UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Propel Orthodontics, LLC

Petitioner

v.

OrthoAccel Technologies, Inc.

Patent Owner

Patent No. 9,662,184
Filing Date: June 20, 2016
Issue Date: May 30, 2017

Title: VIBRATING DENTAL DEVICES

Case No. IPR2018-00296

PETITION FOR *INTER PARTES* REVIEW

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Petitioner, Propel Orthodontics, LLC, requests *inter partes* review of claims 1-27 of U.S. Patent No. 9,662,184 ("the '184 patent") (EX-1001), currently assigned to OrthoAccel Technologies, Inc. This Petition, supported by the Expert Declaration of Dr. Sumit Yadav (EX-1002), establishes that (i) U.S. Patent Application Publication No. 2008/0227046 to Lowe el al. ("*Lowe*") (EX-1003) is prior art to the '184 patent, and (ii) the challenged claims are unpatentable under 35 U.S.C. §§ 102 and/or 103.

I. INTRODUCTION

Lowe is prior art to the '184 patent because OrthoAccel amended all the claims during prosecution of the '184 patent to cover a treatment duration range of 1 to 20 minutes, but the earliest disclosure supporting this duration range was not added until more than a year after *Lowe* published. *Infra* at II(A)(1-5). Thus, *Lowe* is OrthoAccel's own intervening prior art.

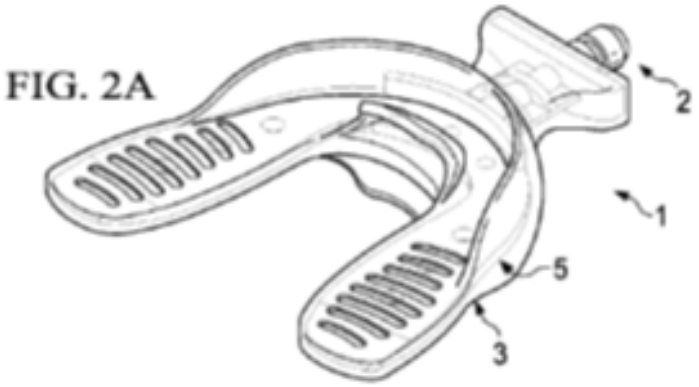
For the reasons discussed below, the Board should institute *inter partes* review of the '184 patent and cancel claims 1-27.

II. U.S. PATENT 9,662,184

A. Overview of the '184 Patent

The '184 patent is entitled "Vibrating Dental Device." EX-1001. The patent purports to disclose: "A faster method of orthodontic remodeling for a patient wearing a vibrating orthodontic remodeling device for about 20 minutes a day to

accelerated tooth movement is described." *Id.*, Abstract. An extraoral vibrator (not shown) is said to connect to the bite plate shown below:



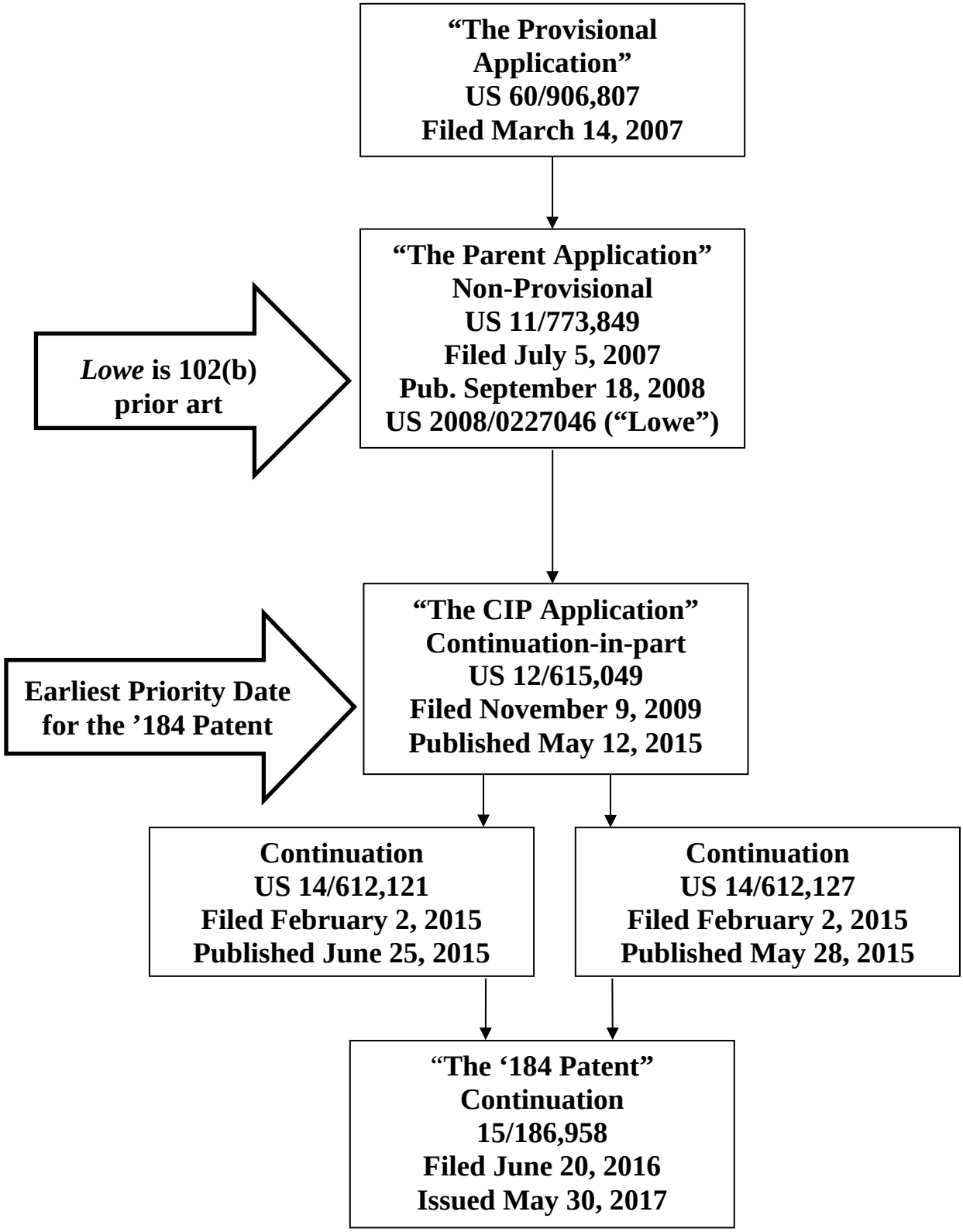
Id., 3:14-17; 8:41-42.

The patent describes various embodiments of the bite plate and an "improved extraoral vibrator." *Id.*, 9:49. The improved vibrator has decreased sound and a frequency of 20-40 Hz. *Id.*, 9:51-55. The treatment duration is "for a period of 1-60 minutes, preferably about 1-30 or 1-10 minutes or 20 minutes." *Id.*, 7:37-38. "In some embodiments, the appliance can be used to speed boney remodeling in orthodontic uses with traditional orthodontic fixed appliances or aligner based treatments or any other appliance used for tooth movement." *Id.*, 7:16-21.

1. Priority Claim

The '184 patent was filed as U.S. Patent Application No. 15/186,958 on June 20, 2016 claiming priority to a series of applications beginning with U.S.

Provisional Application No. 60/906,807 ("the Provisional Application") (EX-1004) filed on March 14, 2007. EX-1001, (63) Related U.S. Application Data. But the earliest disclosure of the limitation "activating said orthodontic remodeling device for 1 to 20 minutes daily" recited in each of the independent claims—claims 1, 10, and 19—was on November 9, 2009. EX-1005, ¶ [0039]. Accordingly, November 9, 2009 is the earliest possible priority date the claims of the '184 patent are entitled. The chart below shows the family chain of applications leading to the '184 patent.


"The Provisional Application"
US 60/906,807
Filed March 14, 2007
"The Parent Application"
Non-Provisional
US 11/773,849
Filed July 5, 2007
Pub. September 18, 2008
US 2008/0227046 ("Lowe")
Lowe is 102(b) prior art
"The CIP Application"
Continuation-in-part
US 12/615,049
Filed November 9, 2009
Published May 12, 2015
Earliest Priority Date for the '184 Patent
Continuation
US 14/612,121
Filed February 2, 2015
Published June 25, 2015
Continuation
US 14/612,127
Filed February 2, 2015
Published May 28, 2015
"The '184 Patent"
Continuation
15/186,958
Filed June 20, 2016
Issued May 30, 2017

The Provisional Application bears little resemblance to the '184 patent. It lacks any of the figures in the '184 patent. And, it also lacks the claimed treatment range of 1 to 20 minutes—only disclosing that "[t]he proposed invention would be worn for approximately twenty minutes daily, but could be worn for longer or shorter periods of time both more or less frequently." EX-1004, 7:25-8:1.

On July 5, 2007, OrthoAccel filed non-provisional U.S. Application No. 11/773,849 ("the Parent Application") (EX-1006) claiming priority to the Provisional Application. Similar to the Provisional Application, the Parent Application also lacks the claimed treatment range of 1 to 20 minutes—only disclosing that "[t]he system can be worn for a predetermined period such as **approximately twenty minutes** daily or any other suitable duration of time, thus the patient can wear the device at home for a modest wear duration." *Id*., 7:6-8 (emphasis added). Thus, the claimed treatment range of 1 to 20 minutes is not disclosed in either of the Priority Applications (i.e., the Parent Application and the Provisional Application).

The Parent Application published on **September 18, 2008** as U.S. Patent Application Publication No. 2008/0227046 to Lowe et al. ("*Lowe*"). EX-1003. More than a year later, on **November 9, 2009**, OrthoAccel filed a continuation-in-part application: U.S. Application No. 12/615,049 ("the CIP Application") (EX-

1005). The CIP Application added the following new matter to the disclosure of the Parent Application:

> Thus, the invention also includes a method for movement of one or more teeth by applying differential vibration to selected areas of a bite plate at frequencies between 1 to 1000 Hz (preferably 10-100 Hz and most preferred 20-40 Hz) and a force of 0.01-2 Newtons (or 0.1-0.5 or 0.2 Newtons) for a period of 1-60 minutes, preferably about 1-30 or 1-10 minutes or 20 minutes.

EX-1005, ¶ [0039]. This is the first disclosure of duration ranges beginning with one minute, as recited in the independent claims of the ’184 patent.

Accordingly, the earliest possible priority date for the independent claims of the ’184 patent is November 9, 2009—the filing date of the CIP Application—because there is no disclosure supporting the claimed duration of 1 to 20 minutes prior to that date. Consequently, *Lowe* (the publication of the Parent Application) is prior art to the ’184 patent’s claims because it published nearly 14 months earlier on September 18, 2008. Pre-AIA 35 U.S.C. § 102(b).

2. The ’184 Patent’s Prosecution History of “1 to 20 minutes”

The originally filed claims recited a duration of use of “about 20 minutes daily.” EX-1007, pp. 93-96. OrthoAccel tried to broaden this limitation to “up to 20 minutes daily” during prosecution in order for the claims to read on Propel’s VPro5 device, which has a duration of use of 5 minutes. *Id*., pp. 135-138.

Ultimately, the claims were amended to change "up to twenty" to "1 to 20" just prior to allowance by an Examiner's amendment following an interview with Applicant.[1] *Id.*, p. 235. The '184 patent is OrthoAccel's first patent in the family that claims a duration other than about 20 minutes.[2]

3. Priority Determination

The Examiner did not make a priority determination on the record during examination of the '184 patent, thus there is no finding for the Board to defer to with respect to priority. For example, in *Power Oasis, Inc. v. T-Mobile USA, Inc.*,

[1] The Examiner's amendment does not specify the reason for the change from "up to twenty" to "1 to 20." EX-1007, p. 235. But in a related application, the same Examiner's amendment was made "in order to avoid 112 new matter issues." EX-1015, p. 6. More recently, in another related application the same examiner rejected an attempt to amend the claims with the "up to 20 minutes daily" limitation, stating that "[n]one of the parent applications provide support for 'up to 20 minutes daily,'" EX-1016, p. 3.

[2] Claim 12 of U.S. 9,668,828; claim 1 of U.S. 8,939,762; claim 1 of U.S. 9,370,405; claim 1 of U.S. 9,370,406; and claim 1 of U.S. 9,700,384, each claims priority to the same Provisional Application as the '184 patent, and all claim a duration of use of 20 minutes.

522 F.3d 1299, 1305 (Fed. Cir. 2008), the Court explained that "absen[t] an interference or rejection which would require the PTO to make a determination of priority, the PTO does not make such findings as a matter of course in prosecution. The PTO's own procedures indicate that examiners do not make priority determinations except where necessary." The Court further explained that "when neither the PTO nor the Board has previously considered priority, there is simply no reason to presume that claims in a CIP application are entitled to the effective filing date of an earlier filed application." *Id*.

After Propel asserted that *Lowe* was prior art to the '184 patent in the related litigation, OrthoAccel has attempted to convince the Examiner that the priority claim to *Lowe* is effective in related application 14/612,081 for the claim limitation of "1 to 20 minutes," after the Examiner previously determined it was not.[3] OrthoAccel conducted an examiner interview on November 17, 2017, during which possible amendments were discussed to have priority date back to Lowe.

[3] On November 2, 2017, (EX-1016) the Examiner in that application stated that "[n]one of the parent applications provide support for 'up to 20 minutes daily,'" EX-1016, p. 3. And the Examiner also stated "the specification appears to only provide for a minimum of 1 minute in paragraph 47." EX-1016, p. 4. Paragraph 47, was added after *Lowe* published. See *Supra* II(A)(1).

EX-1019, p. 2. OrthoAccel conducted another interview on December 6, 2017. EX-1021, p. 5. The evening before the interview—at 5:45 PM—OrthoAccel filed an Information Disclosure Statement (EX-1020) submitting twelve hundred pages of materials from the related litigation that had existed for more than a month. During the interview OrthoAccel apparently discussed the declaration of Dr. Brunski (EX-1022), OrthoAccel's expert in the related litigation. EX-1021, p. 5. Now, it appears the Examiner is taking the position that the claim limitation of "1 to 20 minutes daily" is supported by *Lowe*. EX-1021, p. 5. Given that this discussion was done via examiner interview, there is little to no record of the Examiner's reasoning for apparently reversing his position for the Board to consider.

The Examiner's new position is contrary to the case law, *infra* II(A)(4)(a-d), and the Examiner's reliance on Dr. Brunski's declaration is improper because Dr. Brunski's reasoning is flawed, *infra* II(A)(4)(c-d), and Dr. Brunski in his own declaration admits he does not meet the qualifications of a person of ordinary skill in the art. EX-1022, ¶ 6; *see also* EX-1009 (hearing transcript), p. 5:19-20; p. 6:9-17 ("[H]is credentials exceed that of a person of ordinary skill in the art."). It is illogical that Dr. Brunski's credentials exceed that of a person of ordinary skill in the art when his credentials do not include those necessary to qualify him as a person of ordinary skill in the art (i.e., an orthodontist).

4. The claims of the ’184 patent cannot claim priority before November 9, 2009 because there is no support for the claim limitation “1 to 20 minutes daily” prior to that date.

“It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application as required by 35 U.S.C. § 112.” *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995). The test for whether a claim limitation is supported by an earlier application is whether “one skilled in the art, reading the original specification, would **immediately discern** the limitation at issue.” *Waldemar Link v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed. Cir. 1994) (emphasis added). Even if the limitation is obvious in light of what is disclosed, that disclosure is insufficient for priority purposes. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (“The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification” because a “description which renders obvious the invention for which an earlier filing date is sought is not sufficient.”).

The relevant disclosure regarding duration of use in the Parent Application states that “[t]he system can be worn for a predetermined period such as **approximately twenty minutes daily** or **any other suitable duration of time**.” EX-1006, 7:6-8 (emphasis added). The Provisional Application similarly states “[t]he proposed invention would be worn for **approximately twenty minutes**

daily, but **could be worn for longer or shorter periods of time**." EX-1004, 7:25-8:1 (emphasis added). Nothing in the Provisional Application or the Parent Application supports a duration of "1 to 20 minutes."

a. "approximately" or "about" 20 minutes

"About 20 minutes" does not support a range of "1 to 20 minutes." As explained by Dr. Yadav (and common sense), one skilled in the art would not interpret "about 20 minutes" to include anything but slight variations from 20 minutes, at most a range from 19-21 minutes. EX-1002, ¶ 37. The case law also shows that the disclosure of a specific duration does not support a later claim to a broader range.

For example, in *In re Lukach*, 442 F.2d 967, 968-69 (C.C.P.A 1971) the Court found that a claim recitation of "a Mw/Mn ratio of at least 2.0 and less than 3.0" was not supported by an earlier priority application with a single example disclosing a copolymer having a Mw/Mn ratio of 2.6. The Court explained that

> [t]his single example does not alone provide support for the recited range from 2.0 to 3.0, and nothing has been brought to our attention to show that any other language in the [priority application], taken with the knowledge of persons skilled in the art, points to the recited range. Accordingly, the [earlier priority application] does not, either expressly or inherently, disclose the invention now

> claimed, and appellant is not entitled to the benefit of the [earlier priority application] filing date.

Id., 969; *see also In re Blaser*, 556 F.2d 534, 538 (C.C.P.A 1977) ("up to 1.6 mols" did not provide support for claim to "0.6 to 1.6").

Similar to *Lucack* and *Blaser*, disclosure of about or approximately 20 minutes in the Priority Applications does not support the claimed range of 1 to 20 minutes daily.

b. One of ordinary skill in the art would not immediately discern a range of 1 to 20 minutes from a disclosure of "any other suitable duration," or "for longer or shorter periods."

Catch-all phrases in the Priority Applications such as "any suitable duration" and "for longer or shorter periods" also do not provide support for the later-claimed "1 to 20 minutes" range. As noted by the United States Court of Appeals for the Federal Circuit, such phrases have the opposite effect, in that they do not provide support for *any* specific duration:

> [O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.

Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326-27 (Fed. Cir. 2000). As Dr. Yadav explains, one having ordinary skill in the art would understand that such

phrases simply reaffirm that the only workable duration the inventor possessed was "about 20 minutes." EX-1002, ¶¶ 38-40.

In the related litigation, OrthoAccel cited *Endo Pharmaceuticals Inc. v. Amneal Pharamceuticals, LLC*, 12 Civ. 8115 (TPG), 2015 WL 9459823 (S.D.N.Y. Aug. 18, 2015), which found sufficient written description support in a non-analogous situation. *Id*., *54. In *Endo Pharmaceuticals*, the specification disclosed three different examples of tablet dissolution rates, the slowest being 27.8% per hour and the fastest being 32.3% while claiming a broader range of 15%-50%. *Id*. The Court explained "[a] person of ordinary skill in the art, upon reading the dissolution ranges, would understand that the inventors had chosen ranges encompassing the invention, and also allowing for variation." *Id*. But here, *OrthoAccel* did not give several examples of specific durations or disclose ranges, but instead the only actual duration disclosed was about 20 minutes. And surely a 95% decrease of the disclosed duration of about 20 minutes down to 1 minute is beyond the "allowed variation" the Court had in mind.

In cases with similar facts, the courts have found the written description to be insufficient. For example, in *Small v. Nobel Biocare USA, LLC*, No. 05-cv-3225-NRB, 06-cv-683-NRB, 2013 WL 3972459, *13-14 (S.D.N.Y. 2013), the Court found that a claim recitation that included "the recess and 'part way down' slot depth limitations" unsupported by an earlier priority application, which

described slots of "various depths." The patentee argued "she can claim slots which extend 'part way down' as a limitation to her invention because a person of ordinary skill in the art would understand her description of slots of 'various depths' to include any specific slot depth within the range of all possible depths." *Id.*, *13. The Court rejected that argument because it "relies on the logical fallacy that to disclaim nothing is to claim everything. Patent law requires far more to support a claim of adequate written description." *Id*.

Even specific broader ranges do not support later claimed subset ranges within the broader range. *See Nelson v. K2 Inc*., No. C07-1660 RSL, 2008 WL 4603409, *2-3 (W.D. Wash. 2008) (A claimed ski length of 148-173 cm was not supported by disclosure of a length of 135-180 cm, a claimed ski length to a ski shovel width of 110-120 mm was not supported by disclosure of a shovel width of 105-140 mm, and a claimed ski tail width of 105-115 mm was not supported by disclosure of a ski tail width of 100-130 mm.).

Accordingly, the Priority Applications do not provide sufficient support for the claimed "1 to 20 minutes" limitation of independent claims 1, 10, and 19, making OrthoAccel's own publication—*Lowe*—prior art to all the claims 1-27.

c. In the related litigation, OrthoAccel relies on an expert's unsupported assumptions found nowhere in the priority applications.

In the related litigation, OrthoAccel submitted a declaration (EX-1022) from an alleged expert—not one skilled in the art—to show there was support when the Provisional Application and the Parent Application are combined for the "1 to 20 minute" limitation. OrthoAccel argued that the lower "1 minute" end of the range was supported because the priority applications disclosed a frequency range of 0.1 to 400 Hz. One skilled in the art would know, according to OrthoAccel, that using a frequency of 400 Hz would necessarily mean using a duration of one minute, thereby supporting the lower end of the range. EX-1008, pp. 12-15.

The Priority Applications nowhere support this conclusion. Nowhere do the Priority Applications state that frequency and time are inversely proportional (as they must be to support OrthoAccel's theory); nowhere do the Priority Applications suggest varying the duration and frequency from a starting point of 20 minutes and 20 Hz (a necessary predicate to arriving at 1 minute and 400 Hz given the assumption that frequency and time are inversely proportional); and finally, nowhere do the Priority Applications suggest that a treatment regimen of 1 minute at 400 Hz would be suitable for accomplishing the stated goal of accelerated bone remodeling (OrthoAccel admitted the opposite is true in Court:

"we're not saying – that a product that operates at 400 hertz for 2 minutes is a good product or a desirable product or even a functional product." EX-1009, 3:9-11).

Contrary to OrthoAccel's theory, the Parent Application disclosure of the range of 0.1 to 400 Hz is for a single duration of about twenty minutes and thus would suggest to a person skilled in the art that there is not an inverse relationship between frequency and time—the exact opposite of what OrthoAccel is assuming. One skilled in the art would expect that if there was an inverse relationship between frequency and time then a time range would have been disclosed in conjunction with the frequency range—0.1 to 400 Hz—rather than a specific duration—20 minutes. EX-1002, ¶ 43.

Dr. Yadav confirms that there is no scientific support for the notion that duration and frequency are inversely proportional in the context of treating humans, and that one having ordinary skill in the art would not have considered a 1 minute 400 Hz combination based on the Priority Applications, or the state of the art generally. EX-1002, ¶¶ 44-45. Commercial vibration devices to accelerate tooth movement did not exist in 2007, and orthodontists would not have any expectations as to how they worked. EX-1002, ¶ 46. OrthoAccel claims to be first to market but did not enter the market until years after 2007. EX-1010, p. 2. Even today, OrthoAccel's assumptions have no support—its commercial product

continues to use a 20 minute at 30 Hz treatment (EX-1011, pp. 2-3), and no commercial products come close to using parameters of 1 minute or 400 Hz.

d. The case law does not support OrthoAccel's reliance on unsupported assumptions

OrthoAccel tried supporting their assumptions by citing case law, but the case law does not cure their flawed and contradictory reasoning. For example, OrthoAccel cited *Vanda Pharms. Inc. v. Roxane Labs, Inc.*, 203 F.Supp.3d 412, 430-31 (D. Del. 2017), highlighting the Court found a "dosage range supported even though specification only disclosed indirect relationship/trends between dosage and metabolic biomarkers." EX-1008, p. 14. However, the facts in *Vanda Pharms* are not analogous to this case. *In Vanda Pharms.*, the defendants argued there was a lack of statistical significance in the data and the court found the data in the numerous tables in the specification was sufficient to support possession of the claimed dosage, even if not statistically significant. *Id*., 430-31. OrthoAccel's Priority Applications do not include any data that supports possession of the claimed duration range.

OrthoAccel also cited *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997-99 (Fed. Cir. 2000), highlighting that the Court affirmed "adequacy of written description where specification indicated that one could increase or decrease two or more of the properties of components listed while claims claimed specific combinations noting both that disclosure and testimony from one of

ordinary skill that the specification taught them values from which they practice the invention." EX-1008, p. 14. Again, the facts in *Union Oil Co. of Cal.* are not analogous to this case. In *Union Oil Co. of Cal.* the appellant argued the specification was inadequate because it did not describe the exact chemical component of each combination that falls within the range claims of the patent, which the court highlighted was not the standard. Furthermore, the Federal Circuit found that the specification, including the background and abstract, "discuss thoroughly the claimed ranges and the combinations of multiple properties." *Id.*, 998. The Federal Circuit further highlighted that the adequate specification "teaches the effects of varying the properties" and the specification also "guides the skilled artisan in combining the above properties." *Id.*, 997-98. OrthoAccel's Priority Applications did not disclose duration ranges, did not teach the effects of varying the duration and/or frequency, and did not provide guidance to the skilled artisan on how to vary and combine frequency and duration.

Furthermore, even if all of OrthoAccel's assumptions and reasoning were correct and reasonable—which they are not for the reasons explained above—this manufactured support would still not be sufficient. Establishing that the Priority Applications "potentially" disclose a limitation is not sufficient—the limitation must be "immediately discerned" from the documents. *Waldemar Link v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed. Cir. 1994). And "proof of priority requires

written description disclosure in the parent application, not simply information and inferences drawn from uncited references." *Los Angeles Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly and Co.*, 849 F.3d 1049, 1058 (Fed. Cir. 2017). In *Los Angeles Biomedical*, the priority claim was based on a calculation and "several assumptions regarding the knowledge of a person of skill in the art." *Id*. The priority claim failed because the assumptions "were not knowable from the disclosure in the application, but would at best require persons of skill to look to the prior art and make assumptions. That is not enough to establish priority." *Id*. Because OrthoAccel's priority claim finds no support in the Priority Applications themselves, it fails as a matter of law.

5. Claims 9, 17, 18, 26, and 27 of the '184 patent cannot claim priority before November 9, 2009, because there is no support for the claim limitation "accelerated tooth movement is about 0.5 mm per week" prior to that date.

The earliest disclosure of "accelerated tooth movement of about 0.5 mm per week" is in the CIP Application. This disclosure is found in paragraph [0071] of the CIP Application, which recites:

> The study also measured distances between teeth using a digital caliper. The overall distance in millimeters between the front five teeth, both upper and lower, was calculated during the alignment phase. The gap between teeth due to extractions was measured directly. The overall movement rate during the study was 0.526 mm

per week, which is higher than average movement without the device.

EX-1005, ¶ [0071]. Neither the Provisional Application nor the Parent Application includes this disclosure or any other disclosure sufficient under 35 U.S.C. § 112 to support a claim of accelerated tooth movement of about 0.5 mm per week. Therefore, the earliest priority date claims 9, 17, 18, 26, and 27 are entitled is November 9, 2009.

6. Independent claims 1, 10, and 19

The ’184 patent contains three independent claims, claims 1, 10, and 19. Claim 10 is broader in scope as shown in the table below comparing these three claims. This is because claim 10 removes the requirement of the “bite plate having upper and lower vertical rims on a facial edge thereof to contact both arches of teeth” recited in claim 1 and also removes the requirement of a processor that “captures and communicates device usage data including duration of use and frequency of use” as recited in claim 19. The reference numerals in brackets preceding the claim elements have been added in the chart below.

[1.0] 1. A faster method of orthodontic remodeling, comprising:	**[10.0] 10**. A faster method of orthodontic remodeling, comprising:	**[19.0] 19**. A faster method of orthodontic remodeling, comprising:
[1.1] a) a patient wearing an orthodontic appliance	**[10.1]** a) a patient wearing an orthodontic appliance	**[19.1]** a) a patient wearing an orthodontic

biting an orthodontic remodeling device, said orthodontic remodeling device comprising:	biting an orthodontic remodeling device, said orthodontic remodeling device comprising:	appliance biting an orthodontic remodeling device, said orthodontic remodeling device comprising:
[1.1.1] i) an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator;	**[10.1.1]** i) an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator; and	**[19.1.1]** i) an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator **and captures and communicates device usage data including duration of use and frequency of use**; and
[1.1.2] ii) said extraoral housing operably connected to an intraoral U-shaped bite plate;	**[10.1.2]** ii) said extraoral housing operably connected to an intraoral U-shaped bite plate;	**[19.1.2]** ii) said extraoral housing operably connected to an intraoral U-shaped bite plate;
[1.1.3] iii) said bite plate having upper and lower vertical rims on a facial edge thereof to contact both arches of teeth;		

and		
[1.1.4] iv) wherein during use said orthodontic remodeling device is held in place only by teeth clamping on the bite plate and said orthodontic remodeling device vibrates at a frequency from 0.1 to 400 Hz; and	**[10.1.3]** iii) wherein during use said orthodontic remodeling device is held in place only by teeth clamping on the bite plate and said orthodontic remodeling device vibrates at a frequency from 0.1 to 400 Hz; and	**[19.1.3]** iii) wherein during use said orthodontic remodeling device is held in place only by teeth clamping on the bite plate and said orthodontic remodeling device vibrates at a frequency from 0.1 to 400 Hz; and
[1.2] b) activating said orthodontic remodeling device for 1 to 20 minutes daily;	**[10.2]** b) activating said orthodontic remodeling device for 1 to 20 minutes daily;	**[19.2]** b) activating said orthodontic remodeling device for 1 to 20 minutes daily;
[1.3] wherein said method provides accelerated tooth movement as compared to without using said orthodontic remodeling device.	**[10.3]** wherein said method provides accelerated tooth movement as compared to without using said orthodontic remodeling device.	**[19.3]** wherein said method provides accelerated tooth movement as compared to without using said orthodontic remodeling device.

7. Claims depending from claim 10.

Independent claim 10 has seven dependent claims, namely claims 11-18. These dependent claims, respectively, are essentially identical to dependent claims

2-6, 8, and 9, which depend from independent claim 1, and dependent claims 20-27, which depend from independent claim 19, as shown below. Claim 7 is a unique claim that depends from independent claim 1 as shown in the chart and is addressed independently from the other dependent claims.

2. The method of claim 1, wherein said power source is a battery.	11. The method of claim 10, wherein said power source is a battery.	20. The method of claim 19, wherein said power source is a battery.
3. The method of claim 2, wherein said battery is a rechargeable battery.	12. The method of claim 11, wherein said battery is a rechargeable battery.	21. The method of claim 20, wherein said battery is a rechargeable battery.
4. The method of claim 2, wherein said battery is a rechargeable battery that is charged from a USB port.	13. The method of claim 11, wherein said battery is a rechargeable battery that is charged from a USB port.	22. The method of claim 20, wherein said battery is a rechargeable battery that is charged from a USB port.
5. The method of claim 1, wherein said orthodontic appliance comprises braces.	14. The method of claim 10, wherein said orthodontic appliance comprises braces.	23. The method of claim 19, wherein said orthodontic appliance comprises braces.
6. The method of claim 1, wherein said orthodontic appliance comprises an aligner.	15. The method of claim 10, wherein said orthodontic appliance comprises an aligner.	24. The method of claim 19, wherein said orthodontic appliance comprises an aligner.
7. The method of claim 1, said bite plate having		

upper and lower vertical rims on a lingual edge thereof.		
8. The method of claim 1, wherein said orthodontic remodeling device automatically shuts off after 20 minutes.	16. The method of claim 10, wherein said orthodontic remodeling device automatically shuts off after 20 minutes.	25. The method of claim 19, wherein said orthodontic remodeling device automatically shuts off after 20 minutes.
9. The method of claim 1, wherein said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N and said accelerated tooth movement is about 0.5 mm per week.	17. The method of claim 10, wherein said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N and said accelerated tooth movement is about 0.5 mm per week. 18. The method of claim 17, wherein said accelerated tooth movement is about 0.5 mm per week.	27. The method of claim 19, wherein said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N and said accelerated tooth movement is about 0.5 mm per week. 26. The method of claim 19, wherein said accelerated tooth movement is about 0.5 mm per week.

B. Level of Ordinary Skill in the Art

One of ordinary skill in the art at the time of priority for the ’184 patent (i.e., November 2009), the filing date of the CIP Application, would have a formal

orthodontic training and would have several years of experience as a working orthodontist. EX-1002, ¶ 51.

III. CLAIM CONSTRUCTION

The broadest reasonable construction should be applied to all claim terms in the ’184 patent. For the purposes of this Petition, claims should be given their plain and ordinary meaning to one skilled in the art for any claim term not addressed below.

A. “wherein said . . . accelerated tooth movement is about 0.5 mm per week” (claims 9, 17, 18, 26, and 27)

For the purposes of this petition, the limitation “wherein said . . . accelerated tooth movement is about 0.5 mm per week” should not be given any patentable weight because the clause merely states the intended result of the limitations in the claim.[4] *See Texas Instruments Inc. v. U.S. Intern. Trade Com’n*, 988 F.2d 1165, 1172 (Fed. Cir. 1993) (A “clause that merely states the result of the limitations in

[4] The wherein clause (i.e., “wherein said method provides accelerated tooth movement as compared to without using said orthodontic remodeling device”) of independent claims 1, 10, and 19 should also not be given any patentable weight because the clause merely states the intended result of the limitations in the claim. However, Propel has elected to address this clause in independent claims 1, 10, and 19 because *Lowe* clearly discloses this limitation.

the claim adds nothing to the patentability or substance of the claim."); *see also Minton v. National Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (A "clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

The Examiner correctly took the same position during examination. EX-1007, p. 71 ("that accelerated tooth movement is about 0.5mm per week appears to only be a result of the previous limitations"); p. 151 ("Applicant argues that the prior art methods would not produce 0.5 mm/week of tooth movement and to provide proof. The prior art combination has all the same limitations as that of the present claims and therefore would produce the same results. If this is not believed to be the case, then there may be an enablement issue with the claims if a differentiating limitation that is critical or essential to the practice of the invention resulting in this degree of movement is not included.").

IV. THE CLAIMS OF THE '184 PATENT ARE UNPATENTABLE

Claims 1-27 are anticipated under 35 U.S.C. § 102 and/or obvious under § 103. *Lowe* anticipates claims 1-8, 10-16, and 19-26. *Infra* at IV(B). *Lowe* in view of *Ting* renders obvious claims 9, 17, 18, 26, and 27. *Infra* at IV(C). *Lowe* in view of *Mao* renders obvious claims 9, 17, 18, 26 and 27. *Infra* at IV(D).

A. The Prior Art

1. *Effective Filing Date*

All of the claims of the ’184 patent include the “1 to 20 minutes” limitation. Claims 9, 17, 18, 26, and 27 of the ’184 patent also include the “accelerated tooth movement is about 0.5 mm per week” limitation. As explained above, *supra* II(A)(4-5),support for these limitations did not appear in the priority chain until the CIP Application was filed on November 9, 2009. Accordingly, the earliest effective filing date of all of the claims of the ’184 patent is November 9, 2009.

2. *Lowe*

U.S. Patent Application Publication No. 2008/0227046 to Lowe et al. (“*Lowe*”) was filed on July 5, 2007, as the Parent Application, and published on September 18, 2008. EX-1003. *Lowe* is prior art under 35 U.S.C. §§ 102(b) because it published more than a year before the effective filing date of the ’184 patent. *Lowe* is prior art under 35 U.S.C. §§ 102(a) and 102(e) because it was published prior to the effective filing date of the ’184 patent and names a different inventive entity. *Supra* at II(A)(1-5).

3. *Ting*

International PCT Application Publication Number WO 2007/146187 to Ting et al. (“*Ting*”) (EX-1012) published December 21, 2007. *Ting* is prior art under at least 35 U.S.C. § 102(a), (b), and (e). *Ting* was not cited nor addressed by the Examiner during prosecution of the ’184 patent. *Ting* discloses orthodontic

devices for moving teeth towards a predefined pattern and/or position. EX-1012, 2:5-6. *Ting* discloses the use of appliances with transducer material that generates a cyclic force that provides a stimulation that facilitates tooth movement. *Id*., 2:29-3:3. *Ting* discloses the force systems can be designed for multiple teeth (i.e., entire arch or partial arch) stimulation, and can include, for example, mouth guard like devices, retainer like devices, bleaching tray like devices. *Id*., 7:23-25. *Ting* discloses the system is capable of providing a cyclic force having a frequency from about 20 Hz to about 40 Hz. *Id*., 9:22-33. *Ting* discloses the system is capable of providing a cyclic force having a magnitude of about 0.2 Newton. *Id*., 10:3-11. *Ting* discloses the use of a number of appliances "permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm." *Id.*, 13:13-16. *Ting* also discloses "[s]uccessive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days." *Id*., 24:20-24.

4. *Mao*

U.S. Patent No. 7,029,276 B2 to Mao ("*Mao*") (EX-1013) issued April 18, 2006. *Mao* is prior art under at least 35 U.S.C. § 102(a), (b), and (e).

Mao discloses a device and method for treatment of malocclusion utilizing cyclical forces. EX-1013, Abstract. *Mao* discloses "a method for realigning one or more of the teeth of a mammal in need thereof. That method comprises the steps of (a) applying cyclic forces to at least one tooth of the mammal in which tooth realignment is desired with a peak magnitude of about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz, in a direction of the desired realignment for a predetermined period of time. The application is (b) repeated a plurality of times until a predetermined amount of tooth realignment is obtained." *Id*., 3:36-46.

B. Ground 1: *Lowe* Anticipates Claims 1-8, 10-16, and 19-26

The disclosure of *Lowe* anticipates each and every element of claims 1-8, 10-16, and 19-26 of the '184 patent.

1. *Lowe* anticipates claims 1, 10, and 19 of the '184 patent

One of skill in the art would understand that every element of independent claims 1, 10, 19 is anticipated by *Lowe.* Moreover, OrthoAccel conceded in the related litigation that *Lowe* discloses every element of claim 10 and thus invalidates it under 35 U.S.C. § 102 if claim 10 is not entitled to the priority date of at least the earlier Parent Application—which published as *Lowe*. EX-1008, p. 11, n. 5.

a. *Lowe* anticipates elements [1.0], [10.0], and [19.0]: "A faster method of orthodontic remodeling"

Lowe discloses the preamble of claims 1, 10, and 19, "[a] faster method of orthodontic remodeling" because *Lowe* discloses a system and method wherein

> [a]dvantages of the system may include one or more of the following. The system enhances the traditional orthodontic treatment process with the application of non static forces. In accordance with one embodiment of the system, non-static forces are used to accelerate the remodeling of craniofacial bones in conjunction with orthodontic treatment. The system can be used to treat all forms and classifications of dental malocclusion . . . .

EX-1003, ¶ [0016]. *Lowe* further discloses the system and method produces

> bone remodeling and accelerated tooth movement across all types of displacement includes: rotation, translation, intrusion, extrusion, and tipping. This induced accelerated remodeling of bone is relevant for both the alignment and movement of teeth, in any plane, including horizontal and vertical, anterior and posterior, mesial and distal, and facial (buccal and labial) and lingual.

Id., ¶ [0042]. A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses a device and corresponding faster method of orthodontic remodeling.[5] EX-1002, ¶ 62.

b. *Lowe* anticipates elements [1.1], [10.1], and [19.1]: "a patient wearing an orthodontic appliance biting an orthodontic remodeling device"

Lowe discloses elements [1.1], [10.1], and [19.1] because it discloses

> [t]he system or device 10 [(the claimed "orthodontic remodeling device")] has an intraoral bite plate 20 that is inserted into a patient's mouth. The bite plate [20][6] is connected to an extraoral vibration source 30 and interfaces with the dentition 32. The device 10 is clamped down by the patient's jaw 40 on the bite plate [20] to secure the vibration source 30 between the dental

[5] The Federal Circuit has explained that "the dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching that every claim element was disclosed in that single reference." *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368–69 (Fed. Cir. 2003) (internal citation omitted).

[6] *Lowe* sporadically identifies the bite plate in error as element 10, but it is clear from the specification and figures that the bite plate is identified as element 20 and the system or device is identified as element 10.

> arches 42 and to position the system in the patient's mouth.

EX-1003, ¶ [0033]. *Lowe* also discloses that "[t]he system can be used [by the patient] in conjunction with lingual braces, facial braces, or any combination [(the claimed "orthodontic appliance")] across either arch or any quadrant for both," and that"[t]he system is also compatible with clear aligner technology [(another claimed "orthodontic appliance")] treatment plans, including the Invisalign® treatment approach." *Id*., ¶ [0044]. A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses a patient wearing an orthodontic appliance (e.g., braces or clear aligner) while biting an orthodontic remodeling device 10 made up of bite plate 20 attached to extraoral vibration source 30 as recited in elements [1.1], [10.1], and [19.1]. EX-1002, ¶ 63.

c. *Lowe* anticipates elements [1.1.1], [10.1.1], and [19.1.1]: said orthodontic remodeling device comprising: "an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator" and, the additional recitation in element [19.1.1], "captures and communicates device usage data including duration of use and frequency of use"

***i.* "an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator"**

Lowe discloses "an extraoral housing containing a power source operably coupled to an actuator operably coupled to a processor that controls said actuator" because

> FIG. 1 shows . . . an orthodontic treatment system 10. The system or device 10 [(the claimed "orthodontic remodeling device")] has an intraoral bite plate 20 that is inserted into a patient's mouth. The bite plate [20] is connected to an **extraoral** vibration source 30 and interfaces with the dentition 32

, EX-1003, ¶ [0033] (emphasis added), and because

> FIG. 3 shows an exemplary diagram of control electronics used with the system of FIGS. 1-2. The functional electromechanical components include a processor 50 [(the claimed "processor")] that can be a low power microcontroller. The processor 50 stores instructions and data in a memory 52. The processor drives an actuator 54 [(the claimed "actuator")] such as an electrical motor or a piezoelectric device, among others. The system of FIG. 3 receives energy from a battery [(the claimed "power source")] that can be rechargeable."

Id., ¶ [0036]. A person skilled in the art would have reasonably understood or inferred that a processor that drives an actuator to control the actuator. EX-1002, ¶ 64; *see also* EX-1003, ¶ [0036] (describing "control electronics").

Lowe further discloses the specific aspects of the orthodontic remodeling device identified in elements [1.1.1], [10.1.1], and [19.1.1] as shown below in marked up Figs. 1 and 3:

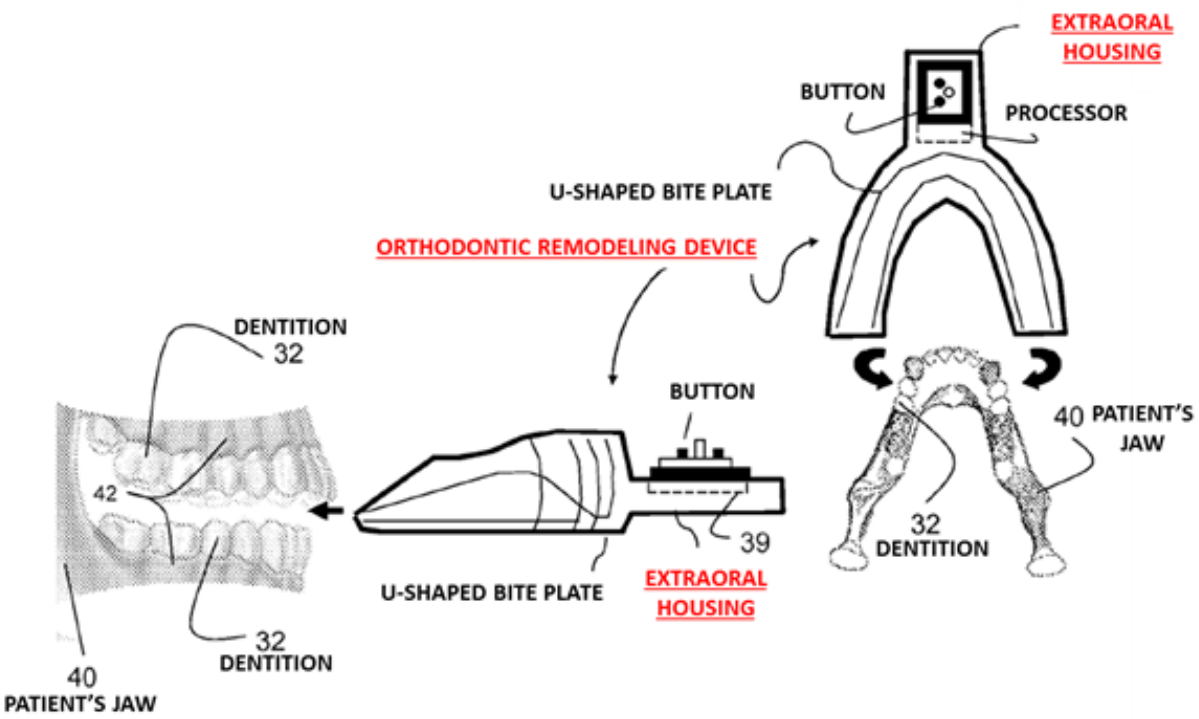


FIG. 1

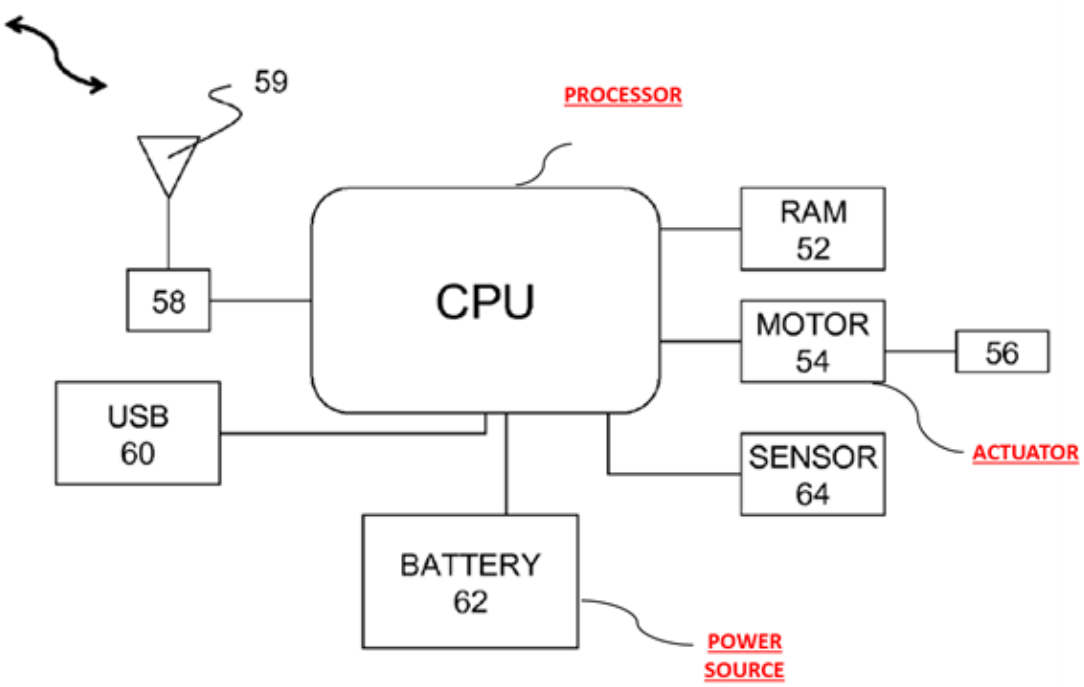


FIG. 3

A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses the orthodontic remodeling device (device 10) comprises an extraoral housing (vibration source 30) containing a power source (battery 62) operably coupled to an actuator (motor 54) operably coupled to a processor (CPU) that controls said actuator. EX-1002, ¶¶ 65-66.

ii. the additional recitation in element [19.1.1], "captures and communicates device usage data including duration of use and frequency of use"

Lowe also discloses that the processor "captures and communicates device usage data including duration of use and frequency of use" because *Lowe* discloses the system and method includes a processor that captures usage frequency and

duration data and communicates it to a remote computer. EX-1003, claims 5, 6, 15, and 16. *Lowe* further discloses "[t]he processor runs software that captures usage frequency [(i.e., the claimed "frequency of use")] and duration [(i.e., the claimed "duration of use")] and can be programmed to change the force, frequency, wave form, amplitude, duration or any other parameter." *Id.*, ¶ [0008]. *Lowe* also discloses "[d]ata capture related to usage frequency and duration updates real time." *Id*., ¶ [0040]. "The processor can [then] communicate usage frequency and duration to a remote computer." *Id.*, ¶ [0008]. A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses a processor (CPU) that captures and communicates device usage data including duration of use and frequency of use. EX-1002, ¶ 67.

d. *Lowe* anticipates elements [1.1.2], [10.1.2], and [19.1.2]: "said extraoral housing operably connected to an intraoral U-shaped bite plate"

Lowe discloses elements [1.1.2], [10.1.2], and [19.1.2] because it discloses "[t]he system or device 10 has an intraoral bite plate 20 that is inserted into a patient's mouth. The bite plate [20] is connected to an extraoral vibration source 30 and interfaces with the dentition 32." EX-1003, ¶ [0033].

Lowe further discloses the specific aspects of the orthodontic remodeling device identified in elements [1.1.2], [10.1.2], and [19.1.2], e.g., that the bite plate is U-shaped, as shown below in annotated Fig. 1:

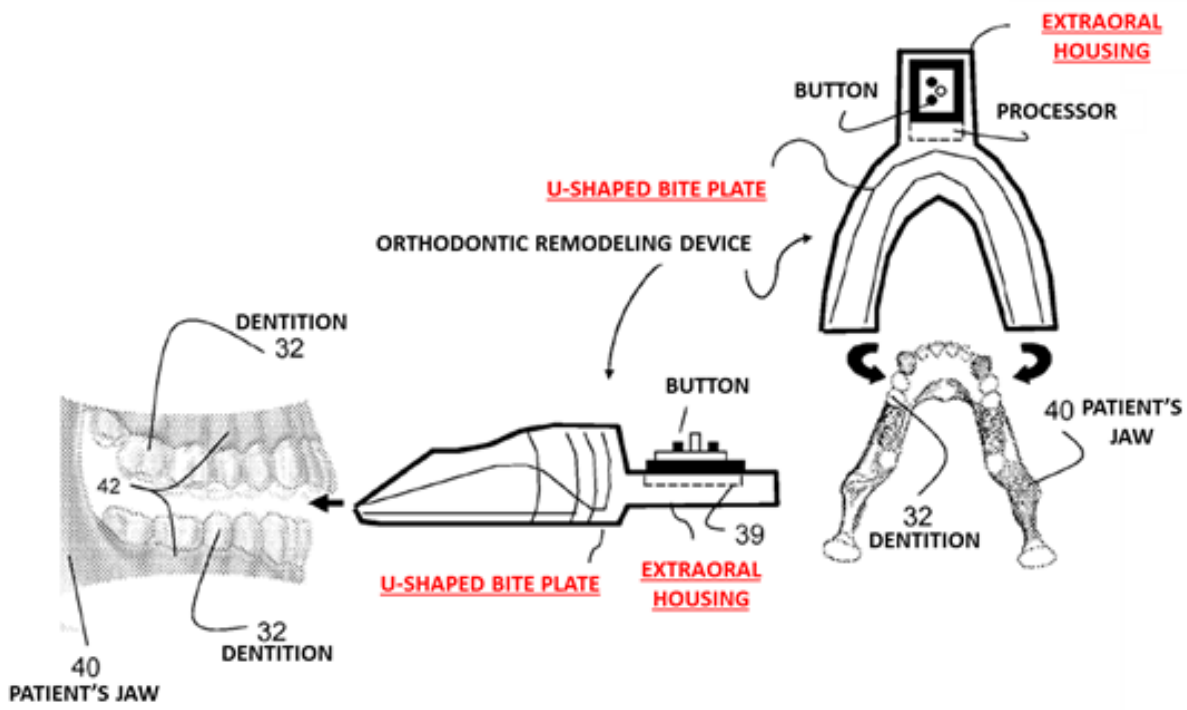


FIG. 1

A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses the extraoral housing (vibration source 30) is operably connected to an intraoral bite plate (bite plate 20). Although *Lowe* does not use the words "U-shaped," a person skilled in the art based on at least FIG. 1 would reasonably understand or infer the shape of bite plate 20 as U-shaped. EX-1002, ¶¶ 68-70.

e. *Lowe* anticipates element [1.1.3]: "said bite plate having upper and lower vertical rims on a facial edge thereof to contact both arches of teeth"

Lowe discloses element [1.1.3] because it discloses the bite plate having upper and lower vertical rims on a facial edge of the bite plate as illustrated below in marked up Figs. 1 and 11:

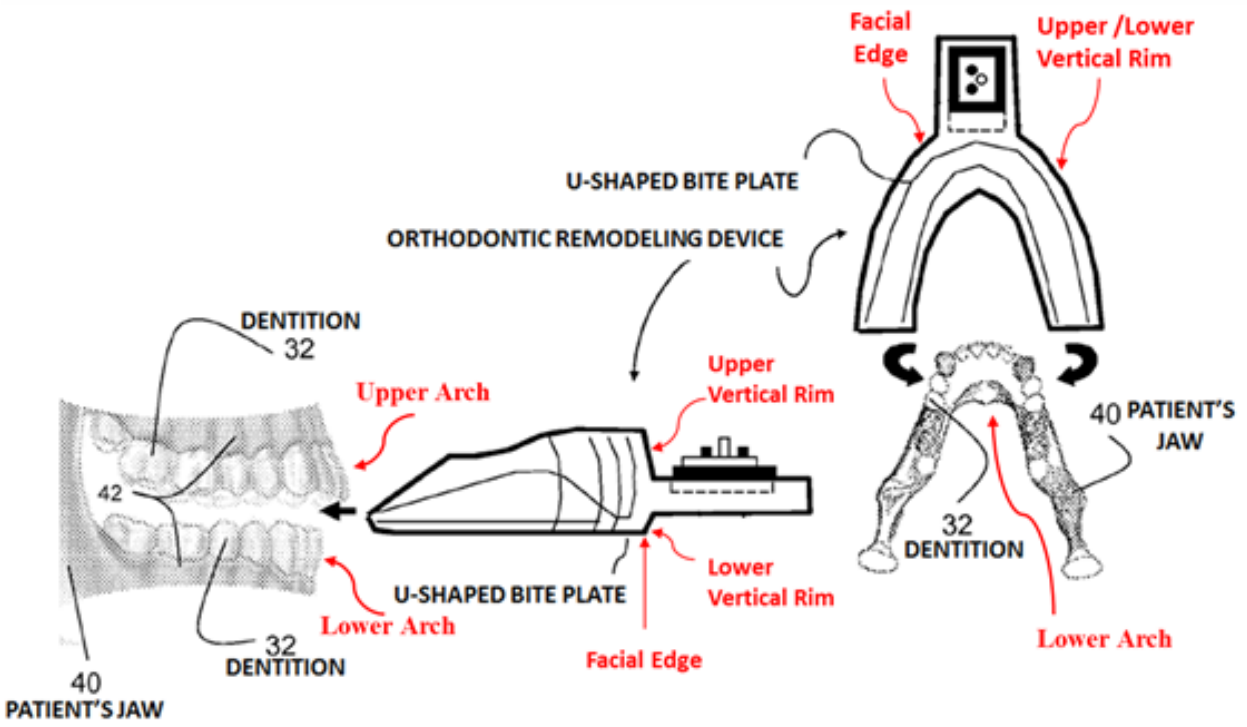


FIG. 1

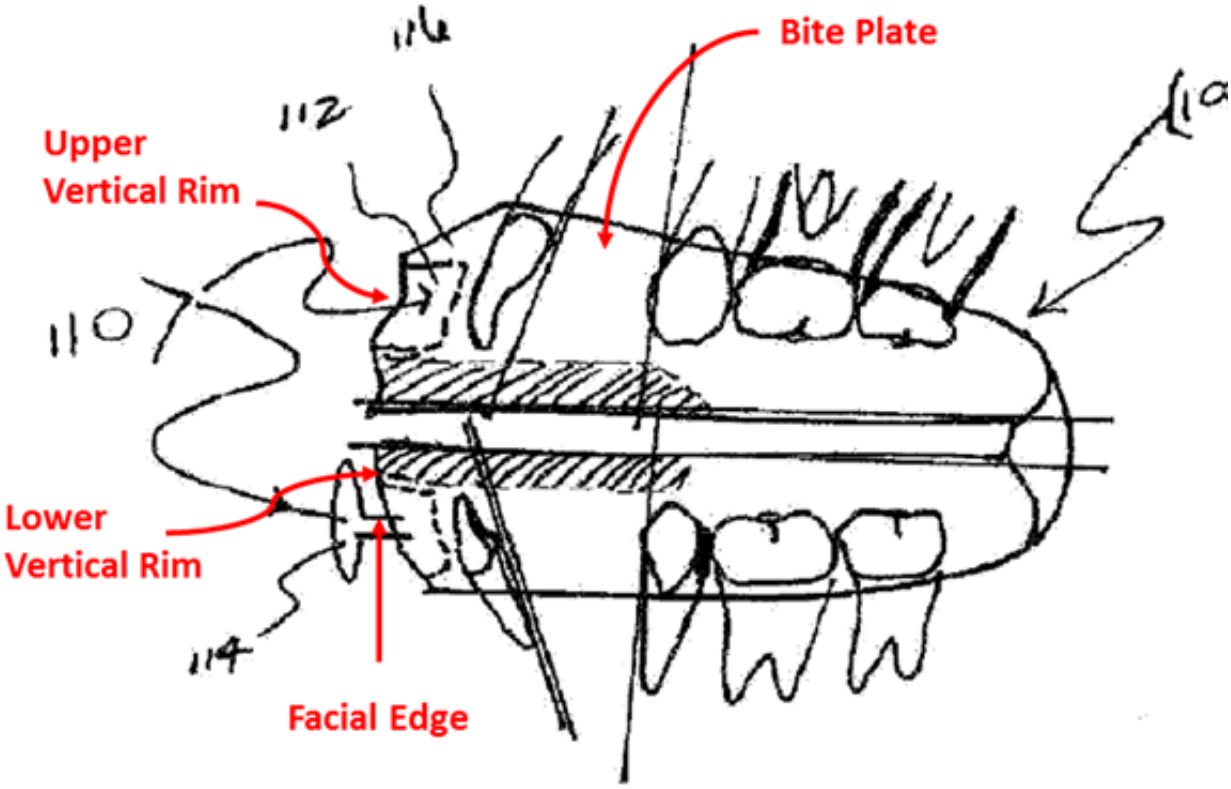


FIG. 11

Lowe also discloses device 10 having a bite plate in Fig. 11 where "the facial flange 116 of the device . . . are spatially in contact with the facial surface surfaces of the maxillary anterior dentition." EX-1003, ¶ [0068]. *Lowe* also discloses "[t]he bite plate can interact with any surface of the dentition, especially occlusal." *Id.*, ¶ [0007]. *Lowe* also discloses "the interface [in the form of a bite plate] can contact the teeth at any point and at one or more points." *Id.*, ¶ [0008]. *Lowe* further discloses

> the [bite] plate or platform, which can be of any shape or thickness, and comprised of any material, sufficient to come into and out of contact with the dentition 32, in part or in whole, vibrates in a manner that delivers the necessary force. The device can have one or more interface points across the dentition, or can interface with the entire dentition in aggregate and in both arches simultaneously.

Id., ¶ [0037].

A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses bite plate 20 of device 10 may have upper and lower vertical rims on a facial edge thereof to contact both arches of teeth as illustrated in Figs. 1 and 11 and described in paragraphs [0007], [0008], [0037], and [0068]. EX-1002, ¶¶ 71-73.

f. *Lowe* anticipates elements [1.1.4], [10.1.3], and [19.1.3]: "wherein during use said orthodontic remodeling device is held in place only by teeth clamping on the bite plate and said orthodontic remodeling device vibrates at a frequency from 0.1 to 400 Hz"

Lowe discloses elements [1.1.4], [10.1.3], and [19.1.3] because it discloses

> [t]he system or device 10 [(the claimed "orthodontic remodeling device")] has an intraoral bite plate 20 that is inserted into a patient's mouth. The bite plate [20] is connected to an extraoral vibration source 30 and

> interfaces with the dentition 32. The device 10 is clamped down by the patient's jaw 40 on the bite plate [20] to secure the vibration source 30 between the dental arches 42 and to position the system in the patient's mouth

EX-1003, ¶ [0033]. A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* disclosing that vibration source 30 is secured by the patient biting on bite plate 20 equates to device 10 being designed to be held in place only by teeth clamping on the bite plate 20. EX-1002, ¶ 74.

Lowe also discloses "[t]he system embodied as the device described here pulsates or vibrates at a frequency of between about 0.1 Hertz to about 400 Hertz." EX-1003, ¶ [0037]. EX-1002, ¶ 75.

g. *Lowe* anticipates elements [1.2], [10.2], and [19.2]: "activating said orthodontic remodeling device for 1 to 20 minutes daily"

Lowe's disclosure anticipates elements [1.2], [10.2], and [19.2] because it discloses device 10's "interface with the dentition 32 can transmit a force of about five Newtons (5N) **for about twenty minutes a day** at a frequency of between 0.1 to 400 Hz as discussed above." EX-1003, ¶ [0039] (emphasis added). About twenty minutes a day is within the range of 1 to 20 minutes daily and "a range is anticipated by a prior art reference if the reference discloses a point within the range." *Ineos USA LLC v. Berry Plastics Corp,* 783 F.3d 865, 869 (Fed. Cir. 2015).

h. *Lowe* anticipates elements [1.3], [10.3], and [19.3]: "wherein said method provides accelerated tooth movement as compared to without using said orthodontic remodeling device"

This limitation merely states the intended result of the process steps set forth in the claim. As such, the limitation should not be given any patentable weight. Regardless, *Lowe* discloses elements [1.3], [10.3], and [19.3] because *Lowe* discloses

> [a]dvantages of the system may include one or more of the following. The system enhances the traditional orthodontic treatment process with the application of non static forces. In accordance with one embodiment of the system, non-static forces are used to **accelerate the remodeling of craniofacial bones** in conjunction with orthodontic treatment. The system can be used to treat all forms and classifications of dental malocclusion . . .

EX-1003, ¶ [0016] (emphasis added). *Lowe* also discloses

> [t]he bone remodeling and **accelerated tooth movement** across all types of displacement includes: rotation, translation, intrusion, extrusion, and tipping. This induced accelerated remodeling of bone is relevant for both the alignment and movement of teeth, in any plane, including horizontal and vertical, anterior and posterior, mesial and distal, and facial (buccal and labial) and lingual.

Id., ¶ [0042] (emphasis added).

A person skilled in the art would reasonably understand or infer from at least this disclosure that the method disclosed by *Lowe* provides accelerated tooth movement as compared to without using said orthodontic remodeling device. EX-1002, ¶¶ 77-78.

2. *Lowe* anticipates claims 2, 11, and 20: "wherein said power source is a battery"; claims 3, 12, and 21: "wherein said battery is a rechargeable battery"; and claims 4, 13, and 22: "wherein said battery is a rechargeable battery that is charged from a USB port"

Lowe discloses claims 2, 3, 4, 11, 12, 13, 20, 21, and 22 because it discloses "[t]he system of FIG. 3 receives energy from a battery 62 [(the claimed power source)] that can be rechargeable." EX-1003, ¶ [0036]. *Lowe* further disclose "[t]he battery 62 can be of any type and can be rechargeable type." *Id. Lowe* also discloses "the rechargeable battery is charged using power from any type of power source including a USB port." *Id.*, ¶ [0008].

Lowe also discloses the power source is a battery and operably connected to a USB port 60 as illustrated in annotated Fig. 3 shown below:

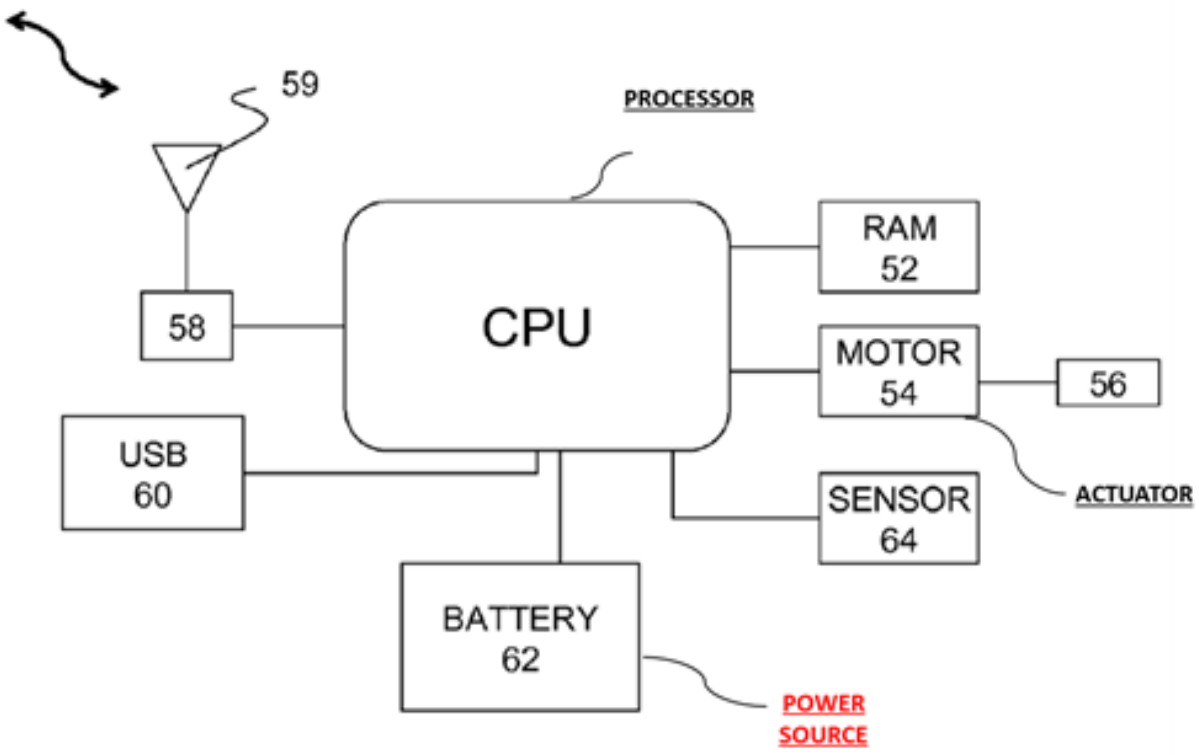


FIG. 3

A person skilled in the art would reasonably understand or infer from at least this disclosure that L*owe* provides a power source that may be a rechargeable battery, which may be charged from a USB port. EX-1002, ¶¶ 79-81.

3. *Lowe* anticipates claims 5, 14, and 23: "wherein said orthodontic appliance comprises braces"

Lowe discloses claims 5, 14, and 23 because it discloses "[t]he system can be used in conjunction with lingual braces, facial braces, or any combination across either arch or any quadrant for both." EX-1003, ¶ [0044]. A person skilled in the art would reasonably understand or infer from at least this disclosure that the

method disclosed by *Lowe* provides an orthodontic appliance that may be braces. EX-1002, ¶ 82.

4. *Lowe* anticipates claims 6, 15, and 24: "wherein said orthodontic appliance comprises an aligner"

Lowe discloses claims 6, 15, and 24 because it discloses "[t]he system is also compatible with clear aligner technology treatment plans, including Invisalign® treatment approach." EX-1003, ¶ [0044]. A person skilled in the art would reasonably understand or infer from at least this disclosure that the method disclosed by *Lowe* provides said orthodontic appliance may be an aligner such as an Invisalign® clear aligner. EX-1002, ¶ 83.

5. *Lowe* anticipates claim 7: "said bite plate having upper and lower vertical rims on a lingual edge thereof"

Lowe discloses claim 7 because it discloses the bite plate having upper and lower vertical rims on a lingual edge of the bite plate as shown below in marked up Figs. 1 and 11:

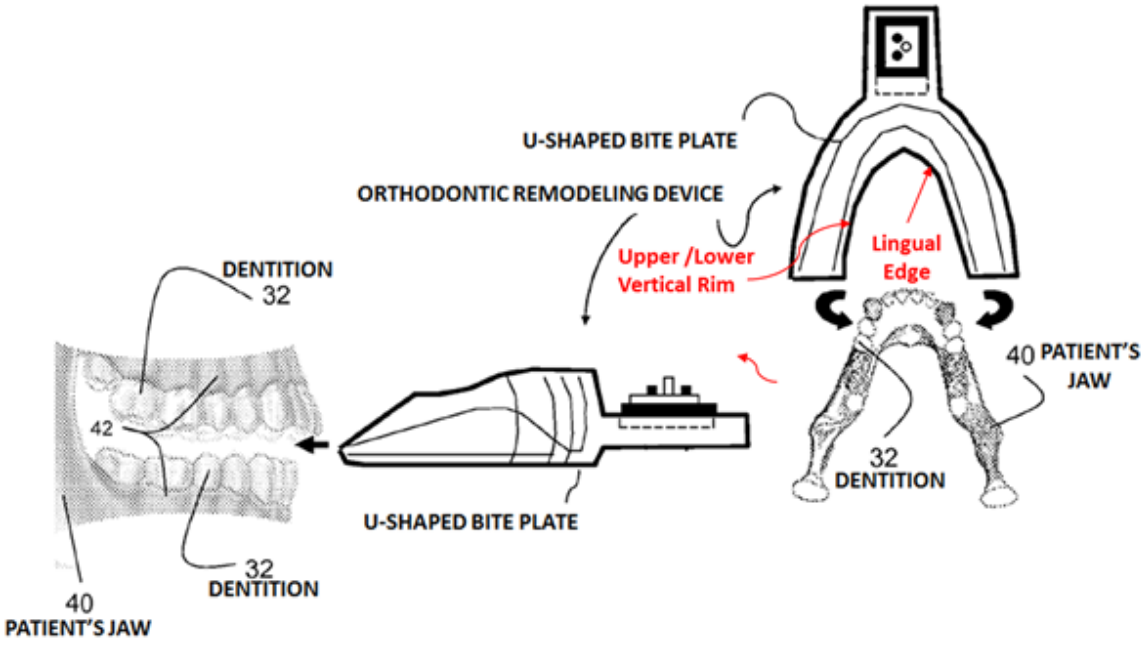
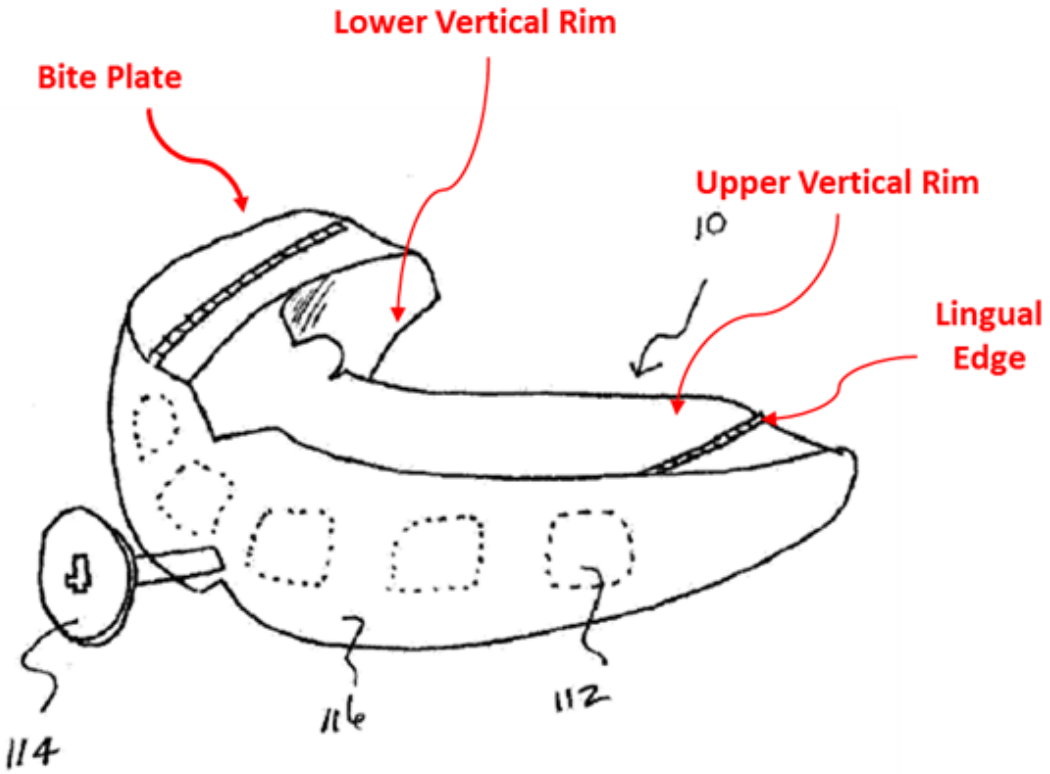

U-SHAPED BITE PLATE
ORTHODONTIC REMODELING DEVICE
Upper /Lower Vertical Rim
Lingual Edge
DENTITION 32
42
40 PATIENT'S JAW
32 DENTITION
U-SHAPED BITE PLATE
32 DENTITION
40 PATIENT'S JAW

FIG. 1


Lower Vertical Rim
Bite Plate
Upper Vertical Rim
10
Lingual Edge
114
116
112

Lowe also discloses "[t]he bite plate can interact with any surface of the dentition, especially occlusal." EX-1003, ¶ [0007]. *Lowe* also discloses "the interface [in the form of a bite plate] can contact the teeth at any point and at one or more points." *Id.*, ¶ [0008]. *Lowe* further discloses

> the [bite] plate or platform, which can be of any shape or thickness, and comprised of any material, sufficient to come into and out of contact with the dentition 32, in part or in whole, vibrates in a manner that delivers the necessary force. The device can have one or more interface points across the dentition, or can interface with the entire dentition in aggregate and in both arches simultaneously.

Id., ¶ [0037].

A person skilled in the art would reasonably understand or infer from at least this disclosure that *Lowe* discloses bite plate 20 of device 10 may have upper and lower vertical rims on a lingual edge thereof to contact both arches of teeth as illustrated in Figs. 1 and 11 and described in paragraphs [0007], [0008], and [0037]. EX-1002, ¶¶ 84-86.

6. *Lowe* anticipates claims 8, 16, and 25: "wherein said orthodontic remodeling device automatically shuts off after 20 minutes"

Lowe discloses claims 8, 16, and 25 because it discloses "[u]pon completion of one (1) twenty-minute duration of activation, the device automatically shuts off." EX-1003, ¶ [0039].

7. *Lowe* anticipates claim 26: "wherein said accelerated tooth movement is about 0.5 mm per week"

As stated above, *supra* III(A), this limitation of claim 26 should not be given any patentable weight because it merely states the intended result of the process steps of the claim.

Even if the limitation is given patentable weight[7], *Lowe* discloses accelerated tooth movement of about 0.5 mm per week, because it discloses the same operational features taught by the '184 patent that result in the claimed movement. *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004) ("the critical question will be whether the . . . [prior art] sufficiently describes an enables one or more embodiments—whatever the settings of their operational features—that necessarily include or result in the [feature or result] . . .").

[7] Propel does not concede that the process taught by the '184 patent will result in the claimed amount of tooth movement.

C. Ground 2: *Lowe* in view of *Ting* renders obvious claims 9, 17, and 27: "wherein said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N and said accelerated tooth movement is about 0.5 mm per week"; and claims 18 and 26: "wherein said accelerated tooth movement is about 0.5 mm per week"

As stated above, *supra* III(A), the intended tooth movement result of about 0.5 mm per week should not be given patentable weight. With respect to the remaining limitations, *Lowe* does not expressly disclose "said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N." Instead, *Lowe* discloses a frequency range of 0.1 Hz to 400 Hz and gives an example of a force of about five Newtons (5N). EX-1003, ¶ [0039]. However, *Ting* discloses orthodontic devices for moving teeth and the use of appliances that generate a cyclic force that provides a stimulation to facilitate tooth movement. EX-1012, 2:5-6; 2:29-3:3.

Ting discloses a cyclic force having a magnitude of about 0.2 Newton. *Id*., 10:3-11. *Ting* discloses providing a cyclic force having a frequency from about 20 Hz to about 40 Hz. *Id*., 9:22-33. Thus, *Ting* discloses the same force as claimed—0.2 N—and discloses an overlapping frequency range—20 Hz to 40 Hz—to the claimed frequency—30 Hz. *In re Wertheim*, 541 F.2d 257, 267 (C.C.P.A. 1976) (Where the claimed values "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists.).

Even if the claimed intended tooth movement result of about 0.5 mm per week is given patentable weight, *Ting* also renders obvious this limitation. Because

Ting discloses the use of a number of appliances "permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm." *Id.*, 13:13-16. *Ting* also discloses "[s]uccessive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days." *Id*., 24:20-24. A person skilled in the art would reasonably understand or infer this disclosure to be that *Ting* discloses a range of tooth movement that includes movement of 0.5 mm per week, which establishes a *prima facie* case of obviousness. *In re Wertheim*, p. 267; EX-1002, ¶¶ 90-92.

It would be obvious to use the force and frequency taught by *Ting* with the method taught by *Lowe* in order to achieve the tooth movement taught by *Ting*. Although the mechanism for vibration is different, both *Ting* and *Lowe* disclose devices and systems for accelerating tooth movement using the application of cyclical forces. Applying the known operating parameters—30 Hz and 0.2 N—disclosed by *Ting* to the *Lowe* method would have yielded predictable results and the known advantages disclosed in *Ting* (i.e., movement of less 2 mm, 1 mm, 0.5 mm per 5 to 10 days overlapping claimed rate of 0.5 mm per week). Accordingly, a person skilled in the art would have found it obvious to vibrate the orthodontic

remodeling device in the method disclosed by *Lowe* "at about 30 Hz and about 0.2 N" so the "accelerated tooth movement is about 0.5 mm per week" based on *Ting*.[8] EX-1002, ¶ 93.

[8] Evidence it was obvious to use vibration of 30 Hz at about 0.2 N to accelerate tooth movement can be found in articles discussing tooth acceleration devices using these parameters and clinical test result published prior to November 9, 2009. For example, in the website article published September 21, 2009 by Kathy Kincade, titled Vibration therapy speeds tooth movement (EX-1017), *Kincade* discloses OrthoAccel's Acceledent device, which is basically disclosed in *Lowe*, applies 20 grams (0.2 N) of force and vibrates at a frequency of 30 Hz and in a study conducted at the University of Texas Health Science Center patients using the Acceledent device exhibited overall tooth movement of 0.526 mm per week during the study. EX-1017, p. 2. Substantially the same information was also being taught in a continuing education program for dentist and/or orthodontist through PennWell Publications, which published the materials in September 2009. EX-1018, pp. 6-7.

D. Ground 3: *Lowe* in view of *Mao* renders obvious claims 9, 17, and 27: "wherein said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N and said accelerated tooth movement is about 0.5 mm per week"; and claims 18 and 26 "wherein said accelerated tooth movement is about 0.5 mm per week"

As stated above, *supra* III(A), the intended tooth movement result of about 0.5 mm per week should not be given patentable weight. With respect to the remaining limitations, *Lowe* does not expressly disclose "said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N." Instead, *Lowe* discloses an overlapping frequency range of 0.1 Hz to 400 Hz and gives one example of a force of about five Newtons (5N). EX-1003, ¶ [0039]. However, *Mao*—addressed in the background section of the '184 patent (EX-1001, 1:47-57), teaches an orthodontic remodeling device for realigning teeth vibrating at an overlapping force range of 0.1 – 5 Newtons (EX-1013, 3:35-45) and a narrower overlapping frequency range of "up to about 40 Hz." *Id*. Here, where the claimed values "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, p. 267.

One of skill in the art would find it obvious to use known techniques disclosed by *Mao* in the method of *Lowe* in the same way, given the studies by Mao that show the disclosed force and frequency resulted in increased bone

remodeling. [9] EX-1013, 8:1-25. EX-1002, ¶¶ 94-95. Furthermore, one of skill in the art would find it obvious to try different frequencies and forces from the finite number disclosed in *Mao*, with a reasonable expectation of success. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402 (2007) ("When . . . there are a finite number of identified, predictable solutions, a person ordinary skill has good reason to pursue the know options within his or her technical grasp."). Accordingly, the combination of *Lowe* and *Mao* render obvious "said orthodontic remodeling device vibrates at about 30 Hz and about 0.2 N." EX-1002, ¶ 95.

During prosecution OrthoAccel argued with respect to *Mao* that "[n]o accelerated tooth movement was ever shown. Furthermore, the device of Mao is on the archwires at the back of the throat, was never built, and if built and tested

[9] In U.S. application 13/609,346, which is in the same family as the '184 patent (i.e., claims priority to the same CIP Application, Parent Application, and Provisional Application), the same examiner as the '184 patent rejected dependent claims reciting force limitations based on *Lowe* in combination with Mao (U.S. Patent No. 6,832,912 – same disclosure as *Mao* besides the claims). EX-1014, p. 857. The Patent Trial and Appeal Board, in its decision mailed September 5, 2017, affirmed the examiner's rejection of these claims and found the combination of *Lowe* and Mao was proper. *Id*., pp. 860-863.

would have caused severe gagging (see FIG. 2), rendering it unusable." EX-1007, p. 84. OrthoAccel did not recognize, however, that Mao also taught the use of an extraoral device, which obviates the distinction made by OrthoAccel to the Examiner. EX-1013, 7:63-67. *Mao* discloses methods for accelerated tooth movement in humans and discloses frequency ranges overlapping with the range recited in the claims. For example, *Mao* discloses a "method for realigning one or more of the teeth of a mammal in need thereof. That method comprises the steps of (a) applying cyclic force to at least one tooth of the mammal in which tooth realignment is desired with a peak magnitude of about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz . . ." EX-1013, 3:38-43. And it is clear from *Mao* that humans were one of the intended mammals because Mao discloses "[e]xemplary mammals are humans . . ." *Id.*, 4:66. *Mao* Fig. 2 is also "a diagrammatic view of an orthodontic device utilizing a device of the present invention in place in a human mouth having a malocclusion." *Id.,* 4:39-41.

One skilled in the art would have the same expectation of success combining *Lowe* and *Mao*, as one would have with the teachings of the '184 patent, because they teach the same parameters. *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2017) ("Conclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success.").

The information in *Lowe*, when combined with *Mao* provides such a reasonable expectation of success. EX-1002, ¶¶ 96-97.

E. As the Examiner has found during prosecution, OrthoAccel's alleged objective evidence of nonobviousness cannot save the claims

While OrthoAccel has not yet presented any evidence of secondary considerations in this proceeding, it presented testimony and documents to attempt to support its contention during prosecution. EX-1007, pp. 171-209; 218. For example, it presented declarations and publications of purported objective evidence of nonobviousness in support of their arguments to overcome the Examiner's § 103 rejections. *Id*. Although the secondary considerations were not addressed by the Examiner during prosecution of the '184 patent, OrthoAccel submitted the same purported objective evidence of nonobviousness in many of their other applications in the same family as the '184 Patent, and the same Examiner previously addressed the evidence and found it to be unpersuasive.

For example, in application 13/609,346, OrthoAccel submitted the same objective evidence of nonobviousness. EX-1014, pp. 553-596. On Appeal OrthoAccel argued nonobviousness based on the evidence. *Id*. 625-627. The Examiner addressed the evidence submitted by OrthoAccel and found it unpersuasive for a number of reasoning, including for example: (1) the study done is not a comparison of the claimed invention with the closest prior art; (2) the

attempted showing of unexpected results are not commensurate in scope with the invention as claimed; (3) the declaration does not prove the results are due to the claimed features, and not to unclaimed features; (4) the declaration does not prove commercial success because there is no evidence that the success is linked to the claimed invention and not to some other factor; and (5) the declaration does not include a description of what was sold including the features of the invention as claimed. *Id*., pp. 814-815.

"For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention*." In re GPAC Inc*., 57 F.3d 1573, 1580 (Fed. Cir. 1995) (citation omitted). The presumption of nexus, if any, is overcome if the objective considerations of non-obviousness flows from unclaimed features or, alternatively, features that are readily available in prior art. *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) ("[I]f the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant"); *Wyers v. Master Lock Co*., 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("[W]here the inventions represented no more than 'the predictable use of prior art elements according to their established functions,'…the secondary considerations are inadequate to establish nonobviousness as a matter of law.") (citing *KSR*, 550 U.S. at 417); *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("Where the

offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.") (Emphasis in original).

A person skilled in the art would understand that the claimed invention represented no more than the predictable use of prior art elements according to their established functions. EX-1002, ¶¶ 98-99.

The Examiner summarized by saying OrthoAccel "has done nothing more than show that there was commercial success of their product. This is not a showing of commercial success sufficient for showing non-obviousness." EX-1014, p. 815. It appears the Board agrees with both the Examiner and Propel—that OrthoAccel's purported objective evidence of nonobviousness is unpersuasive—because the Board affirmed the Examiner's obviousness rejection of claims 25 and 26 based on *Lowe* and Mao[10]. Moreover, as here, secondary considerations of non-obviousness cannot overcome a strong *prima facie* case of obviousness. *See Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

[10] The Mao patent relied upon by the Examiner is different than *Mao* cited herein, but the disclosures are identical besides the claims.

V. MANDATORY NOTICES

A. Real Party-in-Interest

The real parties-in-interest are Propel Orthodontics, LLC and Propel Orthodontics USA, LLC.

B. Related Matters

To Petitioner's knowledge, the '184 patent is the subject of the following case:

Name	Number	District	Filed
OrthoAccel Technologies, Inc. v. Propel Orthodontics, LLC and Propel Orthodontics USA, LLC	3:17-cv-03801-RS	NDCA	July 4, 2017

To the Petitioner's knowledge, the disclosure of the '184 patent is the subject of the following related pending applications:

Application No.	Filing Date
13/609,346	September 11, 2012
14/612,081	February 2, 2015
14/548,072	November 19, 2014
15/801,314	Not Yet Assigned

To the best of Petitioner's knowledge, the '184 patent has not been involved in any other proceedings.

C. Lead and Back-Up Counsel and Service Information

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Propel consents to e-mail service at these e-mail addresses.

VI. CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

This Petition complies with the requirements of 37 C.F.R. § 42.24. As calculated by the word count feature of Microsoft Word 2010, it contains 11,482 words, excluding the words contained in the following: Table of Contents, Table of Authorities, List of Exhibits, Mandatory Notices, Certification Under §42.24(d), and Certificate of Service.

VII. GROUNDS FOR STANDING

Petitioner certifies the ’184 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review of the ’184 patent challenging the patent claims on the grounds identified in this petition.

VIII. STATEMENT OF PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

Petitioner requests review of claims 1-27 based the above grounds. Claims 1-27 are unpatentable under 35 U.S.C. §§ 102 and/or 103. The claim construction, reasons for unpatentability, and specific evidence supporting this request are detailed above.

IX. CONCLUSION

For the reasons set forth above, the challenged claims 1-27 are unpatentable, so trial should be instituted and the claims should be cancelled.

Respectfully submitted,

Dated: December 15, 2017 By: /Christopher S. Schultz/
Christopher S. Schultz, Lead Counsel
Reg. No. 37,929

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **Petition for *Inter Partes* Review** was served on December 15, 2017, by Express Mail at the following address of record for the subject patent. The associated Exhibits 1001 through 1022 and the Power of Attorney were served on December 15, 2017.

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