel. Doctors and consumers purchasing an accelerated vibratory orthodontic device expect that such a device accelerates tooth movement. Defendants' unsubstantiated claim of effectiveness is false, and

[11] *See* OrthoAccel's website listing and linking clinical resources, available at http://acceledent.com/orthodontists/clinical-resources/

without some proof such a statement can threaten the credibility and reputation of not only AcceleDent but also vibrational therapy as a method of accelerating orthodontics.

Propel's False Promotion that VPro5 Simulates Bone Growth and Tooth Remodeling

30. Through their sales team and the POS Facebook page, Defendants also claim that the VPro5 stimulates bone growth and tooth remodeling. As with its claims concerning VPro5's capability for accelerated tooth movement, Defendants have no evidence that their device can offer patients bone growth and tooth remodeling. OrthoAccel has no evidence that Defendants have been able to achieve a measureable result for bone growth and tooth remodeling.

31. Defendants' lack of substantiation for its promotion of VPro5 as a tool for stimulating bone growth and remodeling makes the claim *per se* false. Further, such a claim is material deception likely to influence the doctors to whom Propel's sales team is marketing. Defendants' promotion is deceptive to the doctors and consumers who rely on Propel's marketing. Defendants' claims have harmed OrthoAccel by attributing an unsubstantiated benefit to VPro5 that has not been proven as a benefit from AcceleDent. Further, when these false claims are made along with a price comparison to AcceleDent, doctors are misled about the proven nature of vibratory therapy in devices such as AcceleDent.

Propel's False Promotion that VPro5 Fast Tracks Retention

32. Another false claim made by Defendants though their sales team and POS Facebook page is that VPro5 is effective to fast-track treatment retention. In other words, Defendants claim that use of VPro5 during orthodontic treatment will help keep the teeth in place once treatment is complete. Once again, Defendants have absolutely no support for such a claim. No studies exist substantiating Defendants' claims that VPro5 has any effect on treatment retention, and upon information and belief, no tests have been conducted.

33. Like speeding treatment time, the ability to aid in tooth retention and prevent the need for additional treatment later in life is a benefit that many patients want. Thus, such a claim is a material deception for doctors who are interested in purchasing the best tools for their patients. Defendants' promotion of such a benefit, with absolutely no proof that any such benefit exists, is *per se* false. Defendants' claims have deceived consumers and harmed OrthoAccel by falsely attributing a benefit to VPro5 that has not been proven as a benefit from accelerated vibratory orthodontic devices. Further, when these false claims are made along with a price comparison to AcceleDent, doctors are misled about the proven nature of vibratory therapy in devices such as AcceleDent, thus threatening the credibility of AcceleDent and vibrational therapy as a methodology.

Propel's False Promotion that VPro5 Relieves Orthodontic Pain

34. Through their sales team and POS Facebook page, Defendants advertise relief of orthodontic pain as one of the benefits of VPro5. Not only do Defendants lack any support for their claim that VPro5 is effective to relieve pain, but Defendants' sales team also supports its false claim with a peer-reviewed pain study of the AcceleDent device. In other words, Propel has taken the study that confirms AcceleDent is effective for decreasing patient pain during treatment and attributes its results to VPro5 to compete with AcceleDent, despite lacking support that VPro5 would have the same result.

35. Claiming, without any support, that the VPro5 can decrease patient pain during orthodontic treatment is a material deception likely to influence doctors when selecting a vibratory device to use and recommend to patients. Defendants' false promotion has harmed OrthoAccel by falsely attributing a benefit to VPro5 that has not been proven; thus, creating a false comparison. Defendants' unsubstantiated claim of effectiveness is false and without some

proof of such a claim, threatens the credibility and reputation of not only AcceleDent but also vibrational therapy as a methodology. Further, when these false claims are made along with a price comparison to AcceleDent, doctors are misled into believing that both products have the same clinically proven benefits—particularly here when the same study is falsely claimed to support both products' claims. Defendants' false promotion, therefore, deceives customers in the marketplace and threatens the credibility of AcceleDent and vibrational therapy generally.

c. Propel's Misleading Use of Existing Literature to Promote VPro5

36. Upon information and belief, Propel's sales force has promoted VPro5 with scientific articles and tests that, when examined, do not actually support Propel's claims or are fundamentally flawed and unreliable.

Propel's Misleading Comparison that VPro5's Frequency is More Effective

37. Upon information and belief, Defendants claim that the vibrational frequency of the VPro5, a purported 120 Hz,[12] is more effective for accelerated tooth movement than the 30 Hz of vibrational frequency used by AcceleDent. Further, Defendants claim that due to the higher frequency, five minutes a day is enough time to gain all of VPro's purported benefits.[13] As a result, upon information and belief, Defendants' sales force is promoting VPro5 as "a third of the cost and a third of the time" when compared with AcceleDent.

38. Upon information and belief, Defendants support these claims with two sources. The first is the result of an unpublished test wherein a test subject uses a mouthpiece made up of half AcceleDent running at 30 Hz and half VPro5 running at the purported 120 Hz. According to Defendants, the test showed 41% more tooth movement on the side with VPro5 than AcceleDent. However, the results of any such test are unreliable, because the test is

[12] *See* Ex. K, supra, note 8.
[13] *See* Ex. L, supra, note 9.

fundamentally flawed. Clinical studies on AcceleDent and vibrational therapy have shown that when applied to a patient's teeth, vibrational force is transmitted along the dental arch.[14] Thus, the vibrational force from one side of the patient's mouth is transmitted through the structure of the mouth to the teeth on the other side of the mouth. While each device may have been physically placed on only half of the patient's mouth, the vibration of each device and its effects cannot be isolated. Defendants' reliance on the purported test is therefore unreasonable and its promotion of the VPro5 as a superior product due to the higher frequency is misleading.

39. The second source is an article by Dr. Amit Lala ("*Lala Article*") summarizing some prior research on vibration therapy.[15] The Lala Article summarized research conducted in animal models without the VPro5. Nothing in the article provides a comparative analysis of any accelerated vibratory orthodontic device; much less any reliable comparative analysis showing that a higher frequency is more effective when applied with an orthodontic device. The research cited is not, actually, specific to orthodontic tooth movement, but addresses bone growth generally. In fact, the author concludes it can only be "hypothesized that a vibration device operating in the high frequency range would likely be most effective."[16]

40. The effectiveness of AcceleDent and VPro5's frequency is material to a doctor's decision concerning which product to purchase. AcceleDent has published, peer-reviewed, clinical data supporting its claims that 30 Hz vibrational frequency accelerates tooth movement. Defendants' promotion that the VPro5 is more effective device due to a higher frequency is unsupported by reliable scientific evidence and is therefore misleading.

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[14] D. Liu, et. al., "Transmission of Mechanical Vibration from AcceleDent to Dentition and Skull" incorporated herein by reference for all purposes as Exhibit O.
[15] Lala, et. al., "Vibration therapy in orthodontics: Realizing the benefits." ORTHO INTERNATIONAL, No. 1, 2016, incorporated herein by reference for all purposes as Exhibit P, and available at http://www.dentalnext.ch/articoli-scientifici/.
[16] *Id.*

41. Further, by comparing the vibration force of the VPro5 against that of AcceleDent and claiming that a higher frequency is more effective, Defendants necessarily imply that the products are otherwise comparable, which is also misleading. Upon information and belief, Defendants have no data or clinical study that demonstrates the safety of 120 Hz for five minutes a day. To OrthoAccel's knowledge, no reputable studies exist showing that application of such a strong frequency has no negative effect on root resorption.

42. Defendants' misleading comparison of VPro5 as more effective due to its higher frequency has deceived consumers and harmed OrthoAccel. Defendants' misleading advertising and promotion of VPro5 as better and faster than AcceleDent deceives customers and necessarily diminishes AcceleDent's value.

IV. CAUSES OF ACTION

A. COUNT ONE – VIOLATION OF FEDERAL LANHAM ACT

43. Plaintiff re-alleges and incorporates by reference those facts set forth above.

44. Propel undertook an organized national campaign to advertise and promote direct comparisons between AcceleDent and VPro5. Propel's representations that the VPro5 is FDA registered and cleared; accelerates tooth movement; stimulates bone growth and tooth remodeling; fast tracks retention; and relieves pain are all either false or so completely unsubstantiated they are *per se* false. Further, Propel's reliance on fundamentally flawed studies and deceptive use of unsupportive studies is misleading.

45. Statements concerning the regulatory status of VPro5 and its benefits are material to consumers' purchasing decisions. Propel is making these false statements in its commercial advertising and promotion. The VPro5 is sold in interstate commerce.

46. Further, Propel's misleading promotion and comparisons between VPro5 and AcceleDent are necessarily diminishing AcceleDent's value. OrthoAccel has suffered damages

as a result of Defendants' promotions including, but not limited to, loss of sales due to consumer confusion; dilution of the value of OrthoAccel's brand and the methodology of vibrational therapy; and loss of OrthoAccel's goodwill and reputation.

47. Accordingly, Defendants have violated the Lanham Act, 15 U.S.C. §1114.

B. COUNT TWO – UNFAIR COMPETITION IN VIOLATION OF TEXAS COMMON LAW

48. Plaintiff re-alleges and incorporates by reference those facts set forth above.

49. Defendants' conduct is contrary to honest practice in industrial and commercial matters. Defendants are engaging in false comparative advertising, including making conclusory statements unsupported by reliable tests. Defendants' conduct in violation of the Lanham Act also constitutes a violation of Texas common law.

50. OrthoAccel has suffered damages as a result of Defendants' promotions including, but not limited to, loss of sales due to consumer confusion, dilution of the value of the brand, and loss of OrthoAccel's goodwill and reputation.

V. CONDITIONS PRECEDENT

51. All conditions precedent to OrthoAccel's recovery have occurred or have been performed.

VI. APPLICATION FOR INJUNCTIVE RELIEF

52. Plaintiff re-alleges and incorporates by reference those facts set forth above.

53. The actions of Propel threaten OrthoAccel with irreparable injury for which there is no adequate remedy at law.

54. OrthoAccel seeks preliminary injunction and then a permanent injunction, that Defendants and all persons acting on their behalf, in concert with them or under their control,

including but not limited to Richard Johnson, Bryce Way, Peter Migneault, Jerry Zilles, Kelly Blythe, and Judy Birdaunick, be enjoined from engaging in the following activities:

- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5 is FDA registered or FDA cleared;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5 accelerates tooth movement;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5 stimulates bone growth and tooth remodeling;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5 fast tracks, or otherwise aids retention;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5 relieves pain or discomfort;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial manner that VPro5's higher frequency works better than AcceleDent's lower frequency;
- Representing, orally or in writing, expressly or by implication, in any advertising, promotion, offering for sale, sale of goods and services, or in any commercial

manner that VPro5 is effective to accelerate tooth movement, stimulate bone growth and tooth remodeling, aids retention or relieves pain in less time than AcceleDent.

55. Equity favors the relief that OrthoAccel seeks here. OrthoAccel, its current clients, the entities and doctors that have purchased products from OrthoAccel, and the entities that wish to purchase products with OrthoAccel will be harmed if the relief sought hereunder is denied and Defendants are permitted to continue confusing the market and falsely promoting the VPro5. For all the reasons described above, it is probable that OrthoAccel will succeed in proving that Defendants engaged in false and misleading commercial advertising and promotion of VPro5 throughout the country. Defendants made false statements concerning the regulatory clearance and status of VPro5—a factor that is essential for any doctor considering the purchase of medical device. Defendants have also promoted several purported benefits of VPro5 without any support for their claims and made direct comparisons to AcceleDent's efficacy in reliance on flawed and unsupportive studies, which has the capacity to deceive a substantial segment of the potential customers.

56. If a preliminary injunction is not granted immediately, OrthoAccel will suffer immediate and irreparable injury, loss, and crippling damage to its reputation from which it is unlikely to recover. Namely, consumers will attribute the untested, unproven, and unsubstantiated claims made by Defendants to AcceleDent and vibrational therapy in general. Such a result will irreparably damage not only the reputation of OrthoAccel but also the doctors and other professionals that advocate for vibrational therapy. Additionally, OrthoAccel's customers will be harmed by purchasing products with the mistaken impression that Defendants' false promotion is true. Additionally, Defendants will gain an unfair advantage in competition by

falsely and deceptively attributing benefits to the VPro5 that are false or unproven by reliable scientific means. Due to the reality that this is a cottage industry and this burgeoning technology is fueled by OrthoAccel's innovation, these injuries are shaping the future of OrthoAccel's marketplace share and reputation. This harm far outweighs any harm which Defendants may suffer by their continued false and misleading commercial promotion.

VII. JURY DEMAND

57. Plaintiff hereby demands a jury trial.

VIII. REQUEST FOR RELIEF

Plaintiff respectfully requests:

A. OrthoAccel requests damages in an amount to be determined at trial as a result of Propel's unfair competition and false advertising and promotion, including but not limited to:

i. disgorgement of Defendant's profits;

ii. OrthoAccel's lost profits and price erosion;

iii. OrthoAccel's costs spent responding to Defendant's deceptive advertising;

iv. the present value of future harm caused by lingering impact of Defendant's advertising; and

v. damage to OrthoAccel's goodwill and reputation.

B. OrthoAccel requests attorneys' fees and costs as supported by the evidence and the causes of action pled herein.

C. OrthoAccel requests exemplary damages, special damages, and costs of court.

D. OrthoAccel further requests a preliminary injunction and then a permanent injunction be issued enjoining Defendants, and all persons acting on their behalf, in concert with them or under their control, from the conduct listed above in paragraph 54; and

E. Any such other and further relief, in law or in equity, to which OrthoAccel may have shown itself to justly entitled.

Respectfully submitted,

GARDERE WYNNE SEWELL LLP

By: */s/ James G. Munisteri*

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JURY TRIAL DEMANDED

IN THE UNITED STATES DISTRICT COURT
FOR THE Eastern DISTRICT OF TEXAS
SHERMAN DIVISION

ORTHOACCEL TECHNOLOGIES, INC.	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION NO.** 4:16-CV-350
	§	**JURY TRIAL DEMANDED**
PROPEL ORTHODONTICS, LLC, and PROPEL ORTHODONTICS USA, LLC,	§	
	§	
Defendants.	§	

VERIFICATION

STATE OF TEXAS §
§
COUNTY OF HARRIS §

Before me the undersigned notary public on this day personally appeared Kathleen Malaspina, who, after being duly sworn stated under oath that she is the Chief Innovation Officer of OrthoAccel Technologies, Inc., that she has read the factual allegations in the foregoing Plaintiff's Original Complaint and Application for Temporary and Permanent Injunctions, and Other Relief, and verifies that the factual allegations are within her personal knowledge and/or based upon information provided to her in the performance of her duties, and are true and correct, except for allegations that are specifically made on information and belief.

Kathleen Malaspina

SUBSCRIBED AND SWORN TO BEFORE ME this 23rd day of May, 2016.

MALINDA SCHEIRMAN
My Commission Expires
August 14, 2018

Notary Public in and for the State of Texas