

United States Court of Appeals for the Federal Circuit

05-1426

ORMCO CORPORATION,

Plaintiff/Counterdefendant-
Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,

Counterdefendant-Appellant,

v.

ALIGN TECHNOLOGY, INC.,

Defendant/Counterclaimant-
Appellee.

David L. DeBruin, Michael Best & Friedrich LLP, of Milwaukee, Wisconsin, argued for plaintiff/counterdefendant-appellant and counterdefendant-appellant. With him on the brief was Charles J. Crueger. Of counsel was Richard H. Marschall.

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Appealed from: United States District Court for the Central District of California

Judge Gary L. Taylor

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ALLESEE ORTHODONTIC APPLIANCES, INC.,

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v.

ALIGN TECHNOLOGY, INC.,

Defendant/Counterclaimant-Appellee.

DECIDED: August 30, 2006

Before SCHALL, GAJARSA, and DYK, Circuit Judges.

DYK, Circuit Judge.

Ormco Corporation and its subsidiary, Allesee Orthodontic Appliances, Inc. (collectively “Ormco”), appeal from the judgment of the United States District Court for the Central District of California finding, inter alia, that claims 1-3 and 7 of Align Corporation’s (“Align’s”) U.S. Patent No. 6,554,611 (the ‘611 patent) and claims 10 and 17 of Align’s U.S. Patent No. 6,398,548 (the ‘548 patent) are infringed by Ormco’s “Red, White & Blue” (“RW&B”) orthodontic product; that those claims are not invalid; and that Align did not engage in inequitable conduct during prosecution of the ‘611 and ‘548

patents. We reverse the district court's grant of summary judgment that the patents are not invalid, and hold that all six claims would have been obvious under 35 U.S.C. § 103(a) (2000). We therefore need not reach the district court's finding of infringement. We also need not reach the issue of inequitable conduct because Ormco has agreed that the court need not address the issue of inequitable conduct if the claims are held invalid.

BACKGROUND

Align is the holder of the '611 and '548 patents, which disclose systems of orthodontic devices for moving teeth from an initial configuration to a final configuration. The patents disclose a series of retainers. The first retainer is designed to move a patient's teeth from an initial position to an intermediate position. Once the teeth have reached the intermediate position, the patient discards the first retainer and inserts the next retainer in the series, which moves the teeth an additional amount. The patents disclose at least three retainers in a series. When the patient finishes using the last retainer, the course is complete and the patient's teeth have achieved the final configuration.

Four claims of the '611 patent are pertinent to this appeal—claims 1, 2, 3, and 7. Independent claim 1 of the '611 patent is an apparatus claim that recites:

1. A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:
 - a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;
 - one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements;

a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement;

and instructions which set forth that the patient is to wear the individual appliances in a predetermined order which will progressively move the patient's teeth toward the final arrangement, a package, said package containing said first appliance, said one more [sic] intermediate appliances and said final appliance, wherein the appliances are provided in a single package to the patient.

'611 patent, col. 22, ll. 18-39 (emphasis added). Claim 1 of the '611 patent essentially requires (a) three or more appliances with geometries selected to progressively reposition teeth; (b) instructions regarding order of use; and (c) provision of the appliances in a single package to the patient.

Claim 2 of the '611 patent recites “[a] system as in claim 1, wherein the appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.” '611 patent, col. 22, ll. 40-43.

Claim 3 of the '611 patent recites “[a] system as in claim 2, wherein the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.” '611 patent, col. 22, ll. 44-47 (emphasis added).

Finally, claim 7 of the '611 patent recites “[a] system as in any of claims 1-5 or 6, wherein at least some of the appliances are marked to indicate their order of use.” '611 patent, col. 22, ll. 54-56.

The only claims of the '548 patent at issue in this appeal are claims 10 and 17.

Claim 10 is an apparatus claim that depends from independent claim 1.¹ Claim 1 essentially requires (a) three or more appliances with geometries selected to progressively reposition teeth (b) wherein at least some of those appliances are marked to indicate order of use. Claim 10 of the '548 patent adds an "instructions" limitation to claim 1:

10. A system as in claim 1, further comprising instructions which set forth that the patient is to wear the individual appliances in the order marked on the appliance.

'548 patent, col. 22, ll. 52-54 (emphasis added).

Claim 17 of the '548 patent is a method claim that depends from claim 11. Claim 11 includes the same basic elements as claim 1.² Claim 17 adds an "intervals" limitation to claim 11:

¹ Claim 1 recites:

1. A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:
a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;
one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and
a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement,
wherein at least some of the appliances are marked to indicate their order of use.

'548 patent, col. 22, ll. 15-30.

² Claim 11 recites:

11. A method for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said method comprising:

17. A method as in claim 11, wherein the appliances are successively replaced at an interval in the range from 2 days to 20 days.

'548 patent, col. 23, ll. 23-25 (emphasis added).

II

Two prior art references are potentially pertinent, both of which disclose the use of orthodontic systems by doctors and their patients.

Dr. Truax, an orthodontist, practiced an orthodontic technique that involved taking a single mold of a patient's teeth, repositioning the "tooth cavities" on the mold to their desired positions, then at the same time making three appliances from the repositioned mold, each with a different thickness. A thinner appliance, which applied less force, was to be used before a thicker appliance. Dr. Truax gave each patient one appliance at a time, providing the next appliance in the series after reviewing the patient's progress. The parties dispute whether Dr. Truax provided instructions to the patients regarding order of use of the appliances.

placing a first incremental position adjustment appliance in a patient's mouth, wherein the first appliance has a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement; successively replacing one or more additional appliances, wherein the additional appliances have geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and placing a final appliance into the patient's mouth, wherein the final appliance has a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement, wherein at least some of the appliances are marked to indicate their order of use.

'548 patent, col. 22, l. 55 – col. 23, l. 6.

A second orthodontist, Dr. Rains, practiced a similar technique. Dr. Rains also used a series of three plastic retainers to incrementally adjust patient's teeth. Unlike Dr. Truax, Dr. Rains generally made the appliances one at a time. During each patient visit, Dr. Rains would take a mold of the patient's teeth and then create an appliance based on that mold with the appropriate geometry.

III

On January 6, 2003, Ormco filed suit against Align, alleging that Align's "Invisalign" orthodontic system infringed Ormco's patents. The court granted Align's motion for summary judgment of non-infringement and invalidity of Ormco's patents. This ruling has not been appealed.

Align asserted counterclaims against Ormco, alleging that the Ormco's RW&B orthodontic system infringed claims 1-3, 7, and 8 of Align's '611 patent and claims 1-3, 7, 10-13, and 17-18 of Align's '548 patent.

On June 30, 2004, the district court found that Ormco's RW&B system infringed claims 1-3 and 7 of the '611 patent and claims 1-3, 10-13 and 17 of the '548 patent.³ Although the court found that the evidence was not clear that the RW&B device was provided in a "single package," as the '611 patent claims required, the court held that the claims were nonetheless infringed because it construed claim 1 of the '611 patent to merely require that the appliances be "capable of being provided [to patients in a single package]." Ormco Corp. v. Align Tech., Inc., No. SA CV 03-16-GLT, slip op. at 6 (C.D. Cal. June 30, 2004). The court similarly found the "intervals" limitation of claim 17 of the

³ The parties agree that the district court's decision implicitly held that claim 10 was infringed even though the district court's opinion did not explicitly so state.

'548 patent to be infringed because it found claim 17 only required that the appliances be capable of replacement within that time period. Id. at 6-7.

On August 20, 2004, the court denied Ormco's motion for summary judgment of invalidity of claims 1-3, 7, and 8 of the '611 patent, and claims 1-3, 7, 10-13, 17, and 18 of the '548 patent. On November 4, 2004, the court granted Align's motion for summary judgment rejecting Ormco's defense that Align had engaged in inequitable conduct in prosecuting the '611 or '548 patents, and granted Align's motion for summary judgment that claims 1-3, 7, and 8 of the '611 patent, and claims 1-3, 7, 10-13, 17, and 18 of the '548 patent were not invalid.

The court reopened discovery in response to Ormco's assertion that it had new evidence of invalidity based on the prior orthodontic practices of Dr. Truax and Dr. Rains. On February 24, 2005, the district court ruled on cross motions for summary judgment that claim 1 of the '611 patent was not invalid in view of the Truax and Rains references, and that claims 2, 3, 7, and 8 were not anticipated and would not have been obvious because they were dependent on a valid claim. Although the court held that claims 1-3 and 11-13 of the '548 patent were invalid because they were anticipated by the Rains reference, it held that claims 10 and 17 of the '548 patent were not invalid because they were not anticipated and would not have been rendered obvious by the Rains and Truax references. On March 26, 2006, the court entered a permanent injunction enjoining Ormco from infringing claims 1-3 and 7 of the '611 patent and claims 10 and 17 of the '548 patent.⁴

⁴ The PTO has granted a third party's request for reexamination of the parent patent for the '611 and '548 patents, U.S. Patent No. 5,975,893 (filed Oct. 8, 1997), as well as for the '548 patent.

While the court has not yet entered a final judgment, we have jurisdiction over the appeal from the permanent injunction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

DISCUSSION

Ormco contends that claims 1-3 and 7 of the '611 patent and claims 10 and 17 of the '548 patent are invalid because they would have been obvious or are anticipated under 35 U.S.C. §§ 102(a) (2000) and 103(a). Align does not challenge the district court's determination that other claims of the '548 patent are invalid. We review the district court's grant of summary judgment without deference. Golan v. Pingel Enter., Inc., 310 F.3d 1360, 1367 (Fed. Cir. 2002).

"Prior art" in the obviousness context includes the material identified in section 102(a). See Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346, 1354 (Fed. Cir. 2003). Section 102(a) provides that a person is not entitled to a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). Art that is not accessible to the public is generally not recognized as prior art. See Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002); OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1402 (Fed. Cir. 1997). Pertinent to this appeal, Ormco relies on Dr. Truax's orthodontic practice, and an instruction sheet he distributed to orthodontists, in order to establish the obviousness of the disputed claims. Thus, Ormco relies on "knowledge or use by others" that is corroborated by documentary evidence. Align claims that the Truax reference was not part of the prior art because it was not publicly accessible. However, we conclude that Dr. Truax's practice and his instruction sheet were sufficiently publicly

accessible to qualify as prior art. It is undisputed that Dr. Truax promoted his system to other orthodontists through seminars and clinics and distributed his instruction sheet at those clinics. See Baxter Int'l, Inc. v. Cobe Labs., Inc., 88 F.3d 1054, 1058 (Fed. Cir. 1996) (defining “public use” in 102(b) context as including “any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor” (quoting In re Smith, 714 F.2d 1127, 1134 (Fed. Cir. 1983)); 1-3 Chisum on Patents § 3.05 (2006) (“[A]t most the publicity requirement in Section 102(a) means the absence of affirmative steps to conceal.”).

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We first address Ormco’s argument that claim 1 of the ‘611 patent would have been obvious in view of the Truax reference and regulations of the Food and Drug Administration (“FDA”) that generally require the provision of instructions with medical devices. Under 35 U.S.C. § 103(a), a claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. § 103(a) (2000); Graham v. John Deere Co., 383 U.S. 1, 13-14 (1966). Obviousness is a legal question where, as here, the relevant underlying facts are undisputed. Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004).

Claim 1 of the ‘611 patent requires (a) three or more appliances with geometries selected to progressively reposition teeth, (b) instructions regarding order of use, and (c) a single package for provision of the appliances to the patient.

It is undisputed that Dr. Truax's orthodontic system used several clear plastic appliances that fit over the patient's teeth, each appliance composed of plastic of a different thickness (the thicknesses typically varied from 0.015 to 0.030 inches). A thinner device exerted less force on the teeth than a thicker device, and a thinner device was thus used before the next thicker device. The district court held that Dr. Truax's practice does not meet the "geometry" limitation of claim 1 because the claim requires three or more appliances with "different geometries." In the district court's view, the different thicknesses of Dr. Truax's devices do not qualify as different geometries.

In keeping with the district court's claim construction, Align contends that appliances have different geometries only if the positions of the tooth cavities change from one appliance to another. We disagree. We first look to the specification for guidance as to the meaning of claim language, Phillips v. AWH Corp., 415 F.3d 1303, 1315-16 (Fed. Cir. 2005) (en banc). Here the specification does not define the term "geometry," though Align points out that it discloses only appliances with different tooth positions. See '611 patent, col. 3, l. 22 – col. 4, l. 30; col. 9, ll. 20-61. Thus, the specification's language does no more than describe preferred embodiments, and "we have repeatedly warned against confining the claims to [the disclosed] embodiments." Phillips, 415 F.3d at 1323. Under these circumstances we appropriately look to dictionary definitions.⁵ The parties agree that resort to dictionaries is useful to determine the meaning of the term "geometry." As the district court correctly stated,

⁵ See Phillips, 415 F.3d at 1314 (noting that where the meaning of a claim term is readily apparent, claim construction involves "little more than the application of the widely accepted meaning of commonly understood words" and, in such cases, "general purpose dictionaries may be helpful"); see also AGFA Corp. v. CREO Prods., Inc., 451 F.3d 1366, 1376 (Fed. Cir. 2006).

[t]he ordinary meaning of ‘geometry’ in the context of the claims is a figure characterized by points, lines, or planes.” Ormco Corp. v. Align Tech., Inc., No. SA-CV-03-16-GLT, slip op. at 3 (C.D. Cal. Feb. 24, 2005) (citing Webster’s New World Dictionary Third College Edition 564 (1988)). In other words, geometry means “configuration” or “shape.”⁶ Unlike the district court, we think that objects of different thicknesses plainly have different “configurations” or “shapes.” Furthermore, the specification indicates that “[i]n a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment.” ‘611 patent, col. 9, ll. 25-29. Thus, we conclude that the Truax devices satisfy the “geometries” limitation of claim 1.

We also disagree with the district court’s construction of claim 1 in one other respect. We reject the district court’s conclusion that the “single package” limitation of claim 1 of the ‘611 patent merely requires that devices be “capable of” being provided to the patient in a single package. Here, the claims are written to require that the devices actually be in a single “package.” In similar contexts, our cases have rejected claim constructions that would merely require that infringing devices be capable of being modified to conform to a specified claim limitation.⁷ With these constructions of claim

⁶ See Webster’s Third New International Dictionary 950 (1966) (defining geometry as “configuration” or “surface shape.”); Random House Webster’s Unabridged Dictionary 799 (2d ed. 1998) (defining “geometry” as “the shape or form of a surface or solid”).

⁷ See, e.g., Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1310-11 (Fed. Cir. 2005) (rejecting argument that “to directly infringe, Medtronic need only make devices that are capable of being converted into infringing

1's limitations, we turn to the question of whether the Truax devices rendered claim 1 obvious.

Even though Dr. Truax created several appliances at one time, with the required geometries, Align contends that Dr. Truax never provided his patients with all these appliances in a single package, and that it would not have been obvious to vary Truax in this respect.

A claim can be obvious even where all of the claimed features are not found in specific prior art references, where "there is a showing of a suggestion or motivation to modify the teachings of [the prior art] to the claimed invention." SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1356 (Fed. Cir. 2000) (concluding that patent would have been obvious in light of teachings in prior art which provided motivation and suggestion to modify existing techniques to arrive at method in question).⁸ "A suggestion, teaching, or motivation to combine the relevant prior art

devices"); Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed. Cir. 1996) (rejecting the argument that "a device which is capable of infringing use does not escape infringement although not actually used in an infringing manner," where the claims were written to cover actual use); High Tech Med. Instruments, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1555 (Fed. Cir. 1995) ("The question is not what [a device] might have been made to do, but what it was intended to do and did do [T]hat a device could have been made to do something else does not of itself establish infringement." (quoting Hap Corp. v. Heyman Mfg., Co., 311 F.2d 839, 843 (1st Cir. 1962))). Our conclusion is consistent with Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1343 (Fed. Cir. 2001). Hilgraeve did not suggest that a device would directly infringe a product claim simply because the device could be modified to render it infringing.

⁸ See also Merck & Co. v. Teva Pharmas. USA, Inc., 395 F.3d 1364, 1375 (Fed. Cir. 2005); Valmet Paper Mach., Inc. v. Beloit Corp., 105 F.3d 1409, 1413 (Fed. Cir. 1997) (concluding, without relying on a specific reference, that it would have been obvious to a person of ordinary skill in the art to modify a prior art reference to meet a limitation of a claim); B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1582 (Fed. Cir. 1996); In re O'Farrell, 853 F.2d 894, 902 (Fed. Cir. 1988).

teachings does not have to be found explicitly in the prior art, as ‘the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’” In re Kahn, 441 F.3d 977, 987-88 (Fed. Cir. 2006) (quoting In re Kotzab, 217 F.3d 1365, 1370 (Fed. Cir. 2000)).⁹

However, a reference that “teaches away” from a given combination may negate a motivation to modify the prior art to meet the claimed invention. See, e.g., Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1165 (Fed. Cir. 2006). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” In re Kahn, 441 F.3d at 990 (quoting In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994)) (internal quotation marks omitted).

Align points out that Dr. Truax examined each patient’s progress before giving that patient a new appliance, and that the Truax reference thus does not provide a motivation or suggestion to provide the appliances at one time. Indeed, Align contends, the Truax reference teaches away from providing all appliances at one time. When Dr. Truax was asked whether he ever gave patients more than one appliance at a time, he

⁹ See also Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1125 (Fed. Cir. 2000) (stating that evidence of a motivation to combine prior art references “may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved”).

replied, “No, because we want to manage it [I]t would be ridiculous” to expect the patient to replace appliances on his own. J.A. at 6365. He explained that he provided patients with one appliance at a time because in his view “[s]omeone that knows what they’re doing [i.e., the orthodontist] . . . can see the [tooth] movements [and determine when to change appliances based on those tooth movements]. . . ,” so as to prevent the patient from moving too quickly through appliances. Id. In other words, Truax taught that the treatment was more effective if the orthodontist determined when to change appliances, rather than providing several appliances to the patient and allowing the patient to change from one appliance to the next. Under these circumstances, argues Align, it would not have been obvious to provide all appliances to a patient in a single package.

Understanding the parties’ contentions requires a brief description of the prior art to which the patented invention and Truax were both directed. As the ‘611 patent describes, traditional orthodontic work involved providing the patient with a single device that was adjusted periodically by the dentist. Traditional braces utilized a force-inducing component called an “archwire” to move the patient’s teeth. The archwire “is attached to [“brackets” that have been cemented to the patient’s teeth] by way of slots in the brackets.” ‘611 patent, col. 1, ll. 57-58; col. 1, ll. 50-53. After the archwire has been installed, “periodic meetings with the orthodontist are required, during which the patient’s braces will be adjusted by installing a different archwire . . . or by replacing or tightening existing [wires].” ‘611 patent, col. 1, l. 66 - col. 2, l. 3. Thus, “the use of braces is unsightly [and] uncomfortable” ‘611 patent, col. 2, ll. 8-9.

The patented device here (and Truax) avoided the necessity for adjustment by the dentist by the use of multiple appliances that were changed periodically. Align asserts that there is an important difference between the patented device and Truax in that the patented device avoids a visit to the dentist in order to determine when substitution of the new device is appropriate. But there is nothing in the claim language that requires the devices be substitutable by the patient. In other words, the claims do not require that the device be capable of replacement by the patient rather than the dentist, or preclude visits to the dentist during the treatment regimen. Indeed, the specification makes quite clear that the patient may periodically visit the dentist during treatment.¹⁰ The claim does not preclude returning to the dentist to determine the appropriate time to replace appliances, just as Truax taught.

¹⁰ As the specification explains in the “Brief Summary of the Invention,”

Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual patient.

‘611 patent, col. 3, l. 60 – col. 4, l. 2 (emphasis added); see also ‘548 patent, col. 3, ll. 57-66. The specification states that the orthodontist may, during a patient visit, choose to adjust the treatment schedule:

In general, the transition to the next appliance can be based on a number of factors [and may not occur on a predetermined schedule] [A]ctual patient response can be taken into account In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances

‘611 patent, col. 4, l. 63 – col 5, l. 10; see also ‘548 patent, col. 4, l. 60 – col. 5, l. 7.

Under these circumstances, we do not think that the single package limitation makes the device of the '611 patent claims patentably distinct. Providing the devices to the patient in one package, as opposed to two packages or three packages is not a novel or patentable feature in the light of the well-known practice of packaging items in the manner most convenient to the purchaser.

We also think that adding the instructions limitation does not render claim 1 of the '611 patent non-obvious. The parties dispute whether Dr. Truax provided instructions to his patients regarding the order of use of the appliances. However, Align conceded at oral argument that the general practice of providing instructions on how to use a medical device would have been obvious. Furthermore, statutes and regulations promulgated under the Food, Drug, and Cosmetic Act ("FDCA") generally require instructions for medical devices.¹¹ Whether or not these regulations apply to the specific orthodontic devices involved here, they supply ample evidence of a motivation to provide instructions as to how to use the devices.

Claims 2, 3, and 7, which depend from claim 1, are also invalid. These claims simply add further limitations that were met by Dr. Truax's practice or would have been obvious variations thereof, and the claims including these limitations would have been obvious.

¹¹ See, e.g., 21 U.S.C. § 352 (2000) ("A drug or device shall be deemed to be misbranded . . . [u]nless its labeling bears . . . adequate directions for use."); 21 U.S.C. § 321 (2000) (defining "device" for purposes of the FDCA as "an . . . apparatus . . . which is . . . intended to affect the structure or any function of the body of man . . ."); 21 C.F.R. § 801.5 (2005) (defining "adequate directions for use").

Claim 2 of the ‘611 patent recites “[a] system as in claim 1, wherein the appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.” ‘611 patent, col. 22 ll. 40-43. The instructions for Dr. Truax’s appliances make clear that his appliances were polymeric (plastic) shells with cavities corresponding to the teeth, and that these cavities were shaped to receive and reposition the teeth from one arrangement to a successive arrangement.

Claim 3 of the ‘611 patent claims “[a] system as in claim 2, wherein the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.” ‘611 patent, col. 22, ll. 44-47. It is undisputed that in Dr. Truax’s devices, the tooth positions defined by the cavities in successive devices do not change. Therefore, Dr. Truax’s devices meet the requirement of claim 3.

Finally, claim 7 of the ‘611 patent recites “[a] system as in any of claims 1-5 or 6, wherein at least some of the appliances are marked to indicate their order of use.” ‘611 patent, col. 22, ll. 54-56. Although the parties dispute whether Dr. Truax marked the backs of his devices in pencil to indicate order of use, it is undisputed that Dr. Truax’s instruction sheet calls for the creation of several appliances of different thicknesses at one time, and that these appliances were to be used in a particular order. We agree with Ormco that the thicknesses of the devices served as markings to indicate their order of use, and thus that Dr. Truax’s devices meet the limitations of claim 7. We reject Align’s argument that the markings fail to meet the marking limitation if they are

meant to convey order of use to the orthodontist as opposed to the patient; in either case, the markings satisfy the plain language of the claim.

For the foregoing reasons, we conclude that Ormco has made a *prima facie* showing that claims 1-3 and 7 would have been obvious in view of the Truax reference and the FDA regulations requiring that instructions accompany medical devices.

II

We next address Ormco's contention that claim 10 of the '548 patent would have been obvious in view of the Truax reference and FDA regulations requiring the provision of instructions.

Claim 10 of the '548 patent depends from claim 1. Claim 1 requires (a) three or more appliances with geometries selected to progressively reposition teeth (b) wherein at least some of those appliances are marked to indicate order of use. Claim 10 requires "instructions which set forth that the patient is to wear the individual appliances in the order marked on the appliance." '548 patent, col. 22, ll. 52-54. We have already found that Ormco established obviousness with respect to this same combination of claim elements (in claims 1 and 7 of the '611 patent). For the same reason, claim 10 would have been obvious.

III

We next turn to Ormco's argument that claim 17 of the '548 patent would have been obvious in view of the Truax reference.

Claim 17 depends from Claim 11, which is a method claim corresponding to claim 1. Like claim 1, claim 11 requires (a) three or more appliances with geometries selected to reposition teeth (b) wherein at least some of those appliances are marked to

indicate order of use. Claim 17 adds the limitation “wherein the appliances are successively replaced at an interval in the range from 2 days to 20 days.” ‘548 patent, col. 23, ll. 23-25 (emphasis added).

We reject the district court’s holding that the “intervals” limitation of this claim merely requires that the devices be “capable of” being replaced within a 2 to 20 day interval. Method claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use.¹² Thus, this claim requires that the devices actually be replaced within the specified period.

Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness. See Iron Grip, 392 F.3d at 1322; In re Geisler, 116 F.3d 1465, 1469 (Fed. Cir. 1997). The presumption can be rebutted if it can be shown that the prior art teaches away from the claimed range, or the claimed range produces new and unexpected results. Iron Grip, 392 F.3d at 1322; In re Geisler, 116 F.3d at 1469; Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1577 n.3 (Fed. Cir. 1993) (“[W]hen the difference between the claimed invention and the prior art is the range or value of a particular variable, then a prima facie rejection is properly established when the difference in range or value is minor.”) (emphasis omitted); In re Malagari, 499 F.2d 1297, 1303 (CCPA 1974) (claimed invention is rendered prima facie obvious by the

¹² See, e.g., Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 773 (Fed. Cir. 1993) (holding that “[t]he sale of [an apparatus capable of performing a claimed process is] not a direct infringement because a method or process claim is directly infringed only when the process is performed”); Standard Havens Prods., Inc. v. Gencor Indus., Inc. 953 F.2d 1360, 1374 (Fed. Cir. 1991) (holding method claims were not directly infringed by the mere sale of an apparatus capable of performing the claimed process).

teachings of a prior art reference that discloses a range that touches the range recited in the claim).

Here, Align argues that Dr. Truax's appliances "were made sequentially every 4 to 6 weeks," and thus did not overlap the claimed range. Appellant's Br. at 46. However, Align fails to address the express disclosure in Dr. Truax's instruction sheet, clearly indicating that the appliances are to be replaced every 14 to 21 days. This interval substantially overlaps with the interval specified in claim 17. Align has also failed to show that Truax teaches away from the claimed range or that the claimed range produces new and unexpected results. Under these circumstances, Align has failed to rebut the presumption that the claimed range would have been obvious.

IV

Finally, we consider Align's contention that secondary considerations support the district court's finding of nonobviousness of the claims.

In Graham, the Supreme Court held that "[s]econdary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented" and "may have relevancy" as indicia of obviousness. 383 U.S. at 17-18. A nonmovant may rebut a prima facie showing of obviousness with objective indicia of nonobviousness. WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1359 (Fed. Cir. 1999); see also In re Kahn, 441 F.3d at 990.

Align urges (and the district court agreed) that the novelty of these claims is established by the commercial success of the Invisalign product, by long-felt but

unresolved needs satisfied by the claimed features, and by the fact that others had tried and failed to meet the same needs.

Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success. As we explained in J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563 (Fed. Cir. 1997), “[w]hen a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.” Id. at 1571; see also Brown & Williamson, 229 F.3d at 1130 (stating the presumption that commercial success is due to the patented invention applies “if the marketed product embodies the claimed features, and is coextensive with them.”). Thus, if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant.¹³ So too if the feature that creates the commercial success was known in the prior art, the success is not pertinent.¹⁴

Here, it is undisputed that Align’s Invisalign product is commercially successful. However, the evidence clearly rebuts the presumption that Invisalign’s success was due

¹³ See Brown & Williamson, 229 F.3d at 1130; Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1377 (Fed. Cir. 2000); J.T. Eaton, 106 F.3d at 1571.

¹⁴ See J.T. Eaton, 106 F.3d at 1571 (“[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.”); Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed. Cir. 1983) (holding claims obvious despite purported showing of commercial success when patentee failed to show that “such commercial success as its marketed system enjoyed was due to anything disclosed in the patent in suit which was not readily available in the prior art”).

to the claimed and novel features. Align relies on testimony and an expert report of Dr. Covell, and testimony of Align's own CEO, Thomas Prescott. In large part these witnesses testified that commercial success was due to unclaimed or non-novel features of the device—the aesthetic appeal and improved comfort of transparent devices without brackets and wire, and the computerized design and manufacture of the appliances.¹⁵ Indeed, Align itself only argues that the commercial success is due "partially" to claimed features. Appellee's Br. at 18.

Nonetheless, Align argues that the commercial success was due at least in part to claimed and novel features. Thus, Align's witnesses also suggested that the commercial success was due to reduction in time spent in the dentist's chair, a

¹⁵ J.A. at 3200 (Invisalign resolved "aesthetic concerns associated with braces"); J.A. at 3019 (listing benefit of "[e]limination of abrasive discomfort associated with wires and braces"); J.A. at 3199 (Align's CEO stating that Invisalign was successful because it "reduce[d] the pain of orthodontic treatment, h[e]ld some teeth without moving them (unlike with braces, where all teeth move) and . . . better promote[d] the health of the teeth through ease of brushing and flossing [because they are removable]."); J.A. at 3201 ("[T]he success of Invisalign aligners also results in part from the computerized design and manufacture of the aligners."); J.A. at 3022 ("Because of the 3D graphical imaging and precise computer manipulation of 'virtual' models, more precise tooth movements involving a greater number of teeth are possible with the Invisalign System.") (internal quotations omitted).

The multitude of contemporaneous newspaper articles that Dr. Covell cites, which reviewed the Invisalign system shortly after its introduction, confirm that Invisalign's invisibility, computerized design and manufacturing process, and the absence of metal braces were primary factors that brought about its success. See J.A. at 3023 (listing article titles: "Straight teeth without the suit of armor," "Bracing for a change; INVISALIGN helps correct dental, vanity problems for adults," "Going wireless; Invisalign braces offer a clear alternative to traditional 'railroad tracks,' . . .", "Seen up close, Invisalign's Smile Isn't Perfect; the 'Invisible' Braces Are Pricey and Not Right for Everyone But They Can Make Dentists Rich," "So long metal mouth; 'nearly invisible dental braces taking big bite of orthodontic market.', "Orthodontics via Silicon Valley; A Start-Up Uses Computer Modeling And Venture Capital to Reach Patients," "A Stealth Substitute for Braces, Designed Only for Adults," "Do Those Invisible Braces Live Up to All the Hype?", "Health News, No More Metal Mouth," "Setting the record straight on those invisible braces," "Some orthodontists grit teeth over popular invisible braces.").

reduction resulting from the provision of multiple appliances to the patient at one time.¹⁶ But, as we have noted above, to the extent that such a time savings was the result of the use of multiple appliances (rather than a single device requiring individual adjustment), that feature was not new; Truax had already accomplished this. And to the extent that the time savings resulted from the patient's substitution of a new device without visiting the dentist, that feature was not claimed. Finally, to the extent that these witnesses testified that the aesthetic appeal resulted from changing the devices every two weeks and avoiding the use of dirty and worn devices,¹⁷ this feature was also not new; it had been accomplished by Truax.

We conclude that the evidence does not show that the commercial success was the result of claimed and novel features. Nor has Align submitted probative evidence that claimed and novel features met a long-felt but unresolved need.

With respect to "failures of others," Align has submitted evidence that, prior to the introduction of the successful Invisalign and RW&B products, other orthodontists had tried and failed to develop a functional, invisible orthodontic system. Again, the

¹⁶ J.A. at 3027 ("[T]he use of a series of clear appliances that are designed to be delivered to the patient in one appointment (which must be marked to indicate the order of their use), rather than braces that must be periodically adjusted, contributed to the success of the Invisalign system."); J.A. at 3201 (Align's CEO stated that the success of Invisalign was due at least in part to the fact that patients and orthodontists had a need for less patient time in the orthodontic chair, and "the fact that [the Invisalign product] can be supplied in a single package to the patient, with instructions to the patient regarding order of use, reduces the chair time required.").

¹⁷ J.A. at 3201 (Align's CEO stated that "[t]he use of the Invisalign aligners for 2 weeks at a time also enables the patients to move often to a new appliance, which is naturally more aesthetically pleasing than older appliances that necessarily become dirty and worn.")

evidence does not suggest that these prior attempts failed because the devices lacked the claimed features.

We therefore conclude that the evidence of secondary considerations is inadequate to raise any doubt as to the obviousness of claims 1-3 and 7 of the '611 patent and claims 10 and 17 of the '548 patent.

CONCLUSION

For the foregoing reasons, we hold that claims 1-3 and 7 of the '611 patent and claims 10 and 17 of the '548 patent are invalid as obvious. We therefore reverse the district court's finding that the claims are valid. In light of this holding, we need not reach the district court's finding of infringement. We also need not reach Ormco's contention that Align engaged in inequitable conduct while prosecuting the '548 and '611 patents because Ormco agreed that we need not reach this issue if the claims were held invalid.

REVERSED.

COSTS

No costs.