

United States Court of Appeals for the Federal Circuit

05-1518, -1534, -1575

OPTIVUS TECHNOLOGY, INC.,

Plaintiff-Appellant,

and

LOMA LINDA UNIVERSITY MEDICAL CENTER,

Plaintiff-Appellant,

v.

ION BEAM APPLICATIONS S.A.,

Defendant-Cross Appellant.

Howard B. Miller, Girardi & Keese, of Los Angeles, California, argued for plaintiff-appellant Optivus Technology, Inc.

John W. Holcomb, Knobbe, Martens, Olson & Bear, LLP, of Riverside, California, argued for plaintiff-appellant Loma Linda University Medical Center. With him on the brief were William B. Bunker, Paul A. Stewart, David G. Jankowski, and John N. Kandara, of Irvine, California. Of counsel was Abraham W. Chuang.

Brian E. Ferguson, McDermott Will & Emery LLP, of Washington, DC, and Mark P. Wine, of Los Angeles, California, argued for defendant-cross appellant. With them on the brief were Charles Rosenberg and Cynthia A. Lock, of Los Angeles, California.

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

Judge S. James Otero

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DECIDED: November 16, 2006

Before BRYSON, Circuit Judge, ARCHER, Senior Circuit Judge, and LINN, Circuit Judge.

LINN, Circuit Judge.

Optivus Technology, Inc. (“Optivus”) and Loma Linda University Medical Center (“Loma Linda”) appeal from a final judgment of the United States District Court for the Central District of California. Optivus challenges the district court’s order dismissing its claim under California unfair competition law and granting summary judgment to Ion Beam Applications S.A. (“IBA”) on Optivus’s claims for a violation of the Florida Deceptive and Unfair Trade Practices Act, for a violation of the Lanham Act, and for

intentional interference with prospective economic advantage. Optivus Tech., Inc. v. Ion Beam Applications S.A., No. CV 03-2052 SJO (VBKx) (C.D. Cal. Dec. 30, 2004) (“Unfair Competition Claims Order”). Loma Linda challenges the district court’s order granting summary judgment of invalidity for U.S. Patent Nos. 4,870,287 (the “287 patent”) and 5,260,581 (the “581 patent”) and summary judgment holding that IBA did not infringe the ’287 patent. Optivus Tech., Inc. v. Ion Beam Applications S.A., No. CV 03-2052 SJO (VBKx) (C.D. Cal. Mar. 13, 2005) (“Patent Claims Order”). On cross-appeal, IBA challenges the district court’s denial of its motion to amend the pleadings. Optivus Tech., Inc. v. Ion Beam Applications S.A., No. CV 03-2052 SJO (VBKx) (C.D. Cal. Dec. 29, 2004) (“Motion to Amend Order”). We conclude that the district court erred in dismissing Optivus’s California unfair competition law claim and in granting summary judgment on Optivus’s Lanham Act claim. We otherwise affirm the district court’s rulings. Thus, we affirm-in-part, reverse-in-part, and remand.

BACKGROUND

Optivus and Loma Linda are the purported exclusive licensee and assignee, respectively, of the ’287 and ’581 patents, which relate to the use of proton beams in cancer therapy. The ’287 patent is directed to a proton beam therapy facility that generates a proton beam and delivers it to one of multiple treatment rooms. The treatment rooms are equipped with movable gantries that enable an operator to direct the beam to a patient at a specific angle. The proton beam therapy system is illustrated in figure 1 of the ’287 patent, which is reproduced below.

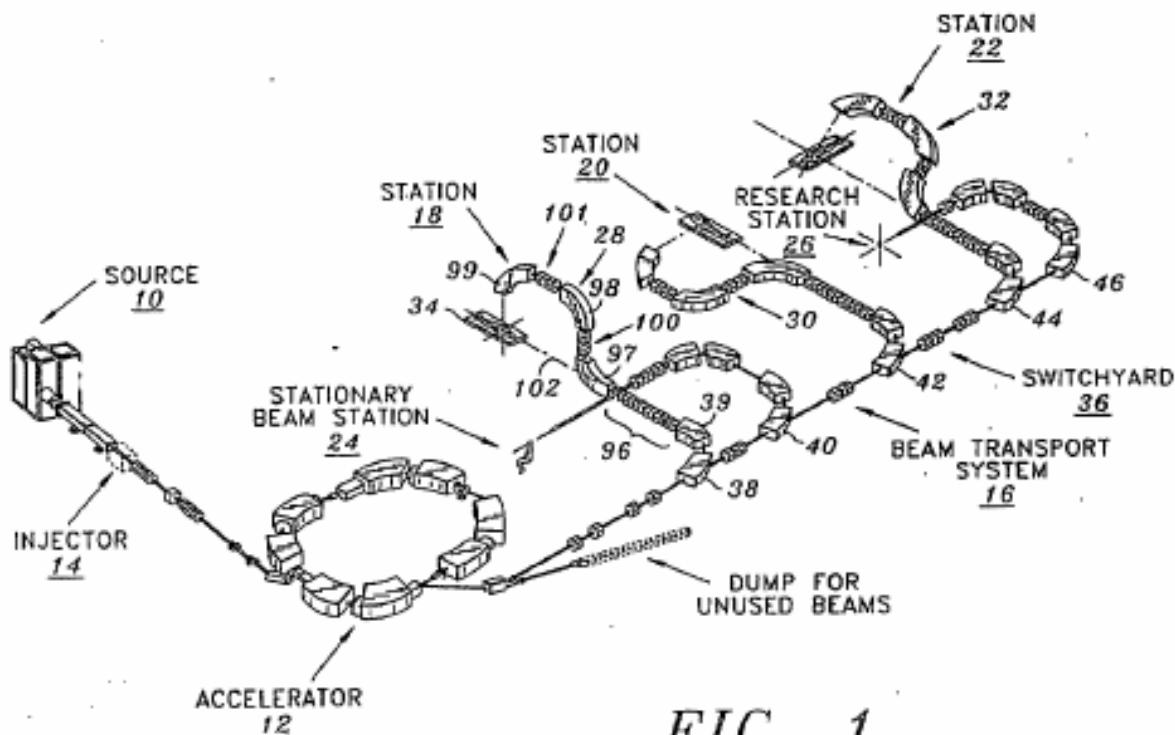


FIG. 1

Claim 1 of the '287 patent is the only independent claim and provides, in relevant part:

1. A proton beam therapy system comprising:
 - a plurality of separate patient treatment stations each having a patient support for orienting a patient in a fixed position;
 - a source of protons;
 - an accelerator for accelerating protons as a beam;
 - an injector for transporting protons from the source to the accelerator;
 - ...
 - a gantry at each treatment station each rotatable about a different axis of rotation and carrying optics for receiving a proton beam on its axis of rotation, transporting the proton beam away from the axis of rotation and returning the proton beam on a path perpendicular to and intersecting the axis at a target isocenter within the patient whereby with rotation of the gantry the proton beam is delivered to the target isocenter from several different angles and
 - ...
 - a control system for the proton beam therapy system including an operator controllable means for (1) selectively switching the first switching magnet between its first and second states and (2) controlling the rotational position of the first gantry to direct the proton beam exiting the first switching magnet in its first state to the target isocenter for the first treatment station along one or more controlled angles.

'287 patent, col. 14, ll. 1-40. The highlighted limitations are at issue on appeal and are termed, respectively, as the "injector" and "controllable means" limitations.

The '581 patent is directed to a safety system for a multi-room proton beam therapy facility that verifies a treatment room selection before the proton beam is sent. A flow diagram of a preferred form of the safety system is depicted in figure 4 of the '581 patent, which is reproduced below.

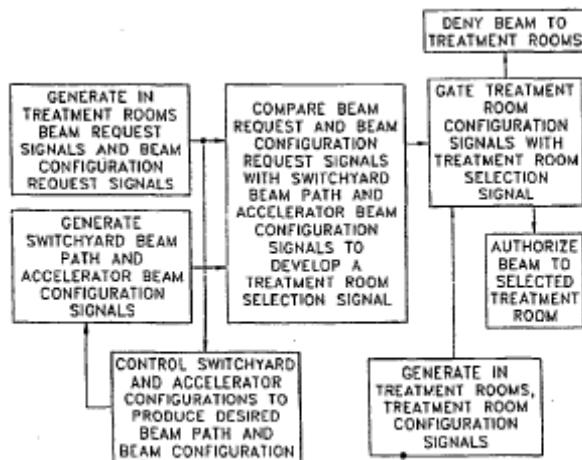


FIG. 4

Claim 1 of the '581 patent is the broadest claim and provides:

1. A method of treatment room selection verification in a radiation beam therapy system comprising radiation beam source, beam accelerator, plurality of treatment rooms and a switchyard for directing accelerated beam from the accelerator to a selected one of the treatment rooms, the method comprising the steps of:
 - (a) receiving a beam request signal from one or more of the treatment rooms;
 - (b) verifying the authenticity of one of the beam request signals from one of the treatment rooms; and
 - (c) authorizing beam transport to the one of the treatment rooms.

'581 patent, col. 9, ll. 1-12. The highlighted limitation is at issue on appeal and is termed the "verifying" step. Also at issue is the "beam path configuration signal" limitation, which is present in claims 2-13. See id., col. 9, ll. 15, 22, 38-39.

Optivus and IBA are competitors engaged in the business of marketing and selling proton beam therapy systems. The University of Florida (“Florida”) was interested in such a system and signed a non-binding letter of intent with Optivus in 1999. That letter ultimately expired on March 15, 2000. After expiration of the letter of intent, Florida gave serious consideration to other vendors and eventually awarded a contract to IBA. In August 2002, Optivus sued IBA for patent infringement. The complaint was later amended to add Loma Linda as a co-plaintiff and to include additional claims for, inter alia, unfair competition under California law, see Cal. Bus. & Prof. Code §§ 17200-17210, (the “California unfair competition law” claim); unfair competition under the Florida Deceptive and Unfair Trade Practices Act, see Fla. Stat. §§ 501.201-501.213, (the “Florida Unfair Trade Act” claim); unfair competition under section 43(a) of the Lanham Act, see 15 U.S.C. § 1125(a), (the “Lanham Act” claim); and intentional interference with prospective economic advantage under Florida tort law (the “intentional interference” claim). IBA filed counterclaims seeking, inter alia, declaratory judgments of invalidity and non-infringement of the ’287 and ’581 patents.

The district court held a claim construction hearing on August 6, 2004 and filed an order construing the relevant limitations of the ’287 and ’581 patents. Optivus Tech., Inc. v. Ion Beam Applications S.A., No. CV 03-2052 SJO (VBKx) (C.D. Cal. Aug. 31, 2004) (“Claim Construction Order”). On November 24, 2004, IBA requested leave to amend its answer to add a defense of unenforceability of the patents at issue due to inequitable conduct; the court denied IBA’s request. Motion to Amend Order, slip op. at 7. On December 30, 2004, the district court dismissed the California unfair competition law claim for failure to exhaust administrative remedies. Unfair Competition Claims

Order, slip op. at 23-25, 36. The district court also granted summary judgment to IBA on the Florida Unfair Trade Act claim, the Lanham Act claim, and the intentional interference claim. Id., slip op. at 25-36. On March 13, 2005, the district court granted summary judgment that the '287 and '581 patents are invalid and that the accused products do not infringe the '287 patent. Patent Claims Order, slip op. at 11-44, 53.

On appeal, Optivus challenges the district court's dismissal of its California unfair competition law claim and the court's grant of summary judgment to IBA on its Florida Unfair Trade Act, Lanham Act, and intentional interference claims. Loma Linda challenges the court's grant of summary judgment of invalidity of the '287 and '581 patents and summary judgment of non-infringement of the '287 patent. On cross-appeal, IBA challenges the district court's denial of IBA's motion to amend its answer to include a defense of inequitable conduct.¹ We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

"We review a district court's grant of summary judgment de novo." Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). Summary judgment is proper only if there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

¹ IBA initially raised a conditional "cross-appeal" challenging the court's construction of the "injector" limitation in the '287 patent, but has conceded in its reply brief that such an argument is an alternative grounds for affirming the judgment of non-infringement and is not a proper cross-appeal. See, e.g., Bailey v. Dart Container Corp. of Mich., 292 F.3d 1360, 1362 (Fed. Cir. 2002).

Because the question of whether the administrative remedies in this case have been exhausted is a question not unique to our exclusive jurisdiction, we apply the law of the regional circuit in which the district court sits. See Midwest Indus., Inc. v. Karavan Trailers Inc., 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc in relevant part). In the Ninth Circuit, on a dismissal for failure to exhaust non-judicial remedies, a district court's underlying factual determinations are reviewed for clear error and its application of substantive law is reviewed de novo. Ritza v. Int'l Longshoremen's & Warehousemen's Union, 837 F.2d 365, 369 (9th Cir. 1988).

Claim construction is an issue of law, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), that we review de novo. See Phillips v. AWH Corp., 415 F.3d 1303, 1328 (Fed. Cir. 2005) (en banc); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Whether an invention would have been obvious is a legal conclusion based on underlying factual findings such as the scope and content of the prior art, Graham v. John Deere Co., 383 U.S. 1, 17 (1966), and the existence of a motivation to combine prior art references, In re Kahn, 441 F.3d 977, 985 (Fed. Cir. 2006). Infringement, whether literal or under the doctrine of equivalents, is a question of fact. Ferguson Beauregard v. Mega Sys., Inc., 350 F.3d 1327, 1338 (Fed. Cir. 2003).

"In review of an order denying a motion to amend, a subject which is not unique to patent law, we look to the law of the regional circuit court." Kalman v. Berlyn Corp., 914 F.2d 1473, 1480 (Fed. Cir. 1990). "In the Ninth Circuit, the denial of a motion to amend is reviewed for abuse of discretion." Filmtec Corp. v. Hydranautics, 67 F.3d 931,

935 (Fed. Cir. 1995) (citing DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 186 (9th Cir. 1987)).

II. Unfair Competition Claims

A. The California Unfair Competition Law Claim

The district court noted that the gravamen of Optivus's California unfair competition law claim was that IBA marketed a medical device that had not been approved by the Food and Drug Administration ("FDA") as evidenced by a letter from the FDA to IBA. Unfair Competition Claims Order, slip op. at 23. Although the court determined that Optivus could validly bring such a claim under California law "so long as [the claim] is not related to the requirements of the medical device, but is instead related to, for example, false advertising," the court ultimately concluded that the FDA letter was not a final determination and that Optivus must first exhaust administrative remedies before it could pursue the California unfair competition law claim. See id., slip op. at 25 ("If Optivus is going to bring suit on the basis of FDA action, that suit must be based on a final agency determination and not an interim letter.").

Optivus argues that the district court erred in dismissing the California unfair competition law claim as "non-justiciable" based on a failure to exhaust administrative remedies, contending that there is no administrative process that Optivus could have exhausted before filing suit. IBA counters that the California unfair competition law claim is based on a FDA regulatory letter to IBA, that the letter was not a final determination, and that the court was correct in concluding that the administrative process must be exhausted before a California unfair competition law claim can proceed based on such a letter. Alternatively, IBA argues that we should affirm

summary judgment because no private right of action exists to enforce the Federal Food, Drug, and Cosmetics Act (the “Act”). In reply, Optivus argues that a final FDA determination is not needed to prove that IBA violated the Act and that precedent in California establishes that a California unfair competition law claim can be based on a regulatory violation that could not be directly enforced by a private right of action.

As support for its conclusion that Optivus must first exhaust administrative remedies, the district court cited Biotics Research Corp. v. Heckler, 710 F.2d 1375 (9th Cir. 1983), Dietary Supplemental Coalition, Inc. v. Sullivan, 978 F.2d 560 (9th Cir. 1992), and Estee Lauder, Inc. v. United States Food & Drug Adminstration, 727 F. Supp. 1 (D. Colo. 1989). We find these cases inapposite to Optivus’s California unfair competition law claim. All three cases involve situations in which the plaintiffs sought judicial review of an FDA action that the court concluded was not final. See Biotics Research, 710 F.2d at 1376, 1378; Dietary Supplemental, 978 F.2d at 562, 563-64; Estee Lauder, 727 F. Supp. at 1, 4-6. In such a situation, “one seeking to contest the agency’s determination must exhaust all administrative remedies before seeking review.” Biotics Research, 710 F.2d at 1377.

Here, Optivus is not seeking to contest an agency determination; rather, it is claiming that IBA engaged in unfair competition under California law by marketing a medical device without FDA approval. In that respect, Optivus is not before an agency and has no administrative remedy to exhaust. While the significance of the FDA letter is an issue to be determined in assessing whether California unfair competition law has been violated, the determination of that issue does not require the exhaustion of an

administrative remedy. We therefore conclude that the district court erred in dismissing the California unfair competition law claim for failure to exhaust administrative remedies.

We also find IBA's alternative argument unpersuasive. Although the Act provides that no private right of action exists to redress alleged violations of the Act, 21 U.S.C. § 337, the California Supreme Court has interpreted California unfair competition law such that "a private plaintiff may bring [an unfair competition law] action even when 'the conduct alleged to constitute unfair competition violates a statute for the direct enforcement of which there is no private right of action.'" Kasky v. Nike, Inc., 27 Cal. 4th 939, 950 (2002) (quoting Stop Youth Addiction, Inc. v. Lucky Stores, Inc., 17 Cal. 4th 553, 565 (1998)). Accordingly, we reverse the district court's dismissal of this claim.²

B. The Florida Unfair Trade Act Claim

The parties agree that prior to July 1, 2001, only a consumer could bring a claim under the Florida Deceptive and Unfair Trade Practices Act. See Fla. Stat. § 501.211, Historical & Statutory Notes (noting the change in section 501.211(2) from "consumer" to "person," effective July 1, 2001). The district court thus required Optivus to allege that IBA engaged in conduct violating the Florida Deceptive and Unfair Trade Practices Act after that date in order to recover damages under its Florida Unfair Trade Act claim. The district court noted that the only alleged misconduct that occurred after July 1, 2001

² IBA cites as supplemental authority the recent decision of a Court of Appeal of the State of California in Farm Raised Salmon Cases, 48 Cal. Rptr. 3d 449 (Cal. Ct. App. 2006), dismissing a suit filed under California unfair competition law as preempted by the Act. Because IBA did not argue preemption in this appeal, the question of preemption is not before us, and we decline to address it on the merits. By declining to address this issue, we do not mean to foreclose whatever right IBA may have to raise the issue of preemption before the district court on remand.

was that IBA marketed its device without FDA approval for eleven days. The court concluded that this marketing activity was inconsequential because Florida had already chosen IBA as its vendor for a new proton therapy system in September 2000. Unfair Competition Claims Order, slip op. at 26-27.

Optivus argues that summary judgment on the Florida Unfair Trade Act claim was not proper because the district court erred in concluding that IBA's misconduct after July 1, 2001 was inconsequential. Specifically, Optivus argues that the loss it suffered occurred after July 1, 2001 when IBA and Florida entered into a binding purchase agreement on December 1, 2002. IBA counters that the alleged misconduct and harm both occurred before July 1, 2001 and thus are not compensable under the statute that was effective at that time.

Optivus's focus on when the loss occurred, as opposed to when the conduct occurred, ignores the principle that legislation is presumed not to be retroactive and that "the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place." See Landgraf v. USI Film Prods., 511 U.S. 244, 265 (1994) (quoting Kaiser Aluminum & Chem. Corp. v. Bonjorno, 494 U.S. 827, 855 (1990) (Scalia, J., concurring)). Optivus does not identify, and we have not found, any reason to depart from this principle. Here, it is undisputed that Florida selected IBA as its vendor in September 2000. In this case, it was that selection of IBA over Optivus that created Optivus's loss, not the formal signing of a purchase agreement. Accordingly, the district court did not err in awarding summary judgment to IBA on this claim.

C. The Lanham Act Claim

The district noted that in order to prevail on the Lanham Act claim, Optivus must demonstrate, inter alia, that IBA made a false statement of fact and the statement was material. Unfair Competition Claims Order, slip op. at 29 (quoting Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997)). The court ultimately concluded that the statements identified by Optivus were not material for purposes of the Lanham Act claim. Id., slip op. at 30-34.

Optivus argues that an issue of fact exists as to whether IBA made a materially false or misleading statement—an element of its Lanham Act claim—that caused Optivus not to be awarded the contract with Florida. Optivus points to IBA's statement to Florida that it would finance \$50 million of the technology component of the proposed system (the "financing statement"), IBA's price quote to Florida (the "low-ball offer"), and IBA's representations to Florida regarding the number of patients that its system could treat in a year (the "patient through-put statement") as false or misleading statements.

IBA counters that Florida denies that IBA made any of the alleged statements and that Optivus improperly relies on "self-serving and hearsay-laden" declarations and testimony to establish that such statements were made.

With respect to the financing statement, Optivus presented declarations to support its allegation that IBA promised to provide or secure financing for Florida's proton therapy facility even though it did not have the ability to follow through on that promise; IBA presented declarations and testimony that no such offer was made. Unfair Competition Claims Order, slip op. at 33. The district court therefore concluded that "[t]he facts presented in the instant case are thus contested." Id. However, the court

determined that there was no evidence that such a statement, even if made, was material to Florida's choice of IBA over Optivus. The district court reached that conclusion "given that Hitachi was ranked second and Optivus third in [Florida's] order of preference for vendors," which would presumably result in a contract with Hitachi had IBA not been selected. Id.

In reviewing the record, we conclude that an issue of fact exists as to the materiality of the financing statement. Although a "Technology Workgroup" developed a rating system that ranked Hitachi second and Optivus last, there is no indication that Florida adopted this ranking without consideration of other factors. Indeed, evidence was introduced suggesting that Hitachi was no longer in consideration in June 2000 due to price and communication issues. Optivus introduced evidence suggesting that Dr. Tischer, a representative for Florida, made statements that indicated that the financing statement was a "significant" or "major" factor in choosing a vendor for the proton beam therapy facility. These statements create a question of fact regarding the materiality of the alleged financing statement. Although Dr. Tischer may deny that such statements were made, resolution of what was said is a credibility determination that is resolved by the trier of fact.

Because the district court correctly identified that the facts surrounding the financing statement are contested, and because Optivus has presented evidence that creates a question of fact as to the materiality of that statement, we conclude that the court erred in granting summary judgment to IBA on the issue of the financing statement. We have considered Optivus's arguments regarding the low-ball offer and the patient throughput statement and find them unpersuasive. Accordingly, we reverse

the district court's summary judgment ruling on the Lanham Act claim only with respect to the financing statement.

D. The Intentional Interference Claim

To establish intentional interference, Optivus must demonstrate:

1. the existence of an advantageous business relationship under which that party has legal rights;
2. an intentional and unjustified interference with that relationship by the defendant; and
3. damage to the plaintiff as a result of the interference with the business relationship.

Ahern v. Boeing Co., 701 F.2d 142, 143-44 (11th Cir. 1983) (discussing Florida law).

The district court concluded that Optivus failed to show the existence of a business relationship with Florida after the letter of intent expired on March 15, 2000. Unfair Competition Claims Order, slip op. at 35.

Optivus argues that the district court erred in granting summary judgment to IBA on the intentional interference claim because issues of fact exist as to whether a business relationship between Optivus and Florida existed at the time of IBA's conduct and as to whether IBA's conduct was legitimate competition. IBA counters that after Optivus's letter of intent expired on March 15, 2000, Optivus had no business relationship with Florida, and thus no legal rights, that would preclude IBA's legitimate competition.

The district court's conclusion was not in error. A business relationship is generally "evidenced by an actual and identifiable understanding or agreement which in all probability would have been completed if the defendant had not interfered." Ethan Allen, Inc. v. Georgetown Manor, 647 So. 2d 812, 815 (Fla. 1994). Optivus's arguments demonstrating a business relationship rely entirely on events and interactions that

occurred before March 15, 2000. To the extent these exchanges did create a business relationship, that relationship clearly ended with the expiration of the letter of intent. Optivus points to no evidence of an actual and identifiable understanding or agreement between it and Florida after the letter of intent expired. Moreover, Optivus points to no conduct by IBA before the letter of intent expired that could constitute an intentional and unjustified interference. Accordingly, the district court did not err in awarding summary judgment to IBA on this claim.

II. The Patent Claims and Defenses

A. The '287 Patent

Loma Linda argues that the district court erred in holding that no issue of fact exists on the obviousness of the '287 patent over a neutron therapy facility at the University of Washington and a Conceptual Design Report reference (the "CDR"). Specifically, Loma Linda argues that modifying the University of Washington facility as described by the district court would result in a "death ray" and thus teaches away from an invention designed to treat patients; that there is no evidence supporting the court's conclusion that a motivation to combine references exists; and that no evidence supports that the CDR was publicly disseminated so as to qualify as prior art. Loma Linda also argues that the district court erred in applying the law by determining the obviousness of limitations, rather than the invention as a whole; by placing the burden of proving non-obviousness on Loma Linda; and by disregarding secondary considerations of non-obviousness.

IBA counters that the '287 patent is obvious over the University of Washington facility in view of the CDR, that the CDR provides an unquestionable motivation to

combine the two references, and that Loma Linda and Optivus admitted that the CDR was a publication and thus qualifies as prior art. Loma Linda replies that it did not concede, but rather disputed, that the CDR qualified as prior art.

As an initial matter, we note that Loma Linda does not argue in its opening brief that the prior art combination utilized by the district court—the CDR and the University of Washington facility—fails to read on every limitation of the '287 patent. Although Loma Linda argues in its reply brief that IBA has not shown that the combination meets the “gantry” or “controllable means” limitations, we consider this argument waived because it was not raised in Loma Linda’s opening brief. Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 800 (Fed. Cir. 1990) (“[A]n issue not raised by an appellant in its opening brief . . . is waived.”). We therefore focus on the issues raised by Loma Linda in its opening brief: (1) whether the University of Washington facility teaches away from modification; (2) whether the CDR qualifies as prior art; (3) whether evidence supports a motivation to combine; and (4) the propriety of the court’s application of the law.

First, Loma Linda’s argument that the University of Washington facility teaches away from modification is unpersuasive. The University of Washington facility uses neutrons, rather than protons, to treat cancer. The facility directs a proton beam at a beryllium plate to cause nuclear reactions that produce neutrons, which then travel towards the patient. Loma Linda makes much of the fact that the proton beam used in the University of Washington facility is of such high intensity that if it were modified by removing the beryllium plate, it would kill patients rather than cure them. “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.” Kahn, 441 F.3d at 990 (quoting In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994)). As the district court noted, “the common denominator among the individuals listed [by the parties as demonstrating ordinary skill] is a working familiarity with particle beam technology, particularly as it applies to cancer treatment.” Patent Claims Order, slip op. at 10. Clearly, one of ordinary skill in the art would not simply remove the beryllium plate and direct the high intensity proton beam at a patient without further calculation or adjustment. Nothing about the University of Washington facility can be said to discourage a person having ordinary skill in the art from modifying it to enable proton therapy or to lead the skilled artisan in a path divergent from the path taken by Loma Linda.

Second, we decline Loma Linda’s invitation to question the status of the CDR as prior art. Loma Linda is correct that neither the “Transmittal of Publication” submitted during prosecution of the ’287 patent nor Optivus’s Statement of Genuine Issues of Material Fact (Optivus’s “genuine issues statement”) characterize the CDR in such a way as to qualify as an admission that the CDR was prior art. However, in IBA’s motion for summary judgment of invalidity, it submitted argument and evidence identifying the CDR as a prior art reference and utilizing that prior art to demonstrate obviousness. Loma Linda’s response to that motion did not dispute that the CDR was prior art; in fact, its response made no reference to the CDR at all. Optivus’s response to IBA’s motion likewise did not dispute that the CDR was prior art; indeed, its response referred to and discussed the teachings of the CDR in the context of discussing “prior art” and

“references.” Optivus’s genuine issues statement—the only record citation that Loma Linda points to as evidence of its position on the CDR’s prior art status—notes only that the CDR was not characterized as prior art during prosecution of the patent; it does not dispute that the CDR was prior art. Here, IBA supported its motion for summary judgment of invalidity with evidence sufficient, if unopposed, to establish that the CDR was prior art; the burden of production then shifted to Loma Linda to identify genuine issues that preclude summary judgment. See Fed. R. Civ. P. 56(e); 10A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2727 (3d ed. 1998) (“[I]f the movant makes out a prima facie case that would entitle him to a judgment as a matter of law if uncontested at trial, summary judgment will be granted unless the opposing party offers some competent evidence that could be presented at trial showing that there is a genuine issue as to a material fact.”). Because Loma Linda’s submissions to the district court failed to identify a genuine issue regarding the publication status of the CDR, we decline to consider the merits of that argument on appeal. Singleton v. Wulff, 428 U.S. 106, 120 (1976) (“It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below.”).

Third, Loma Linda’s argument that there is an issue of fact regarding the motivation to combine is unpersuasive. The CDR provides an overview of proton beam cancer therapy from its first proposal in 1946 to the state of the art at the time of the study and notes that recent technological developments in diagnostic and alignment devices had reawakened interest in proton beam therapy. A stated design goal of the proposed facility in the CDR was to create a facility with more treatment rooms, more advanced beam control, and the availability of different energies to treat different tissue

depths. The study discusses proton, neutron, and other particle therapy methods and specifically notes that a neutron therapy facility was in operation at the time of the study. However, the CDR argues that protons have important advantages over neutron and other particle therapy methods. In considering motivation in an obviousness analysis, we ask “whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.” Kahn, 441 F.3d at 988. Here, there is no question that the CDR establishes that a person having a working familiarity with particle beam technology as it relates to cancer treatment, motivated by the need for more effective and efficient proton therapy facilities, would have been led to combine the University of Washington’s neutron therapy facility with the proton beam therapy design outlined in the CDR. We see no error in the district court’s conclusion that a motivation to combine the two references exists as a matter of law.

Finally, the district court’s application of the law does not warrant reversal. The court analyzed the level of skill in the art, the scope and content of the prior art, the differences between the claimed invention and the prior art, and the alleged secondary considerations of non-obviousness. See Patent Claims Order, slip op. at 9-32. The court determined that a motivation to combine the prior art references existed, id., slip op. at 17, and that the references did not teach away from combination or modification, id., slip op. at 30-32, thereby guarding against a hindsight reconstruction of the invention. See Kahn, 441 F.3d at 987 (holding that the motivation-suggestion-teaching test, much like the analogous-art test, is used to defend against hindsight). As

discussed above, the combination of prior art references was proper, and Loma Linda's opening brief does not contest the district court's conclusion that the combination reads on every limitation in the '287 patent.

Loma Linda points to the court's statement that "[t]here is no indication that the desire or ability to provide proton therapy, as opposed to neutron therapy, was non-obvious," Patent Claims Order, slip op. at 17, as a misallocation of the burden of proof. That statement reflected the court's determination that the prior art indicated the motivation and ability to develop proton therapy facilities; it in no way demonstrates a misallocation of the burden of proof. The whole of the district court's opinion indicates that, consistent with Federal Rule of Civil Procedure 56(e), it placed the burden on IBA to support its motion with credible evidence and, upon a *prima facie* showing, shifted the burden of production to Loma Linda to produce evidence demonstrating a genuine issue for trial. The district court also did not disregard secondary considerations of obviousness. Patent Claims Order, slip op. at 24-30. We find Loma Linda's arguments regarding skepticism in the art, commercial success, and long-felt need to be unpersuasive. Because the district court correctly allocated the burden of proof and made the relevant inquiries into obviousness law, and because "[w]e sit to review judgments, not opinions," Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540 (Fed. Cir. 1983), we see nothing in the district court's application of the law that warrants a reversal.

Accordingly, we affirm the district court's summary judgment holding the '287 patent invalid. Having affirmed the judgment of invalidity, we need not address the

judgment of non-infringement. See id. at 1541 (“The claims having been found invalid, the issue [of infringement] has been rendered moot.”).

B. The '581 Patent

Loma Linda argues that the district court erred in holding that no issue of fact exists on the obviousness of the '581 patent over the Fermilab National Accelerator Laboratory Neutron Facility (the “Fermilab” facility). Specifically, Loma Linda argues that there is no evidence indicating that the Fermilab facility employed a safety system with the “verifying” step or the “beam path configuration signal” limitation as required by claims of the '581 patent.³

IBA responds that the Fermilab facility possesses all of the claimed steps and limitations. IBA also responds that Loma Linda did not argue in the district court that the Fermilab facility lacked the “beam path configuration signal” limitation and should not be permitted to do so on appeal.

The “verifying” step in claim 1 of the '581 patent requires “verifying the authenticity of one of the beam request signals.” '581 patent, col. 9, ll. 9-10. Loma Linda does not dispute the court’s construction of this step, which was interpreted to mean “to confirm or establish the genuine or trustworthy nature of one of the beam request signals from one of the treatment rooms.” Claim Construction Order, slip op. at

³ Loma Linda also argues that the district court improperly “mined the record” and held the '581 patent obvious in view of the Harvard Cyclotron Laboratory, the details of which Loma Linda argues were incomplete and uncorroborated. The district court, however, independently held the '581 patent invalid based on the Fermilab facility alone. Patent Claims Order, slip op. at 43. Further, Loma Linda presents a conditional appeal arguing that we should address the construction of the “beam path configuration signal” limitation if we decide to remand. Because we affirm the district court’s judgment of invalidity based on the Fermilab facility, we do not address these arguments.

31. IBA presented evidence demonstrating that the Fermilab facility authenticated a beam request signal before sending the signal. Loma Linda's arguments and expert testimony assert that the "verifying" step requires authentication after the signal has been sent, focusing on the proposition that a signal cannot be confirmed as genuine until it has been made. Such an analysis, however, ignores that the court interpreted the "verifying" step as to confirm or establish authentication. Authenticating a signal before it is sent establishes the genuine nature of the signal. As the district court noted in response to the same argument below: "The word 'after' appears nowhere in claim 1. There are no such limitations on the terminology in the '581 patent. The patent at issue is written with expansive and highly inclusive language." Patent Claims Order, slip op. at 43 n.31. Because Loma Linda's evidence failed to address the entirety of the court's construction, it did not properly rebut IBA's evidence demonstrating that the Fermilab facility possessed the "verifying" step. We therefore conclude that the district court did not err in holding that the Fermilab facility employed a safety system with the "verifying" step.

This court does not need to reach the merits of whether the Fermilab facility employed a safety system with the "beam path configuration signal" limitation because Loma Linda waived this argument by failing to raise it below. Loma Linda argues that the signals used in the Fermilab facility fail to include information about the physical properties of the proton beam, as required by the court's construction. IBA submitted evidence to demonstrate that the Fermilab facility possessed the "beam path configuration signal" limitation. Loma Linda fails to identify—and we fail to find—any support in the record to indicate that it contested this evidence before the district court.

We therefore decline Loma Linda's invitation to consider its arguments based on the "beam path configuration signal" limitation for the first time on appeal. Singleton, 428 U.S. at 120. Accordingly, we affirm the district court's summary judgment holding the '581 patent invalid.

C. The Motion to Amend

On cross-appeal, IBA argues that the district court abused its discretion in denying IBA's motion to amend the pleadings to add a defense of patent unenforceability due to inequitable conduct after the motion cut-off date had expired. Loma Linda counters that the court's denial was proper because IBA was not diligent and had filed the motion for dilatory purposes.

After a scheduling order has been entered, a party "must show good cause for not having amended [its complaint] before the time specified in the scheduling order expired." Coleman v. Quaker Oats Co., 232 F.3d 1271, 1294 (9th Cir. 2000). "This standard 'primarily considers the diligence of the party seeking the amendment.'" Id. (quoting Johnson v. Mammoth Recreations, Inc., 975 F.2d 604 (9th Cir.1992)). The district court determined that IBA's motion was not supported by any evidence, was inexcusably delayed, would result in prejudice to Loma Linda and Optivus, and was likely filed in bad faith. Motion to Amend Order, slip op. at 5-7. We are not persuaded that these determinations were in error. Accordingly, we conclude that the district court did not abuse its discretion in denying IBA's motion to amend.

CONCLUSION

Because the district court misapplied the law in requiring Optivus to exhaust administrative remedies before pursuing the California unfair competition law claim, we

reverse the court's dismissal of that claim and remand for further proceedings. Because a question of fact exists as to whether the financing statement was material, the district court erred in granting summary judgment to IBA on the Lanham Act claim. We therefore reverse summary judgment on the Lanham Act claim only with respect to the financing statement and remand for further proceedings. We otherwise affirm.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

No costs.