

# United States Court of Appeals for the Federal Circuit

2006-1240, -1274

ORMCO CORPORATION,

Plaintiff/Counterdefendant-  
Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,

Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,

Defendant/Counterclaimant-  
Cross Appellant.

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

Anne M. Rogaski, Townsend and Townsend and Crew LLP, of Palo Alto, California, argued for defendant/counterclaimant-cross appellant. With her on the brief were Daniel J. Furniss, Gary H. Ritchey, and Nancy L. Tompkins.

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

Judge Christina A. Snyder

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DECIDED: August 24, 2007

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Before LOURIE and DYK, Circuit Judges, and O'MALLEY, District Judge.\*

Opinion for the court filed by Circuit Judge LOURIE. Opinion concurring in part and dissenting in part filed by District Judge O'MALLEY.

LOURIE, Circuit Judge.

Ormco Corporation ("Ormco") appeals from the decision of the United States District Court for the Central District of California granting summary judgment in favor of

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\* Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

Align Technology, Inc. (“Align”) that the asserted claims of Ormco’s U.S. Patents 6,616,444 (“the ’444 patent”), 6,244,861 (“the ’861 patent”), 5,683,243 (“the ’243 patent”), and 5,447,432 (“the ’432 patent”) (collectively, the “Ormco patents”) were not infringed and are invalid. Align cross-appeals from the decision of the trial court granting summary judgment of invalidity of certain claims of Align’s U.S. Patent 6,398,548 (“the ’548 patent”) in favor of Ormco and Ormco’s subsidiary, Allesee Orthodontic Appliances, Inc. (“AOA”). Because the court correctly granted summary judgment as to some but not all of the claims of the Ormco patents, we affirm in part and reverse in part the judgment as to the Ormco patents. Because the court correctly granted summary judgment of invalidity of the specified claims of the ’548 patent, we affirm that judgment.

#### BACKGROUND

Ormco filed suit on January 6, 2003, alleging that Align’s Invisalign® process infringed the ’861, ’243, and ’432 patents. Ormco later amended its complaint to allege infringement of the ’444 patent as well. Ormco alleges infringement of claims 1-5 and 8-79 of the ’444 patent; claims 1, 3, 4, 9-12, and 16-18 of the ’861 patent; claims 1 and 2 of the ’243 patent; and claims 1, 9, and 10 of the ’432 patent. The Ormco patents relate to the computer-aided design and manufacture of custom orthodontic appliances. They share a common specification, which is also shared with additional patents not asserted in this suit, including U.S. Patent 5,431,562 (“the ’562 patent”). The ’562 patent is a parent of the ’243 patent, the ’861 patent, and the ’444 patent. The application leading to the ’562 patent was filed on the same day as the application leading to the ’432 patent.

Align counterclaimed for declaratory judgment of noninfringement and invalidity and also alleged infringement by Ormco and AOA of U.S. Patent 6,554,611 (“the ’611 patent”) and the ’548 patent. The ’611 and ’548 patents relate to the use of a series of individual orthodontic appliances to incrementally reposition teeth.

In a May 13, 2004, Order, the trial court granted Align’s motion for summary judgment of noninfringement. Ormco Corp. v. Align Tech., Inc., No. 03-cv-00016, slip op. (C.D. Cal. May 13, 2004). In that Order, the court found that statements in the shared specification of the Ormco patents, the prosecution history of the ’562 patent, the prosecution history of the abandoned 07/775,589 application (of which the ’432 patent is a continuation-in-part), and the prosecution history of the ’432 patent limited the claims of the Ormco patents to a process in which final treatment positions for teeth are automatically determined. The court then determined that there were no genuine issues of material fact precluding summary judgment. The court accordingly granted summary judgment of noninfringement in favor of Align because Align’s system relies on “skilled operators” rather than computers to determine the finish positions of the teeth.

The court also granted Align’s motion for summary judgment of nonenablement of Ormco’s patents on August 20, 2004. Ormco Corp. v. Align Tech., Inc., No. 03-cv-00016, slip. op. (C.D. Cal. Aug. 20, 2004). In determining whether Align had presented clear and convincing evidence of nonenablement, the court relied on its prior ruling that “the scope of Ormco’s claims [was] limited to ‘automatic computer determination of the finish positions of teeth.’”

In reviewing the evidence, the court first noted testimony from the inventors indicating that Ormco software had never been used to automatically determine tooth positions without any human intervention. The court found that additional testimony from one inventor that the unmodified output of Ormco's first software design, the Elan, had been used to generate appliances for actual patients was not credible because of the lack of corroboration from documents or other sources. The court also found that the statements of Ormco's expert, John Grubb, that Elan had been used to treat patients without operator intervention were also not credible because his expert report lacked sufficient foundation to support such an opinion. The court further found other statements from the inventors unpersuasive because they were equivocal and indicated at best that the Elan software might be used to treat patients without human adjustment of tooth positions, but not that the software had actually been used in such a way. The court also found testimony that Ormco's new software, the Insignia, could be used to automatically generate orthodontic appliances similarly unpersuasive in light of the fact that the manual override had been used in all forty of the test cases using that software.

Finally, the court granted summary judgment of invalidity of claims 1-3 and 11-13 of Align's '548 patent in favor of Ormco and AOA on February 25, 2005. Ormco Corp. v. Align Tech., Inc., No. 03-cv-00016, slip. op. (C.D. Cal. Feb. 25, 2005). The court first construed the claim terms "system" and "geometry," using a dictionary to give them their ordinary meaning. The court then determined that Dr. Rains' use of the STARS system for orthodontic treatment anticipated all of the limitations of claims 1-3 and 11-13 of the '548 patent. The court rejected Align's arguments that a "system" required that the orthodontic appliances be produced at the same time and that "mark[ing]" the

appliances required that the marks indicate order of use to the patient, rather than the orthodontist.

Ormco timely appealed, and Align timely cross-appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

We review de novo a grant of summary judgment by a district court. Optivus Tech., Inc. v. Ion Beam Applications S.A., 469 F.3d 978, 984 (Fed. Cir. 2006). Summary judgment is appropriate if “there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). “When ruling on a motion for summary judgment, all of the nonmovant’s evidence is to be credited, and all justifiable inferences are to be drawn in the nonmovant’s favor.” Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 1379 (Fed. Cir. 2000).

### A. Noninfringement

“We review a district court’s grant of summary judgment of non-infringement without deference.” O2 Micro Int’l, Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1359 (Fed. Cir. 2006). Our de novo review of summary judgment of noninfringement requires two steps—claim construction, which we review without deference, and infringement, which we review to determine whether there was no genuine issue of material fact. See Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999).

On appeal, Ormco argues that the district court erred when it interpreted the claims to require automatic determination of finish tooth positions, contrary to their plain

language, and when it failed to tie that interpretation to specific language in each claim. Ormco further argues that the statements referenced by the court to support its application of the automatic determination limitation do not meet the standard for an intentional disavowal of claim scope and that statements from the prosecution history of the '562 patent are limiting only as to the particular claim language with respect to which they were made (e.g., “ideal dental archform”).

In response, Align argues that a patentee can make a disavowal of scope as to the general nature of an invention that in turn limits all claims even though specific claim language is not being interpreted. Align argues that the statements in the Ormco patents' specification and the prosecution history of the '562 patent constitute such a disclaimer. In the alternative, Align argues that all of the asserted claims except claims 37-40, 45, and 69 of the '444 patent contain express language that requires a construction that includes the automatic determination limitation.

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation and internal quotations omitted); see also Vitronics Corp. v. Conceptronc, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“[W]e look to the words of the claims themselves . . . to define the scope of the patented invention.”). However, “claims ‘must be read in view of the specification, of which they are a part,’” Phillips, 415 F.3d at 1315 (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996)), and “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct

construction,” id. at 1316 (quoting Renishaw PLC v. Societa’ per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)) (emphasis added).

Consistent with that precedent, we conclude that the district court correctly determined, as to most, but not all, of the asserted claims of the Ormco patents, that requiring automatic determination of finish tooth positions is a proper construction of the asserted claims. Interpreting most of the claims to require automatic determination of finish tooth positions “most naturally aligns with the patent’s description of the invention.” From the beginning of the common specification of the Ormco patents, it is clear that the inventors’ primary basis for distinguishing their invention was its high level of automation in the design of custom orthodontic appliances as compared to the prior art. In the Background of the Invention, the inventors stated, “In reality, the treatment of patients is in many cases more of an art than a science, with results ranging from poor to excellent, and generally variable.” ’444 patent col.3 ll.7-10. The inventors specifically stated that the prior art had encountered difficulties in “the task of developing an automated system that includes reliable and efficient decision making algorithms and techniques for automatically determining an ideal finish position of the teeth.” Id. at col.3 ll.17-22 (emphases added).

The specification then indicates a clear emphasis in the patent on removing the referenced variability in the orthodontic treatment process by relying on a predetermined set of calculations rather than human judgment to determine final tooth positions. “A primary objective of the present invention is to provide a practical, reliable and efficient custom appliance automated design and manufacturing system and methods of automatically designing custom orthodontic appliances and treating patients therewith.”



'444 patent col.3 ll.41-45 (emphases added). “In accordance with the preferred embodiment of the present invention, there is provided a computerized system and method with which finish positions of the teeth of a patient are derived from digitized information of anatomical shapes of the patient’s mouth . . . .” ’444 patent col.4 ll.16-20 (emphases added). “The computer 30b at the appliance facility 13 calculates, based on the digitized information 26, the final position of the patient’s teeth . . . .” ’444 patent col.14 ll.6-8 (emphases added).

Nowhere does the specification suggest or even allow for human adjustment of the computer-calculated tooth finish positions. Statements in the specification cited by Ormco to support human participation in the process are limited to input from the orthodontist and/or computer operator at the start of the process (i.e., when particular “landmarks,” data points related to teeth and jaw anatomy and geometry, are selected for input into the automatic calculation process) and not related to determination of tooth finish positions. See, e.g., ’444 patent col.10 l. 63 – col.11 l.2, col.13 ll.51-57. The first of those passages again emphasizes that the invention “applies automated decision making processes in the appliance design.” Id. at col.10 ll.66-67.

The specification goes on to state, “In the computer analysis procedure (95), the digitized information input by the input procedure (94) is analyzed to calculate the finish position of the teeth, so that the custom appliance (25) can be designed in computerized design procedure (96) and manufactured in computer controlled manufacturing procedure (97).” Id. at col.24 ll.25-30 (emphases added). Further, the detailed recitation of the formulas and algorithms for automatic calculation of final tooth positions that follows, see id. at col.39 l.41 – col. 53, l. 52, concludes with the statement,

“At this point, the final positions of the maxillary teeth have been calculated, and thus, the finish positions of all of the teeth.” Id. at col.53 ll.50-52. There is no discussion of operator or orthodontist review or adjustment of those finish positions or of the bases on which such review and adjustment might be made. Instead, the specification turns to a description of the “Appliance Design Procedure,” which utilizes the finish tooth positions that have been automatically determined. The specification thus provides clear indication that the invention is in the automatic determination of tooth position.

While all those statements by the inventors in the specification of the Ormco patents, standing alone, may not be conclusive in showing that the claims require completely automatic determination of final tooth positions, those in the prosecution history make it even clearer. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” Phillips, 415 F.3d at 1317 (emphasis added). Thus, we turn to the prosecution history of the Ormco patents, and other patents from the same family, to determine if there are statements there that should further inform our construction of the claims. As the district court correctly observed, we have held that “prosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications.” Omega Eng’g, Inc. v. Raytek Corp., 334 F.3d 1314, 1333 (Fed. Cir. 2003). When the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue. See, e.g., Wang

Lab., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1384 (Fed. Cir. 1999); Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990). In this case, the specifications of the prior '562 patent, which is the parent of three of the patents in issue, and all the presently litigated patents, have the same content. Thus, the prosecution history of the claims of application number 07/973,973, which led to the '562 patent, are relevant in construing the claims of the '432, the '243, the '861, and the '444 patents.

The claims of the parent 07/973,973 application were rejected by the United States Patent and Trademark Office ("PTO") under 35 U.S.C. § 103 in an Office Action on September 13, 1993, based in part on U.S. Patent 5,011,405 to Lemchen. In a Response on March 16, 1994, the inventors made a number of statements characterizing the Lemchen patent and seeking to distinguish their invention. The first part of the Response describing Lemchen, noted by the district court, states:

Using such a CAD [computer-aided design] program in a conventional manner, as Lemchen describes, an operator would manipulate the tooth images to provide the desired occlusion. This would presumably involve some decision making by the operator. As the operator manipulates the images, the computer, under the control of the conventional CAD program, would perform the calculations that would generate data of the tooth movements made by the operator and thus of the finish positions of the teeth.

(emphases added). This passage illustrates the inventors' characterization of the Lemchen prior art, viz., that it involves use of an operator. The inventors then distinguish between their automated design process and processes that are merely computer assisted and involve human input in a further characterization of the Lemchen patent:

The Lemchen patent relies, to produce the calculations, on the conventional calculation techniques employed in generalized CAD software. This in turn relies on a user interactive interface by which an

operator contributes human decision making powers to manipulate images until the operator is satisfied that finish tooth position criteria have been met. . . . However, with conventional CAD programs, the reliance on human decision making is heavy, and rigorous fully automated arrival at tooth finish positions is lacking.

(emphases added). The inventors thus distinguished Lemchen by emphasizing its reliance on an operator for the decision-making process.

Further statements by the inventors in arguing for allowance of their claims in their Response continued to characterize their method by which final tooth positions may be determined. They stated, “The present invention of applicants is directed toward the most complete and fully automated method for orthodontic appliance design and manufacture made.” (emphasis added). None of the prior statements in the Response were limited to particular claims. Again, in a section entitled “Deriving Finish Positions from Derived Ideal Dental Archform,” the inventors argued, “The judgment, or decision making, on the acceptability of tooth positions must be imposed externally of Lemchen’s system. This leads to human error and inconsistencies from patient to patient. Lemchen does not disclose this being done automatically thereby avoiding such errors and inconsistencies.” In that same section, the inventors conclude, “Therefore, Lemchen, while primarily concerned with bracket placement, uses a user interactive computer system to calculate tooth finish positions, [but] applicants have provided a computerized system with the intelligence to decide for itself the best finish positions of the teeth.” (emphasis added). That statement was directed to amended claims 1-30, 35-38, and 65-72, but was not associated with particular language from those claims. Furthermore, the method of amended claim 1 included the step of “deriving with the computer tooth finish positions,” demonstrating that the same subject

matter of automatic determination of finish tooth positions was included in those claims. In an effort to further bolster their arguments to the examiner, the applicants also submitted a Declaration from an orthodontist, Michael W. Scott. Dr. Scott's declaration states, "In applicants' overall method, it is a computer, not an orthodontist or an orthodontically skilled computer operator that makes the decision on the finish positions in which the teeth are to be placed."

With these and other similar statements from the prosecution history of the '562 patent in mind, we address the claims of the Ormco patents involved in this lawsuit. Ormco has asserted infringement of claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 10-17, 23-29, 30-36, 46-68, and 70-79 of the '444 patent.

All of the above claims require determining the finish positions of the teeth. E.g., '432 patent, claim 1 ("producing desired tooth position signals containing digitized data of desired positions of a plurality of the patient's teeth"); '243 patent, claim 1 ("a computer programmed . . . to calculate finish positions of the teeth of the patient"); '861 patent, claim 1 ("determining treatment positions of the teeth"); '444 patent, claim 10 ("a computer programmed to apply at least some automated tooth position criteria to produce a digital model of the teeth of the scanned shapes in desired positions"). Although their claim language does not expressly recite automatic control of the finish tooth positioning, that is what they mean, and that is all that the specification describes; the specification does not support operator positioning. Moreover, the prosecution of the '562 patent, with the same specification, makes clear that the inventors understood their invention to encompass only automatic positioning because they so argued in

order to distinguish their claims over Lemchen. We are mindful of the precaution that we must not incorporate into the claims limitations only found in the specification. We are not doing so here, nor did the district court. We are interpreting the claims in light of the specification. The situation here involves specifications that in all respects tell us what the claims mean, buttressed by statements made during prosecution in order to overcome a rejection over prior art. Accordingly, to attribute to the claims a meaning broader than any indicated in the patents and their prosecution history would be to ignore the totality of the facts of the case and exalt slogans over real meaning. We thus agree with the district court that in light of the specification of the Ormco patents and statements from the prosecution history of the parent '562 patent, the claims specified above require automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

Ormco has also asserted infringement of claims 1-5, 8, 9, and 18-22 of the '444 patent. Claims 2-5, 8, and 9 depend from independent claim 1. The method of claim 1 does include the limitation "through an operator interacting with a computer located remote from the orthodontic practitioner, altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired arrangement of the teeth of the patient." Ormco argues that the specific recitation of an operator in this clause differentiates this claim from other claims in which the operator is not mentioned and supports the scope of the claim to allow for the operator to select the finish tooth positions or at least aid in the process. We do not agree. The role of an operator in this claim and its dependent claims is only to help generate and enter the tooth data into the computer that is needed

for the automatic process to operate. The operator does not determine the finish positions of the teeth; that is still done automatically. Thus the district court did not improperly construe claims 1-5, 8, and 9 of the '444 patent to require automatic determination of tooth positions.

The method of claim 18 includes the limitation of “a computer . . . programmed to select geometric parameters on the patient’s teeth from the digitized data by operator-interaction and to produce a digital model of the teeth in desired positions.” Claims 19-22 of the '444 patent depend from independent claim 18. As with claim 1, the fact that a role for the operator is required by the claim language at the beginning of the process does not support Ormco’s argument that determination of finish tooth positions in claim 18 is not done automatically. Thus, in light of the specification of the Ormco patents and statements from the prosecution history of the '562 patent as a whole, “altering the graphic representation to arrange a plurality of the teeth in relation to each other . . . to produce a digital model of a desired arrangement of the teeth of the patient” and “produc[ing] a digital model of the teeth in desired positions” each require automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

We reach a different conclusion with respect to claims 37-40, 45, and 69. The district court treated those claims in the same manner as all the others. Align argues that the methods of claims 37-40, 45, and 69 similarly relate to automatic design or automatic calculation of finish tooth positions. We do not agree. Those claims relate to the preliminary gathering and organization of tooth data as an aid to further unspecified orthodontic treatment or for use in creation of a digital model, not to the specific

automatic determination of finish tooth positions. Such preliminary gathering and organization do not, by themselves, determine finish tooth positions. We therefore conclude that claims 37-40, 45, and 69 do not require automatic computer determination of finish positions of teeth, and that the district court thus erred in so concluding. However, each of the dependent claims 41-44 requires “manipulating the separate digital representations of the generated data in a computer to rearrange the shapes of the individual teeth” into “desired relative positions.” Such rearrangement requires determination of the finish positions of the teeth and therefore as with the other claims in suit discussed previously, automatic determination of those finish positions is implicit in those claims. Thus, in light of the specification of the Ormco patents and statements from the prosecution history of the '562 patent as a whole, “manipulating . . . the individual teeth” into “desired relative positions” requires automatic computer determination of the finish positions of the teeth without human adjustment of the final results.

In summary, we conclude that all of the asserted claims of the Ormco patents, except claims 37-40, 45, and 69 of the '444 patent, require automatic computer determination of the finish positions of the teeth without human adjustment of the final results. Since Ormco does not challenge the district court's finding that Align relies on skilled operators rather than a fully automated computerized process to determine finish positions of the teeth, we affirm the district court's grant of summary judgment of noninfringement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent. However, because claims 37-40, 45, and 69 of the



'444 patent do not require automatic computer determination of teeth finish positions, we reverse the district court's grant of summary judgment of noninfringement as to those claims and remand for further proceedings consistent with this opinion.

We accept that Ormco's argument, and that of the dissent, that the district court failed to conduct a claim construction in this case focusing on specific claim language, is not lacking in force. However, we review decisions, not opinions, see Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540 (Fed. Cir. 1983), and when we are able to fully comprehend the specification, prosecution history, and claims and can determine that, to the extent we have indicated, the district court arrived at the correct conclusion, we need not exalt form over substance and vacate what is essentially a correct decision.

#### B. Nonenablement

Enablement is a question of law that we review de novo. Liquid Dynamics, Corp. v. Vaughan Co., Inc., 449 F.3d 1209, 1224 (Fed. Cir. 2006). As this was a summary judgment determination, all facts must be construed in the light most favorable to the nonmoving party. The party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention. See Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1186 (Fed. Cir. 2002); Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1378 (Fed. Cir. 1999).

As an initial matter, the district court's grant of summary judgment of nonenablement hinged upon its construction of the claims of the Ormco patents. Because the court erred in construing claims 37-40, 45, and 69 of the '444 patent, we

reverse the grant of summary judgment of nonenablement as to those claims and remand for further proceedings consistent with this opinion.

As for the other claims, Ormco argues that the determination of enablement should focus only on the specification of its patents rather than on its development work on its commercial Elan and Insignia software. In the alternative, Ormco argues that its evidence demonstrated that the Elan and Insignia products were capable of automatically determining final tooth positions. Align responds that an inventor's inability to actually practice his invention is proof of lack of enablement, that mere uncorroborated inventor testimony on enablement is insufficient to create triable issues of fact, and that the method taught in the specification of the Ormco patents cannot determine useful tooth finish positions because it fails to account for the initial tooth positions and thus fails to address problems such as tooth collisions or excessive application of force.

We agree with the district court's summary judgment on enablement. The district court reviewed deposition testimony of the inventors stating that the Elan and Insignia software incorporated the automatic determination aspect of the invention, but did not accept that assertion as sufficient to create triable issues of fact given other more specific admissions by the inventors. Ormco has implicitly conceded that the Elan and Insignia software represented attempts to follow the patents' specifications by arguing that those products demonstrated enablement of the Ormco patents.

But during his May 12, 2004, deposition, Dr. Andreiko, one of the inventors of the Ormco patents, testified that Ormco had never attempted to create a computerized system that automatically determined tooth positions without human decision making.

He also testified that the manual override had been used on all of the approximately forty cases treated using the Insignia product and that, while it was a goal to have the software generate final tooth positions that would not require use of the override, variations in human anatomy had prevented the attainment of that goal. Dr. Andreiko was also unsure if the problems due to variations in human anatomy could be overcome. No convincing countering evidence was produced by Ormco.

If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement. Substantial doubt concerning the enablement of the invention was cast by the inventors in this case. The district court so concluded, and we have no reason to disagree. We thus affirm the summary judgment of nonenablement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent because clear and convincing evidence establishes that a person of ordinary skill in the art did not and could not accomplish automatic computer determination of teeth finish positions based upon the Ormco patents' specification.

### C. Cross-Appeal

Anticipation is a question of fact, but, in reviewing a grant of summary judgment of invalidity for anticipation, we determine de novo whether the evidence creates genuine issues of material fact that should have precluded summary judgment. See Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1375 (Fed. Cir. 2006); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed. Cir. 2001).

On cross-appeal, Align argues that the district court misconstrued the term “system” in claims 1-3 of the ’548 patent in concluding that orthodontic appliances created by an iterative process could fulfill the requirements of that term. Align also argues that the district court erred in construing the language “marked to indicate their order of use” from claims 1 and 11 of the ’548 patent because the court found that the information on order could be conveyed to the orthodontist rather than the patient. Finally, Align argues that there was no public use of Dr. Rains’ devices, particularly as to the “marked” limitation.

In response, Ormco argues that our recent decision in Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299 (Fed. Cir. 2006) (“Ormco I”), requires that we affirm the district court’s decision. Ormco also argues that the district court’s construction of the “system” and “marking” language was correct and that the finding of anticipation by Dr. Rains’ work should thus be affirmed. Finally, Ormco argues that the district court erred in its evaluation of Dr. Harrell’s work, which also would have rendered Align’s claims obvious.

We agree with Ormco that under the law of the case doctrine, the decision of this court in Ormco I controls the outcome of the cross-appeal here, and we therefore affirm the district court’s summary judgment ruling that claims 1-3 and 11-13 of the ’548 patent are invalid. “Under [the law of the case] doctrine a court adheres to a decision in a prior appeal in the same case unless one of three exceptional circumstances exist: (1) the evidence in a subsequent trial is substantially different; (2) controlling authority has since made a contrary decision of the law applicable to the issues; or (3) the earlier ruling was clearly erroneous and would work a manifest injustice.” Gould, Inc. v. United

States, 67 F.3d 925, 930 (Fed. Cir. 1995). Because none of those exceptional circumstances exists in this case, the doctrine applies.

In Ormco I, this court decided that claims 10 and 17 of Align's '548 patent were invalid as obvious. Claim 10 is dependent on independent claim 1, and claim 17 is dependent on independent claim 11. Because claims 10 and 17 were found to have been obvious, the broader claims 1 and 11 must also have been obvious. Claims 2 and 3, and 12 and 13, of Align's '548 patent are also dependent on independent claims 1 and 11, respectively. Thus, their validity can only be sustained based upon the language of the dependent claims themselves. In Ormco I, this court decided that claims 2 and 3 of Align's '611 patent, which are dependent claims, were invalid as obvious. The language of claims 2 and 3 of the '611 patent is exactly the same as the language of claims 2 and 3 of the '548 patent. Furthermore, the language of claims 12 and 13 of the '548 patent differs from the language of claims 2 and 3 of the '611 patent only in that the word "method" replaces "system" and in that they depend on claims 11 and 12, respectively. Such a difference is not patentably significant. Therefore, claims 2 and 3 and 12 and 13 of the '548 patent must be invalid as obvious as well.

We thus affirm the district court's grant of summary judgment of invalidity as to claims 1-3 and 11-13 of the '548 patent.

#### CONCLUSION

For the reasons stated, we affirm the district court's grant of summary judgment of noninfringement and nonenablement as to claims 1, 9, and 10 of the '432 patent; claims 1 and 2 of the '243 patent; claims 1, 3, 4, 9-12, and 16-18 of the '861 patent; and claims 1-5, 8-36, 41-44, 46-68, and 70-79 of the '444 patent. We reverse the district

court's grant of summary judgment of noninfringement and nonenablement as to claims 37-40, 45, and 69 of the '444 patent and remand for further proceedings consistent with this opinion. Finally, we affirm the district court's grant of summary judgment of invalidity as to claims 1-3 and 11-13 of the '548 patent.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

# United States Court of Appeals for the Federal Circuit

2006-1240, -1274

ORMCO CORPORATION

Plaintiff/Counterdefendant-Appellant,

and

ALLESEE ORTHODONTIC APPLIANCES, INC.,

Counterdefendant,

v.

ALIGN TECHNOLOGY, INC.,

Defendant/Counterclaimant-Cross  
Appellant.

O'MALLEY, District Judge,\* concurring in part and dissenting in part.

I concur in the majority's decision that claims 37-40, 45, and 69 of the '444 patent do not require automatic computer determination of teeth finish positions, and that the law of the case doctrine bars Align's cross-appeal. I respectfully dissent, however, from those portions of the majority's decision that affirm the district court's grants of summary judgment to Align on the issues of non-infringement and non-enablement. I believe that the district court failed to construe properly the relevant claim terms, and improperly analyzed and shifted the burden of proof on the issue of enablement. I further believe that an insufficient record exists to support an attempt to correct the district court's omissions by construing the claims on appeal. I find further that the majority's decision, while acknowledging the need to construe the claims, improperly imports limitations

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\* Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

from both the specifications and an ancestor patent into many of those claims. For these reasons, I would reverse and remand.

I.

Align's principal argument, implicitly accepted by the majority, is that neither the district court, nor this court on review, need begin the infringement analysis with the language of the claims. Instead, Align argues that an examination of the specification of the patents in suit and the prosecution history of an antecedent patent permits a court to find that the heart of Ormco's invention is the practice of automatically determining finish tooth positions and to compare the accused product to that finding, rather than to the claims of the governing patents. I disagree.

At the outset, it is apparent that the trial court improperly considered the question of infringement without actually construing the claim terms at issue. Indeed, the district court specifically stated that it, "was not interpreting the specific language of the claims to favor one side or another." Ormco Corp. v. Align Tech., Inc., No. 03-cv-00016, slip op. n.1 (C.D. Cal. May 13, 2004).<sup>1</sup> Though this court has undertaken claim construction in the first instance, it has also remanded cases for further construction in the absence of any meaningful claim construction by the district court. The court has rejected the assertion that, because it conducts a de novo review of claim construction, a district court's claim construction "does not matter" and the absence of a claim construction is not error. Nazomi Commc'n, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1371 (Fed. Cir. 2005). In Nazomi, the court explained, in remanding for further claim construction, that

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<sup>1</sup> The district court cited Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1347 (Fed. Cir. 2004), as support for its claim construction approach. In Microsoft, however, contrary to the approach taken by the district court here, this court turned to the specification and prosecution history only after an examination of the claim language. See id.



“[t]his court’s review of a district court’s claim construction, albeit without deference, nonetheless is not an independent analysis in the first instance. Moreover, in order to perform such a review, this court must be furnished ‘sufficient findings and reasoning to permit meaningful appellate scrutiny.’” Id. (citing Gechter v. Davidson, 116 F.3d 1454, 1458 (Fed. Cir. 1997)). The district court here has furnished this court with no such findings. See also Shuffle Master, Inc. v. Vendingdata Corp., 163 Fed. Appx. 864, 868-69 (Fed. Cir. 2005) (“While claim construction is a question of law, the district court’s analysis is important to the process of claim construction, and in this context, as in others, we decline to construe the claim without the guidance of the district court’s construction.”); Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1311 (Fed. Cir. 2003) (finding: “[i]n order to review the court’s finding of non-infringement, we must know what meaning and scope the district court gave to the asserted claims”); Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 791 (Fed. Cir. 1995) (stating that the “entire omission of a claim construction analysis from the opinion . . . provide[s] an independent basis for remand”).

While I sympathize with the district court’s desire to resolve the case before it without resort to the daunting task of construing ninety-two claims in four separate patents, a non-infringement decision which eschews the very exercise of claim construction is inconsistent with this court’s repeated directives to district courts.<sup>2</sup> I

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<sup>2</sup> There are legitimate ways in which district courts can streamline the claim construction analysis when faced with myriad claims from multiple patents. District courts may choose, for instance, to construe only the independent claims of the various patents, or may direct the parties to identify the most representative claims for construction. In that way, the district court can provide guidance as to its construction of the most critical or oft-repeated claim terms and, thus, provide a roadmap with respect to the direction any additional claim construction might take. Employing strategies to

believe, accordingly, that the district court's failure to construe the claim language in this case, standing alone, warrants remand.

## II.

Rather than remand the matter, the majority chooses, instead, to conduct its own infringement analysis. It opens that analysis by recognizing that claim construction begins with the language of the claims themselves. In support, the majority cites Phillips and Markman for the truisms that, "the claims of a patent define the invention to which the patentee is entitled the right to exclude," and that, though claims, "must be read in view of the specification, of which they are a part," it is the language of the claims that is to be construed, not the specification. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The majority, nevertheless, appears to ignore its own opening admonitions in the remainder of its opinion. First, the majority does not "begin" with the language of the claims. Indeed, it never actually tells us what word or words in the claims in suit it purports to construe. At best, after examining the specification of one of the patents in suit (but not its prosecution history), and the prosecution history of a patent which is not in suit, it backs into a form of claim construction by asserting that all of the claims address themselves to the practice of determining finish tooth positions. Nowhere, however, does the majority tell us what language is used in which claims to describe that practice, or why such language is in need of interpretation.

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streamline the claim construction process is fundamentally different, however, from avoiding the process altogether.

The majority concedes, as it must, that none of the claims in suit “expressly recite automatic control of the finish tooth positioning.” Despite the absence of this language in the claims, however, the majority concludes that this unstated (and seemingly important) limitation is “what [the claims] mean.”

In its analysis of the specification, the majority first cites to general statements in the Background and Summary of Invention sections of the patent where the inventors discuss the benefits of computer-assisted (i.e., automated) methods for designing orthodontic appliances, most particularly the greater accuracy that can be gained by reducing reliance on human decision-making. It then examines the preferred embodiments and concludes that those embodiments only contemplate human or operator input into the process at the front end—i.e., when the user first inputs the data into the computer for processing. From these portions of the specification, the majority concludes that the essence of Ormco’s invention requires, “automatic determination of the finish positions of teeth without human adjustment of the final results.” This exercise of attempting to glean the intended invention from sources other than the claims themselves is precisely what Align asked that we do. (See Appellee’s Br., 36, 39 (“Ormco made it very clear in the specification . . . that the very nature of its invention was for automatic computer determination of the finish positions of teeth . . . ;” and “the statements Align drew from the specification and the file histories are admissions concerning the fundamental nature of Ormco’s invention, not narrow statements concerning the meaning of some particular specific term.”) (emphases in original).)

This court, however, has rejected a claim construction process based on the “essence” of an invention. See, e.g., Allen Eng’g Corp. v. Bartell Indus., Inc., 299 F.3d

1336, 1345 (Fed. Cir. 2002) (“It is well settled that ‘there is no legally recognizable or protected essential element, gist or heart of the invention in a combination patent.’”) (citing Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 345 (1961)). Indeed, this court has done so quite forcefully and quite recently. See MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) (“We sympathize with the district court’s choice, since we agree that [the feature] is an essential element of the invention . . . . However, we cannot endorse a construction analysis that does not identify ‘a textual reference in the actual language of the claim with which to associate a proffered claim construction.’”) (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999)). Simply stated, “automatic determination of finish tooth positions without human adjustment of the final results” is a limitation that the majority has amalgamated from the specification of one of the patents in suit without reference to the specific language of any claim of any of the patents.

The court’s recent decision in Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc., 473 F.3d 1173 (Fed. Cir. 2006), counsels against this practice. In Ventana, the issue was the proper construction of the term “dispensing” in a patent claiming automated methods for staining microscope slides. Ventana, 473 F.3d at 1176. The district court construed “dispensing” to require “direct dispensing,” because the embodiments in the specification involved direct dispensing (much as the district court here determined that processing, determining, and calculating orthodontic solutions require automatic processing, automatic determining, and automatic calculating). Id. at 1178. On appeal, Biogenex argued that the specification, when read in its entirety, would lead to the “inescapable conclusion” that the heart of the invention

involved “direct dispensing,” and that the specification implicitly defined the term “dispensing” to mean “direct dispensing.” This court, in Ventana, rejected that narrowed construction of the claims, noting this court’s previous repeated warnings against confining claims solely to disclosed embodiments. Id. at 1181 (“[While] the fact that the disclosed embodiments are limited can assist in interpreting claim language . . . [it] does not in and of itself mean that the method claims at issue are limited to the disclosed embodiments.”); see also Phillips, 415 F.3d at 1323 (rejecting, “the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment”). The court should do so again here.

As mentioned above, there are four separate patents in suit, the ’444, the ’861, the ’243, and the ’432. Ormco points to ninety-two claims in those patents which it claims Align has infringed, seventy-six of which are found in the ’444 patent. By way of example, independent claim 1 of the ’444 patent claims:

A method for use in the orthodontic correction of maloccluded teeth of a patient in accordance with the individual anatomy of the patient and a prescription of an orthodontic practitioner for treatment of the patient, the method comprising:

generating data by scanning shapes of the teeth of a patient;

displaying a graphic representation of the teeth of the patient with a computer from the generated data; and

through an operator interacting with a computer located remote from the orthodontic practitioner, altering the graphic representation to arrange a plurality of the teeth in relation to each other in accordance with the prescription, to produce a digital model of a desired arrangement of the teeth of the patient that includes data of the shapes of a plurality of the teeth positioned relative to each other.

’444 patent col.67 l.57 – col.68 l.6. Though this claim does not exclude operator involvement in the process and, indeed, claims the involvement of an operator in certain

steps of the process, and though the claim never uses the term “automatically,” the majority concludes that this claim, and virtually every other claim in suit, claims a process that is “completely automatic” and allows for no skilled operator involvement. In short, the majority has: imported the terms “automatically” and “automated” from the specification to the claims; found that the terms “automatically” and “automated,” when used in the specification, are the same terms (without a record of how one skilled in the art would construe those terms);<sup>3</sup> concluded that, in every instance, the words “automatically” and “automated” mean “completely automatically” or “completely automated;” found that, where a claim is silent on the issue, use of an operator is wholly precluded; and found that, where involvement of an operator is claimed, that operator cannot be skilled. Given the limited record in the trial court, I cannot find support either in the claims or in the record for these determinations.

In reaching these conclusions, moreover, the majority necessarily ignores those places in the claims where the addition of an automatic process is discussed. For instance, claim 4 of the '444 patent recites: “The method of claim 3 further comprising: generating machine code in response to the designed geometry; and transmitting the machine code to a manufacturing machine to substantially automatically operate the machine in accordance with the shapes of the plurality of teeth.” '444 patent, col. 68, ll. 19-26 (emphasis added). Why would a claim use the phrase “substantially

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<sup>3</sup> The absence of a record regarding how one of ordinary skill in the art would have understood the terms “automated” and “automatically” at the time the application was filed is particularly important. In fast-moving technologies, like the computer technology at issue here, words can mean vastly different things at different points in time. Thus, what we would consider to be meaningful advances in the use of computers in a particular process (i.e., injecting automation into a process previously done by hand) today could be far different from what one skilled in the art would understand was possible—and, thus, was novel—even a few years earlier.

automatically operate the machine” if the inventors intended that every claim included a requirement that the machine be operated “completely” or “wholly” automatically? Who or what completes the “substantial” operation of the machine if not an operator? These kinds of questions emphasize the need for an assessment of the actual language used in the claims, rather than a construction of the invention that is reached despite that language.

Apparently recognizing the danger of counseling a district court to rely on language from the specification to the exclusion of language in the claims themselves, and recognizing that the statements in the specifications are less definitive than Align claims, the majority concedes that “standing alone” the statements in the specification may not be conclusive to show that the claims require completely “automatic determination of finish tooth positions.” To support its construction of the invention, accordingly, the majority turns to the prosecution history of the ’562 patent and finds that the doctrine of prosecution history disclaimer mandates the conclusion the majority reaches. This approach is similarly unavailing. See Armament Sys. & Procedures, Inc. v. Monadnock Lifetime Prods., 168 F.3d 1319 (Table), 1998 WL 537746, at \*\*3 (Fed. Cir. Aug. 7, 1998) (citing Markman, 52 F.3d at 980) (emphasis added) (noting that “Monadnock next argues that the prosecution history requires that the four-step process be read into claim 1 of the ’297 patent. Again we disagree,” and finding that “any argument based on prosecution history must fail for the same reason as the specification argument: lack of textual support in the claim”); id. (“Accordingly, statements appearing in the file history of the patent are not sufficient to add entirely new limitations to a claim.”).

Prosecution disclaimer requires a patentee to clearly and unmistakably disavow certain interpretations, and I find no such disavowal here. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005) (“There is no ‘clear and unmistakable’ disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term.”); Omega Eng’g, Inc. v. Reytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Importantly, while the quotations lifted from the ’562 patent history do appear to support the majority’s conclusion that the process contemplated in that potential invention was a highly automated one, that language was proffered to the examiner in connection with claims in that patent which do not share claim language with the majority of the claims at issue in this suit. The amendments were all made in response to the examiner’s concerns regarding the formation of “ideal dental archforms,” and the use of a computer to “derive . . . tooth finish positions . . . to place the teeth on the ideal dental archform.” That process simply is not claimed in the ’444 patent. The majority concedes this fact, but finds no limitations on the application of prosecution disclaimer posed by it. The majority cites Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377, 1384 (Fed. Cir. 1999), and Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990), for the proposition that statements in the prosecution history of an ancestor patent are relevant as long as the patents in suit address the same general subject matter.

The court’s more recent decisions, however, set forth a more restrictive rule—requiring common language or a linguistic “hook” among the claims before resort to a parent application’s prosecution history is appropriate. Invitrogen Corp. v. Clontech



Labs., Inc., 429 F.3d 1052, 1078 (Fed. Cir. 2005) (“[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application.”); ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1383 (Fed. Cir. 2003) (“Although a parent patent’s prosecution history may inform the claim construction of its descendent . . . prosecution history is irrelevant to the meaning of [a] limitation [if] the two patents do not share the same claim language.”); Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305-06 (Fed. Cir. 2001) (finding prosecution history of parent patents to be irrelevant where “there are no common claims in dispute”); see also Alloc, Inc. v. Int’l Trade Comm’n, 342 F.3d 1361, 1381 (Fed. Cir. 2003) (Schall, J., dissenting) (“Statements . . . made during the prosecution of a parent application can only apply to continuation applications if the parent and child patents contain the same claim limitations.”); Serrano v. Telular Corp., 111 F.3d 1578, 1584 (Fed. Cir. 1997) (stating that “[t]he patentee’s statement concerning whether the prior art discloses a ‘send’ signal means is relevant only to those claims which require the generation of such a signal, and those claims are not asserted here” and reasoning that “[a]lthough statements in a file history may of course be used to explain and potentially limit the meaning of claim limitations, . . . [they] cannot be used to add an entirely new limitation to the claim”) (emphases added). Here, however, neither Align, the district court, nor the majority has identified any linguistic hooks between the ’562 and ’444 patents.<sup>4</sup>

Again, the court’s recent decision in Ventana provides guidance on the issue. In Ventana, this court rejected the argument that, in prosecuting an ancestor patent, the

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<sup>4</sup> Ormco concedes that there are linguistic hooks to some claims in some of the patents, particularly in the ’432. This appears true, however, only as to a minority of the ninety-two asserted claims.

applicants disclaimed certain devices that could not dispense reagent “directly to a sample,” explaining that: “[b]ecause claims 1 and 5 of the [descendent] patent use different claim language . . . the alleged disclaimer [of the ancestor patent] . . . does not apply to the asserted claims of the [descendent] patent.” Ventana, 473 F.3d at 1182 (emphases added, citations omitted) (also stating that the court examines a patent’s prosecution history to “determine whether the inventor disclaimed a particular interpretation of a claim term during the prosecution of the patent in suit or . . . of an ancestor application. But the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language.”) (emphasis added). In Ventana, the court correctly examined the specific language of the claims, not the general subject matter of the invention, when it looked to the prosecution history of the ancestor patents. Thus, in Ventana, although the claims of the descendent patent involved similar subject matter and, indeed, shared some common language, this court nonetheless held that critically different language between the claims precluded the use of disclaiming statements made while prosecuting the ancestor patent to limit the claims of the descendent patent. In sum, the only potential relevance of the ’562 prosecution in this case would be to illuminate the construction of a word or linguistic hook shared by the patents in suit.<sup>5</sup> Invitrogen, 429 F.3d at 1078 (stating: “a prosecution disclaimer or prosecution history estoppel argument, . . . falters on the principle that the prosecution of one claim term in a parent application will

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<sup>5</sup> Ormco also correctly points out that claims 1 and 37 of the ’444 patent were allowed in the first office action and that those claims of the ’444 patent that were rejected over Lemchen were allowed after Ormco made amendments having nothing to do with automatically determining the finish positions of teeth. Thus, the majority’s present application of the ’562 history, to the exclusion of the ’444’s own prosecution history, would seem to render the ’444’s prosecution meaningless.

generally not limit different claim language in a continuation application”). Align has not provided those hooks.

### III.

The district court’s rulings regarding enablement were based wholly upon this flawed claim construction and, therefore, are unsustainable as well. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) (stating: “an enablement inquiry typically begins with a construction of the claims”). Specifically, the district court found that, because he believed the patent intended a wholly automatic process, and he did not find that the inventors had ever successfully performed the process in the absence of any operator involvement, the invention was not enabled by the patent. Because, as discussed above, the first of the district court’s premises was based on a flawed infringement analysis, its non-enablement conclusion must also be reversed. There are, moreover, additional flaws with the trial court’s analysis of the enablement of Ormco’s patents that should be noted.

An enablement inquiry turns on whether the specification of a challenged patent: “provide[s] sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation.” Warner-Lambert Co. v. Teva Pharm. USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005) (citations omitted). “Furthermore, ‘[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.’” Id. (quoting In re Wands, 858 F.2d 731, 737 (Fed. Cir.1988)). “Some of these considerations, commonly referred to as ‘the Wands factors,’ include ‘(1) the quantity of experimentation necessary, (2) the amount of direction or guidance

presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” Id. (quoting Wands, 858 F.2d at 737).

Here, however, the district court did not examine the specifications to determine whether one of ordinary skill in the art could make and use the invention without undue experimentation. Indeed, there is no indication that the district court considered any of the factors enumerated in Wands. Ormco Corp. v. Align Tech., Inc., No. 03-cv-00016, slip op. at 3-7 (C.D. Cal. Aug. 23, 2004). Instead, Align only produced, and the district court only focused on, evidence of whether Ormco had perfected a commercially successful version of the invention. Commercial success, however, is not determinative of enablement. See CMFT, Inc. v. Yieldup Int’l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003) (“Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.”).<sup>6</sup> I believe, therefore, that the district court’s limited, improper examination of the enablement issue could not have supported summary judgment in Align’s favor on this issue.

#### IV.

For the foregoing reasons, I cannot endorse the district court’s infringement analysis or its analysis of enablement, and cannot agree with the majority’s construction

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<sup>6</sup> It is also apparent that the district court improperly shifted the burden of proof to Ormco by requiring it to produce corroborated testimony on the issue of enablement. “[C]orroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest.” Finnigan Corp. v. Int’l Trade Comm’n, 180 F.3d 1354, 1369 (Fed. Cir. 1999) (emphasis added). Here, Align, not Ormco, sought invalidation of the patent.

of the claims in the face of an inadequate record upon which to do so. While it ultimately may be true that some language of some of the claims in suit may require the very “construction” the district court and the majority afford them (because the specification is critical to a proper claim construction process, and a parent application does meaningfully inform construction of similar claim language in later patents), it is impossible to tell from the current record whether, and to what extent, that fact is true. It appears, moreover, that, as to many, if not most, of the critical claims at issue, the construction the majority endorses is simply not supported by a proper application of this court’s precedents. Accordingly, I would reverse the district court’s grants of summary judgment, and remand with direction that the claim language at issue be construed and that a record supporting that construction be developed.