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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION FOUR

PATRICIA A. MURRAY DENTAL CORPORATION et al., Plaintiffs and Appellants, v. DENTSPLY INTERNATIONAL, INC., Defendant and Respondent.	A141377 (City & County of San Francisco Super. Ct. No. CGC-04-432370)

Plaintiffs brought this action on behalf of California dentists who purchased the Cavitron ultrasonic scaler (Cavitron) for use during oral surgical procedures. Plaintiffs sued defendant Dentsply International, Inc. (Dentsply)—the manufacturer and marketer of the Cavitron—asserting causes of action under the Unfair Competition Law (UCL) (Bus. & Prof. Code, §§ 17200 et seq.) and for breach of express warranty. The gist of plaintiffs' claims is that the Directions for Use (Directions) indicate Cavitrons can be used in " '[p]eriodontal debridement for all types of periodontal diseases,' " which by implication includes oral surgery, but in fact they cannot because the device accumulates biofilm[1] in its waterlines and is incapable of delivering sterile water during surgical procedures. This is the second appeal in this case. In the first appeal, we reversed the trial court's denial of class certification and remanded for the limited purpose of deciding whether the named representatives could meet the UCL standing requirements specified in *In re Tobacco II Cases* (2009) 46 Cal.4th 298 (*Tobacco II*), and if not, whether amendment should be permitted. (*Weinstat v. Dentsply International, Inc.* (2010)

[1] As will be described in further detail, biofilm is a naturally occurring bacteria that adheres to solid surfaces in virtually all aquatic environments.

180 Cal.App.4th 1213, 1236 (*Weinstat*).) After certifying the class and conducting a nearly month-long bench trial, the trial court found in favor of Dentsply on all claims. The trial court found that plaintiffs, as licensed California dentists, were well aware that biofilm forms in all dental waterlines and that Cavitrons do not produce sterile water. Accordingly, the trial court determined that the dental professionals already knew the facts which they claim ought to have been disclosed. As such, the evidence failed to establish that the class was likely to be misled. Similarly, the trial court concluded that the weight of the evidence established that dental professionals did not understand the warranty that the Cavitron was suitable for use in " '[p]eriodontal debridement for all types of periodontal diseases,' " as a statement that the Cavitron delivered sterile water, or water without biofilm. Finding substantial evidence supports the trial court's rulings, we affirm the judgment.

I. EVIDENCE

A. The Cavitron

The Cavitron ultrasonic scaler is a prescription dental device that enables mechanized debridement of calculus from tooth root surfaces. It serves the same function as a dentist's hand scaler, but its tip vibrates at high frequency (25,000 or 30,000 hz) to assist in removing calculus deposits. Because the vibration generates heat, it sprays water from its vibrating tip to act as a coolant and to provide lavage (flushing) at the treatment site. All Cavitrons, except the "Select" model, are designed to be plumbed to an external water source. (*Weinstat*, *supra*, 180 Cal.App.4th at p. 1220.)

The Cavitron has been widely used for over 40 years in a range of surgical and nonsurgical dental procedures. Class representative Dr. Patrick Keeley first learned about using Cavitrons during surgical procedures while he was in dental school in the 1970's. Dr. Keeley regarded the Cavitron as the "premier[ ]" scaler. And when the time came to get an ultrasonic scaler for his practice, he purchased a Cavitron because he "wanted the best" scaler. Dr. Keeley was quite familiar with using Cavitrons, as he had used them throughout his "entire career." Like Dr. Keeley, class representative Dr. Patricia Murray's exposure to Cavitrons spanned many years, beginning in dental

school, where its instructional uses included periodontal surgery. Dr. Murray estimated that, between 2001 and 2006, she performed approximately 3,000 surgical procedures using a Cavitron.

B. The Cavitron is a Regulated Medical Device

The Cavitron is a "Class II" medical device regulated by the Food and Drug Administration (FDA), and is classified as a "surgical device."[2] (21 C.F.R. § 872.4850 (2014).) It is only sold to licensed dentists. As noted in *Weinstat*, "the Cavitron comes under the purview of the FDA, with its sale restricted to dental professionals. The original iterations of the Cavitron predate the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act. Because the subsequent, post-MDA versions are substantially equivalent to the preexisting technology, the newer versions have been cleared for marketing by the Food and Drug Administration through a premarket *notification* process rather than the full premarket *approval* process. (See 21 U.S.C. § 360(k); 21 C.F.R. § 807.92(a)(3) (2009).). . . [¶] Under the Federal Food, Drug and Cosmetic Act, a medical device is deemed misbranded unless its labeling bears 'adequate directions for use.' (21 U.S.C. § 352(f)(1).) '*Adequate directions for use* means directions under which the layman can use a device safely and for the purposes for which it is intended.' (21 C.F.R. § 801.5 (2009).) By definition, 'adequate directions for use' cannot be prepared for prescription devices such as the Cavitron, because these devices must be used under the supervision of a licensed practitioner. However, such devices will escape the deemed designation of being 'misbranded' where, among other conditions, '[l]abeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is

[2] The FDA classifies numerous devices as "surgical devices," including hand instruments (21 C.F.R. § 872.4565); dental operating lights (21 C.F.R. § 872.4630); and dental injecting needles (21 C.F.R. § 872.4730).

intended, including all purposes for which it is advertised or represented . . . .' (*Id.*, § 801.109(c) (2009).) Dentsply accomplishes this directive by providing 'Directions []', . . . which it expects the dentist to read and follow in using the Cavitron." (*Weinstat, supra,* 180 Cal.App.4th at pp. 1218–1219, fns. omitted.)

C. Cavitron Directions

In 1993, the Directions indicated the Cavitron's use for "root planing during surgery." Dentsply also began marketing DiamondCoat handpiece scaling tips for use in surgical debridement. In 1997, new Cavitron models were introduced in which the indications were stated in broader language to encompass " '[a]ll general supra and subgingival scaling applications' and '[p]eriodontal debridement for all types of periodontal diseases.' " (1997 Directions). (*Weinstat*, *supra*, 180 Cal.App.4th at p. 1219.) The 1997 Directions were in effect during the class period.

Dr. Keeley testified that he never heard any contraindications about the Cavitron and assumed it could be used in surgery. Dr. Keeley admitted that he never read any Cavitron product literature before purchasing the device. He also admitted that he did not read the Directions. It was only after speaking with counsel, did Dr. Keeley ask his officer manager to get a copy of the Directions. Dr. Keeley first read the Directions while preparing for his deposition.

Dr. Murray also did not read the Directions prior to her 2002 purchase. She testified that she would not have purchased a $3,000 device if she knew it could not be used in surgery, because she already had $300 units that could have been used for nonsurgical purposes.

Dr. Mark Ryder, one of Dentsply's experts, testified that it was not necessary for the Cavitron to include a biofilm warning because any dental healthcare professional, whether a periodontist, general dentist, or hygienist "has a fundamental understanding of what biofilms are, both the biofilm on the tooth surface and the biofilm that accumulates in the waterline or could potentially accumulate in a waterline." As such, Dr. Ryder opined that there was no need for the Directions to warn against using Cavitrons in surgery.

In June 2005, while this action was pending, Dentsply sent letters to over 20,000 California dentists emphasizing that "conventional ultrasonic scalers do not deliver sterile fluids unless specifically equipped with a sterile water delivery system. Therefore, if in your professional judgment, any dental procedure requires the delivery of sterile fluids, choose a sterile delivery system." And, beginning with the release of the 2006 Cavitron model, the accompanying Directions added a warning advising against the use of the product where asepsis[3] is required or deemed appropriate. Further, the Directions for the first time "strongly recommended" that the waterlines be flushed weekly with a sodium hypochlorite (bleach) solution. (See *Weinstat*, *supra*, 180 Cal.App.4th at p. 1220.)

D. Periodontal Disease and Treatment

Periodontitis is a bacterial infection within a " 'periodontal pocket' " that forms between the gum and adjacent tooth root surface and jaw bone. If untreated, it can lead to loss of the tooth or adjacent teeth. Periodontitis is treated by debriding (scraping, scaling, or planing) the bacteria-laden calculus (tartar) to remove it from the root and bone surfaces.

In more serious cases, periodontal debridement requires the opening of a gum with a scalpel to expose the infected root and bone surface beneath the gum. While the periodontal pocket itself is infected, cutting the gum exposes normally sterile internal (subcutaneous) tissues and blood vessels to infection from outside agents. On some occasions, this procedure entails cutting (recontouring) the adjacent bone. Periodontal debridement may be performed during various procedures, such as tooth extractions, gingivectomies, and dental implants. Basic periodontal debridement may be performed by periodontists, general dentists, and dental hygienists. However, periodontal debridement with surgical aspects may only be performed by general dentists and periodontists.

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[3] "Asepsis is the 'condition of being asceptic [*sic*],' i.e., free 'from pathogenic microorganisms.' (Merriam–Webster's Collegiate Dict. (10th ed. 2001) p. 67 [definitions for 'aseptic' and 'asepsis'].)" *Weinstat*, *supra*, 180 Cal.App.4th at p. 1220, fn. 7.)

E. Dental Unit Waterlines: Biofilm and Water Quality

A "dental unit" is comprised of the dentist chair, with its directed light, instrument tray, rinsing cup, and automated instruments, including the high-speed hand drill, with lines for electrical power, rinse water, air, and evacuation from the mouth. The most common dental unit is the "A-Dec." Dental unit waterlines represent "the tubes that connect the highspeed handpiece, air/water syringe and ultrasonic scaler to the water supply." (American Dental Association (ADA), ADA Statement on Dental Unit Waterlines, 127 J. of Am. Dental Assn. (JADA) (Feb. 1996) p. 185.)

Biofilms represent "microbial communities that adhere to solid surfaces in the presence of moisture, and are found virtually everywhere in nature. Protected by a thin slime layer . . . these microorganisms, which can include a wide variety of bacteria . . . colonize and replicate in water sources forming a biofilm . . . . Since they are everywhere, biofilms are found in virtually all municipal water lines, including drinking fountains, faucets, showerheads, and dental unit waterlines." (OSHA Review, Regulatory Compliance and Employee Training Information for the Dental Profession, Dental Unit Water Quality, Vol. XIV, No. 14 (July/Aug. 2005) pp. 1–2 (OSHA Review).)

Biofilm contamination of dental unit waterlines was first documented in the 1960's, but it was not until the 1990's that it garnered substantial interest in the dental industry. (OSHA Review at p. 1.) The ADA, as early as 1978, suggested flushing dental unit waterlines with germicides as a means of controlling biofilm formation. (Shearer, Biofilm and the Dental Office, 127 JADA (Feb. 1996) pp. 181, 187.) Since that time, the ADA has sought to develop a consensus solution for improving the quality of dental unit water. (*Ibid.*) In 1995, the ADA issued its "Statement on Dental Unit Waterlines" (1995 ADA Statement), advising that various microorganisms in dental unit waterlines "inevitably" form biofilm on the interior surfaces of waterline tubing. (*Id.* at pp. 185, 187.) The 1995 ADA Statement acknowledged that then-existing commercially available options for improving water quality were limited and involved some additional expense. (*Id.* at pp. 185–186.) The included use of 1) independent water reservoirs; 2) chemical treatment regimens; 3) daily draining and air purging regimens; and 4) point-of-use

filters. (*Id.* at p. 186.) The ADA urged manufacturers of dental equipment to "develop accessory components that can be retrofitted to dental units," to allow water to be supplied by an independent water reservoir and chemically treated to control biofilm. (*Id.* at p. 185.) The 1995 ADA Statement was included in the February 1996 JADA cover story, "Biofilm in the Dental Office." (*Id.* at pp. 181–188.) The cover story noted the absence of any scientific documentation establishing that biofilm in dental unit waterlines represents a definable public health risk. (*Id.* at p. 184.)

California dentists are required to take continuing education classes in infection control every two years. Dr. Randall Rowland, one of plaintiffs' experts, taught courses on infection control, which included topics on water quality and biofilm. Dr. Rowland had described water quality issues as a "hot subject" in continuing education starting in the mid-1990's. Dr. Rowland agreed that the 1995 ADA Statement advised dentists that a combination of various commercially available options were required to control biofilm. Both Dr. Rowland and Dr. Ryder agreed that California dentists understood biofilm forms in all dental waterlines. Dr. Rowland agreed that it had become the practice among California dental professionals to disinfect their waterlines as a result of biofilm accumulation.

Dr. Rowland explained that by the 1990's, it had become common practice for California dentists to "close" their dental waterline systems to ensure an end-to-end treatment of the water. Systems can be closed in a variety of ways, including the use of bleach or other chemical to reduce the bacteria count. Dr. Keeley closed his system in the 1990's, and his officer manager, Patricia Mitchell, taught continuing dental education classes at his office on ways to control biofilm through waterline maintenance. Based upon coursework that she completed in 1990's and literature that she reviewed, as part of state mandatory continuing dental education on infection control, Mitchell understood that biofilm contamination in dental waterlines occurs when biofilm forms on the wall of small bore plastic tubing that delivers water to dental handpieces, ultrasonic scalers, and air water syringes. Mitchell implemented water treatment protocols for Dr. Keeley's office that included ultrasonic scalers connected to dental units.

Dr. Keeley testified that it was his responsibility to comply with the Center for Disease Control (CDC) guidelines and California dental practices regulations. He was aware that infection control standards were evolving and he made an effort to stay informed about infection control practices. He attended Mitchell's course, as it was required to maintain his license in California.

Dr. Murray has a doctorate in microbiology and has taught dentistry, using Cavitrons. Dr. Murray also taught oral microbiology and infection control at the university level for 10 years. Since the mid-1990's, Dr. Murray weekly ran a 10 percent bleach solution through her Cavitrons. She was familiar with the Occupational Safety and Health Administration (OSHA) guidelines, California Dental Regulations and CDC guidelines.

Dr. Murray was also familiar with a 2001 article published in the Journal of Periodontology entitled "Evaluation of Ultrasonic Scaling Unit Waterline Contamination After Use of Chlorine Dioxide Mouth Rinse Lavage." The article was cowritten by one of Dr. Murray's colleagues, Dr. Robert Wirthlin. Dr. Murray was present for the experiments that Dr. Wirthlin conducted using Cavitrons. Dr. Murray also consulted on the methodology Dr. Wirthlin used to conduct his experiments. The article begins by stating that "[d]ental unit waterlines are a source of cross-contamination from . . . biofilm . . . ." (Wirthlin & Marshall, Evaluation of Ultrasonic Scaling Unit Waterline Contamination After Use of Chlorine Dioxide Mouth Rinse Lavage, J. Periodontol (Mar. 2001) p. 401.) The article described biofilms in dental unit waterlines as "a particularly vexing problem." (*Ibid.*) The article further stated: "The same problems occurring in fixed dental units occur in portable accessory equipment such as ultrasonic scalers . . . . Typical ultrasonic scaling units might have over 16 feet of fine tubing, from the water connection to the end of the handpiece, in which to form biofilm." (*Id.* at p. 403.)

Dr. Murray maintained, however, that she had no understanding that biofilm would form within Cavitrons. Dr. Murray did not have any information that was not

privileged—i.e., independent from the information provided by class counsel that the Cavitron had a level of biofilm not present in her dental units.[4]

F. Surgical Standards and Water Quality Guidelines

In 1993, the CDC released its "Recommended Infection-Control Practices for Dentistry, 1993." (CDC, Morbidity and Mortality Weekly Report, Recommendations and Reports, Vol. 42, No. RR-8 (May 1993) (1993 CDC Recommendations).) The recommendations included a section on dental unit water quality, advising: 1) sterile water for surgical procedures that involved the cutting of bone; and 2) thorough flushing of all waterlines between each patient and at the beginning of each day. (1993 CDC Recommendations at pp. 7–8.)

Then, in 1994, the Dental Board of California (DBC) adopted the 1993 CDC Recommendations as legal mandates, requiring minimum water quality standards in California as set forth in the Dental Practices Act (DPA). (Cal. Code Regs., tit. 16, §§ 1000, 1005 (June 29, 2014).) As revised in 1996, the DPA required California dentists to use sterile water in "surgical procedures involving soft tissue or bone" and defined " 'surgical procedures' " as "entries into normally sterile areas of the body." (Cal. Code Regs., § 1005, subds. (a)(5), (b)(2) (July 8, 1996).) Later versions continued to require sterile water in "surgical procedures involving soft tissue or bone," but no longer defined "surgical procedures."

In 2003, the CDC released updated recommendations in its "Guidelines for Infection Control in Dental Health-Care Settings — 2003" (2003 CDC Guidelines). (CDC, Morbidity and Mortality Weekly Report, Recommendations and Reports, Vol. 52, No. RR-17 (Dec. 2003).) The 2003 CDC Guidelines advised that all dental health care professionals "should be trained regarding water quality, biofilm formation, water treatment methods, and appropriate maintenance protocols for water delivery systems."

[4] Co-Counsel Edwin Zinman is a licensed attorney and licensed dentist. Drs. Zinman and Murray had known each other since 1985; Dr. Murray has acted as a paid expert in Dr. Zinman's dental malpractice claims. Dr. Zinman has also referred plaintiff patients to Dr. Murray for treatment as part of the damages requested in such dental malpractice claims.

(*Id.* at p. 29.) They recommended sterile water in surgical procedures where an increased potential for infection exists and drinking or potable[5] water for all routine dental procedures. (*Id.* at pp. 29, 45.) According to the OSHA Review, surgical procedures "are difficult to define objectively, since most dental treatments involve the release of blood, even if in small amounts." (OSHA Review, at pp. 2–3.) The 2003 CDC Guidelines defined surgical procedures as being more invasive in nature, involving incision or excision, exposing the normally sterile areas of the oral cavity. (2003 CDC Guidelines, at p. 32.) Some examples included biopsy, periodontal surgery, implant surgery, and teeth extractions. (*Ibid.*)

The 2003 CDC Guidelines cautioned that "[c]onventional dental units cannot reliably deliver sterile water even when equipped with independent water reservoirs because the water-bearing pathway cannot be reliably sterilized." (2003 CDC Guidelines, at p. 29.) Instead, "[d]elivery devices (e.g., bulb syringe or sterile, single-use disposable products) should be used to deliver sterile water . . . ." (*Ibid.*) The 2003 CDC Guidelines further noted that oral surgery and implant handpieces, including ultrasonic scalers were commercially available that bypass the dental unit to deliver sterile water or other solutions by using single-use disposable or tubing capable of being sterilized. (*Ibid.*)

Dr. Keeley agreed that most procedures, whether surgical or nonsurgical, produce blood. He also agreed with the OSHA Review that it is difficult to define "surgery" for purposes of sterile water delivery. Dr. Keeley explained that in any given procedure a dentist may switch between treated drinking water and sterile water. He gave the example of doing three quadrants of scaling and surgery on two teeth. In that situation, he said a dentist might scale with the treated water and then switch to sterile water when in the surgical area. Based on his professional judgment and training, Dr. Keeley

[5] The Environmental Protection Agency standard for safe drinking water is water having fewer than 500 "colony forming units" per milliliter of water (cfu/ml). (2003 CDC Guidelines, at p. 29.)

selected the type of water depending on the nature of the procedure and the needs of the patient.

Dr. Keeley understood that water for the Cavitron came from his A-Dec unit and he knew the water from the dental tray was not sterile. He said he never really thought about infection control, explaining that his staff "took care of that." Dr. Keeley acknowledged that if he was performing a procedure with an increased potential for infection, he was required to use an FDA-approved sterile delivery method. However, he never assured himself that the Cavitron was an FDA-approved sterile delivery device. Dr. Keeley conceded there simply was no explanation for why he did not think about the quality of the water or fluids he put into patients' mouths during procedures. He further agreed that other professional dentists in California would have likely thought about the quality of water going into their patients' mouths during periodontal dental procedures. Dr. Keeley had no nonprivileged source of information—i.e., independent of information provided by counsel—that led him to understand that the Cavitron did not deliver sterile water. Dr. Keeley had not stopped using the device prior to his call from Dr. Zinman.[6]

Dr. Murray, like Dr. Keeley, used her professional judgment when deciding whether to use water from her A-Dec unit or sterile water from a bulb syringe. Although Dr. Murray knew that once sterile water was input in an A-Dec unit, it came out unsterile, she still expected the Cavitron hooked up to her A-Dec unit to output sterile water. Upon further cross-examination, she admitted that even if sterile water was input into a Cavitron, the output into a patient's mouth would not be sterile. Between 2001 and 2006, Dr. Murray had performed approximately 3,000 surgeries using a Cavitron. And, each time she performed one of those procedures, she was aware that the Cavitron did not provide sterile water. Based on her professional judgment as a trained periodontist and microbiologist, she deemed the Cavitron was safe for those procedures.

[6] Dr. Keeley had known Dr. Zinman for approximately 30 years. Dr. Zinman called Dr. Keeley two weeks after he had purchased his Cavitron. During that conversation, Dr. Keeley agreed to be a class representative.

II. DISCUSSION

A. Standard of Review

We generally apply the familiar substantial evidence test when the sufficiency of the evidence is at issue on appeal. Under this test, " '[W]e are bound by the established rules of appellate review that all factual matters will be viewed most favorably to the prevailing party [citations] and in support of the judgment . . . . "In brief, the appellate court ordinarily *looks only at the evidence supporting the successful party, and disregards the contrary showing*." [Citation.] All conflicts, therefore, must be resolved in favor of the respondent.' " (*Campbell v. Southern Pacific Company* (1978) 22 Cal.3d 51, 60; accord, *Western States Petroleum Association v. Superior Court* (1995) 9 Cal.4th 559, 571.) "When we consider whether the evidence was sufficient to support the . . . verdict, we review the entire record in the light most favorable to the judgment to determine whether there are sufficient facts, contradicted or uncontradicted, to support the judgment. [Citation.] Substantial evidence is evidence that is reasonable and credible. In evaluating the evidence, we accept reasonable inferences in support of the judgment and do not consider whether contrary inferences may be made from the evidence." (*Mammoth Lakes Land Acquisition, LLC v. Town of Mammoth Lakes* (2010) 191 Cal.App.4th 435, 462–463.)

However, when the trier of fact has expressly or implicitly concluded the party with the burden of proof did not carry the burden and that party appeals, " 'it is misleading to characterize the failure-of-proof issue as whether substantial evidence supports the judgment . . . . [¶] Thus, where the issue on appeal turns on a failure of proof at trial, the question for a reviewing court becomes whether the evidence compels a finding in favor of the appellant as a matter of law. [Citations.] Specifically, the question becomes whether the appellant's evidence was (1) "uncontradicted and unimpeached" and (2) "of such a character and weight as to leave no room for a judicial determination that it was insufficient to support a finding." ' " (*Dreyer's Grand Ice Cream, Inc. v. County of Kern* (2013) 218 Cal.App.4th 828, 838; accord, *In re I.W.* (2009) 180 Cal.App.4th 1517, 1528.)

"Where, as here, the judgment is against the party who has the burden of proof, it is almost impossible for him to prevail on appeal by arguing the evidence compels a judgment in his favor. That is because unless the trial court makes specific findings of fact in favor of the losing plaintiff, we presume the trial court found the plaintiff's evidence lacks sufficient weight and credibility to carry the burden of proof. [Citations.] We have no power on appeal to judge the credibility of witnesses or to reweigh the evidence." (*Bookout v. State of California ex rel. Department of Transportation* (2010) 186 Cal.App.4th 1478, 1486.)

B. Fraudulent Practices Under the UCL

1. Applicable Law

The UCL prohibits as unfair competition "any unlawful, unfair or fraudulent business act or practice. . . ." (Bus. & Prof. Code, § 17200.) Written in the disjunctive, this language "establishes three varieties of unfair competition . . . ." (*Podolsky v. First Healthcare Corp.* (1996) 50 Cal.App.4th 632, 647.) We are concerned with the third prong of the statute—an allegation of a fraudulent business practice, specifically claims of misrepresentations regarding the Cavitron's safety for surgical use and the concomitant nondisclosure of biofilm risk by Dentsply.[7]

Under the "fraudulent" prong, a business practice violates the UCL if it is "likely to deceive the public." [Citations.] It may be based on representations to the public which are untrue, and ' "also those which may be accurate on some level, but will nonetheless tend to mislead or deceive . . . . A perfectly true statement couched in such a manner that it is likely to mislead or deceive the consumer, such as by failure to disclose other relevant information, is actionable under" ' the UCL. [Citations.] The determination as to whether a business practice is deceptive is based on the likely effect such practice would have on a reasonable consumer." (*McKell v. Washington Mutual*,

[7] In the trial court, plaintiffs also claimed that Dentsply violated the unlawful prong by reason of its failure to comply with the MDA. Plaintiffs have not raised this issue on appeal.

Inc. (2006) 142 Cal.App.4th 1457, 1471; see *Paduano v. American Honda Motor Co., Inc.* (2009) 169 Cal.App.4th 1453, 1469.)

In cases involving advertising or statements that are not literally false, " '[l]ikely to deceive' implies more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the phrase indicates that the ad is such that it is probable that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." (*Lavie v. Proctor & Gamble Co.* (2003) 105 Cal.App.4th 496, 508 (*Lavie*); accord, *Chapman v. Skype Inc.* (2013) 220 Cal.App.4th 217, 226; *People ex rel. Department of Motor Vehicles v. Cars 4 Causes* (2006) 139 Cal.App.4th 1006, 1016.)

"The fraudulent business practice prong of the UCL has been understood to be distinct from common law fraud. 'A [common law] fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages. None of these elements are required to state a claim for injunctive relief' under the UCL. (*Day v. AT & T Corp.* (1998) 63 Cal.App.4th 325, 332; see *State Farm Fire & Casualty Co. v. Superior Court* (1996) 45 Cal.App.4th 1093, 1105[, disapproved on other grounds in *Cel–Tech Communications, Inc. v. Los Angeles Cellular Tel. Co.* (1999) 20 Cal.4th 163, 184–185].) This distinction reflects the UCL's focus on the defendant's conduct, rather than the plaintiff's damages, in service of the statute's larger purpose of protecting the general public against unscrupulous business practices. (*Fletcher v. Security Pacific National Bank* (1979) 23 Cal.3d 442, 453.)" (*Tobacco II, supra,* 46 Cal.4th at p. 312.)

2. Plaintiffs Failed to Prove the Directions Were Likely to Mislead a Significant Portion of the Targeted Consumers Acting Reasonably

The Directions provided that the Cavitron could be used in " '[p]eriodontal debridement for all types of periodontal diseases.' " To be sure this wording is not a model of clarity, periodontal debridement can be just a deep cleaning or it could involve surgical aspects, such as cutting open a gum. Add to that the ambiguous reference to "all

types of periodontal diseases," which arguably could include diseases requiring surgery, the Directions, to the general public, could be viewed as representing that the Cavitron is suitable for surgical use. However, the fatal flaw in this reasoning is that the targeted consumers of this product are licensed dental professionals.

Whether a statement or advertisement is likely to mislead is generally a question of fact. (See *Linear Technology Corporation v. Applied Materials, Inc.* (2007) 152 Cal.App.4th 115, 134 ["[w]hether a practice is deceptive, fraudulent, or unfair is generally a question of fact which requires 'consideration and weighing of evidence from both sides' "]; accord, *Paduano v. American Honda Motor Co*mpany, *Inc.* (2009) 169 Cal.App.4th 1453, 1459 [reversing order granting summary adjudication in favor of defendant].) Although California courts have held " 'the primary evidence in a false advertising case is the advertisement itself' " (*Brockey v. Moore* (2003) 107 Cal.App.4th 86, 100), it is not the only evidence bearing on the question whether a statement or advertisement is likely to mislead.

Several cases examine the knowledge base of the targeted consumer in assessing whether, under the circumstances, the conduct or advertisement is likely to deceive the targeted consumer. This inquiry is relevant to the reasonableness of the consumer and should not be confused with actual reliance, which is not an element of fraud under the UCL.[8]

In *Lavie*, *supra*, 105 Cal.App.4th 496, the court refused to apply a " 'least sophisticated consumer' " standard rather than the " 'reasonable consumer' " standard to determine whether ads for an over-the-counter pain relief product were likely to mislead or deceive the public. (*Id.* at p. 504.) There, the court held "the standard applied in UCL and false advertising cases is that of the ordinary consumer acting reasonably under the circumstances. Where the advertising or practice is targeted to a particular group or type

[8] Plaintiffs argue that the trial court improperly incorporated a reliance element into its fraud analysis under the UCL. The trial court, however, addressed reliance in terms of whether plaintiffs had established standing. We express no opinion on the standing analysis, as we have directly proceeded to merits.

of consumers, either more sophisticated or less sophisticated than the ordinary consumer, the question whether it is misleading to the public will be viewed from the vantage point of members of the targeted group, not others to whom it is not primarily directed." (*Id.* at p. 512.) In reaching this conclusion, *Lavie* discussed and distinguished *Chern v. Bank of America* (1976) 15 Cal.3d 866 (*Chern*), and *South Bay Chevrolet v. General Motors Acceptance Corporation* (1999) 72 Cal.App.4th 861 (*South Bay*).

Both *Chern* and *South Bay* challenged the identical banking practice of lending money at a " 'per annum' " interest rate that was based on a 360-day year, rather than a full year, thus favoring lenders. *Chern* held that, "[i]n the absence of any evidence" that the general public understood the "365/360" lending practice, the practice was misleading, i.e., likely to mislead future bank customers from the general public, under the UCL as a matter of law, despite the class representative's discovery of the loan terms shortly before signing the agreement. (*Chern*, *supra*, 15 Cal.3d at pp. 873, 876.)

The *South Bay* plaintiffs challenged the same practice on behalf of car dealerships who received General Motors financing (GMAC) and cited *Chern*. (*South Bay*, *supra*, 72 Cal.App.4th at 881–882.) However, *South Bay* affirmed the judgment in GMAC's favor because dealerships using GMAC financing typically understood the 365/360 method, and "[Business and Professionals Code] section 17200 is directed toward protecting the general public, not automotive dealerships aware of GMAC's use of the 365/360 method." (*Id.* at p. 870.)

As noted in *Lavie*, "*South Bay* was a case involving loans made to 'a financially sophisticated automotive dealership with knowledge of the lender's use of the 365/360 method in the parties' ongoing relationship.' ([*South Bay*, *supra*,] 72 Cal.App.4th at p. 884.) Because the practice was directed to automobile dealerships and not to the general public, the court affirmed the trial court's use of a 'reasonable dealership' standard, distinguishing *Chern* as a case directed toward the consuming public. ([*South Bay*, *supra*, 72 Cal.App.4th] at p. 884.)" (*Lavie*, *supra*, 105 Cal.App.4th at p. 512.)

As a question of fact, it was squarely within the province of the trial court to evaluate whether the Directions were likely to deceive a significant portion of licensed

dentists acting reasonably by examining the language in the Directions and weighing, on the one hand, Dr. Keeley's and Dr. Murray's explanations for their belief that the Directions, on its face, included surgical use, and on the other hand, the vast amount of evidence presented regarding the biofilm and related water quality issues, which included: the CDC guidelines requirement of sterile water for surgical procedures; the CDC guidelines recommendation that all dental healthcare professional "should be trained regarding water quality, biofilm formation, water treatment methods . . . ." (2003 CDC Guidelines at p. 29); the ADA position that all dental waterlines inevitably form biofilm; the acknowledgment from Drs. Keeley and Murray that they used their professional judgment to select the water quality based on the patient's needs in light of the particular procedure performed; and that Drs. Keeley and Murray each used sterile bulb syringes if sterile water was required.

Dr. Murray testified that she used the Cavitron in thousands of surgeries based on her belief that the treated, potable water coming out of her dental unit was sufficiently safe. Dr. Murray conceded that she knew if she put sterile water into a Cavitron, the output would not be sterile. The trial court found Dr. Murray's testimony that she expected that the Cavitron would put out sterile water was not credible, in light of the fact that she has a doctorate in microbiology, directly assisted in experiments with waterline biofilm, and has known about the standards on sterile water in surgery since the mid-1990's.

Like Dr. Murray's credibility,[9] the trial court was exclusively responsible for weighing the evidence, and Dentsply, as the prevailing party, is afforded the benefit of all

[9] The trial court also found plaintiffs' regulatory expert, Timothy Ulatowski, to be lacking in credibility because he did not know what was commonly known to dental practitioners. As such, he had no basis for opining what information should have been included in the Directions. Similarly, the trial court was not persuaded by the opinion of plaintiffs' human factors expert, Alison Vrendenburgh. The trial court determined Vrendenburgh was similarly not in a position to render an opinion about the type of warnings that were advisable. We will not second-guess these determinations. (See *In re Maya L.* (2014) 232 Cal.App.4th 81, 104, fn. 6 ["[a]s a reviewing court, we have no power to revisit the credibility of witness[es] or reweigh the evidence."].)

reasonable inferences in support of the judgment. (See *Paulus v. Crane Co.* (2014) 224 Cal.App.4th 1357, 1363.) The evidence at trial established that California dentists are aware of the applicable water quality standards and the accumulation of biofilm in all dental waterlines, yet they still use the Cavitron even though they know this is inconsistent with the CDC and other guidelines. And, when sterile water is required, California dentists use sterile bulb syringes or other methods that bypass the waterlines. A reasonable inference from this evidence is that dentists do this not because of the Directions but because of their professional judgment on the needs of the patient in light of the procedures performed.

Plaintiffs already knew the facts they contend should have been disclosed. They know all dental waterlines contain biofilm and that Cavitrons do not deliver sterile water.

In sum, plaintiffs failed to carry their burden of proof. Their evidence was not uncontroverted or unimpeached and of such character and weight as to leave no room for judicial determination that it was insufficient to support the trial court's conclusion that a dentist acting reasonably under the circumstances—that is, using their professional knowledge concerning biofilm and its impact on water quality—would find the Directions as misleading them into believing the Cavitron was safe for surgical use.

B. Breach of Warranty

As we explained in *Weinstat*, "Section 2313, subdivision (1)(a) and (b) of the California Uniform Commercial Code governs this cause, providing that express warranties are created as follows: '(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. [¶] (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.' Hence, to prevail on a breach of express warranty claim, the plaintiff must prove (1) the seller's statements constitute an ' "affirmation of fact or promise" ' or a ' "description of the goods" '; (2) the statement was ' "part of the basis of the bargain" '; and (3) the warranty was breached." (*Weinstat, supra*, 180 Cal.App.4th at p. 1227, fn. omitted.)

In *Weinstat*, *supra*, we concluded that the Directions had formed an express warranty. (180 Cal.App.4th at p. 1229.) "Without question, a dental professional would expect that the Directions would accompany the class II medical device, and the device would be safe for the uses indicated therein." (*Ibid.*) At issue, is the content of that warranty. Plaintiffs contend the statement that the Cavitron was suitable for " '[p]eriodontal debridement for all types of periodontal diseases,' " constitutes a warranty that the Cavitron could be used in surgery.

Plaintiffs once again have failed to carry their burden of proof. The Cavitron is available only as a subset of the public and a sophisticated one at that—licensed dentists.

Their evidence was not uncontroverted or unimpeached and of such character and weight to leave no room for judicial determination that it was insufficient to support the trial court's conclusion that Dentsply promised or affirmed that the Cavitron was safe for surgical use. The Directions do not expressly state that the Cavitron can be used in surgery. Unlike the state of the evidence during class certification, the record on appeal establishes substantial evidence that plaintiffs were aware of the biofilm risk posed by Cavitron usage, but they purchased and used it anyway. (Cf. *Weinstat*, *supra*, 180 Cal.App.4th at p. 1235.)

III. DISPOSITION

The judgment is affirmed. Dentsply is entitled to costs on appeal. (Cal. Rules of Court, rule 8.278(a)(1).)

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REARDON, J.

We concur:

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RUVOLO, P. J.

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RIVERA, J.

Trial Court:	City & County of San Francisco Superior Court
Trial Judge:	Hon. Curtis E.A. Karnow
Counsel for Appellants:	Bullivant Houser Bailey, Paul D. Nelson, Duane Morris, Ronald E. Ruma, Paul J. Killion, Law Offices of Edwin J. Zinman, Edwin J. Zinman
Counsel for Respondent:	Lewis Brisbois Bisgaard & Smith, Pamela M. Ferguson, Goodell, DeVries, Leech & Dann, Linda S. Woolf, Richard M. Barnes, Derek M. Stikeleather