Filed 2/9/10 McGuan v. Endovascular Technologies CA6

NOT TO BE PUBLISHED IN OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SIXTH APPELLATE DISTRICT

MICHAEL J. MCGUAN, Plaintiff and Appellant, v. ENDOVASCULAR TECHNOLOGIES, INC., et al., Defendants and Respondents.	H033287 (Santa Clara County Super. Ct. No. CV025603)
LILLIAN JOHNSON, Plaintiff and Appellant, v. ENDOVASCULAR TECHNOLOGIES, INC., Defendant and Respondent.	H033290 (Santa Clara County Super. Ct. No. CV037784)

The Food and Drug Administration (FDA) approved the ANCURE ENDOGRAFT System (Ancure Device) for use by surgeons to treat abdominal aortic aneurysms. Plaintiffs Michael J. McGuan and Lillian Johnson, who suffered severe injuries after they were implanted with this device, brought products liability and personal injury actions

against defendants Endovascular Technologies, Inc. (EVT), Guidant Corporation (Guidant), Advanced Cardiovascular Systems, Inc., and Origin Medsystems, Inc.[1] The trial court granted defendants' motions for summary judgment on the ground that plaintiffs' claims were preempted by federal law. The trial court also denied plaintiffs' motions to amend their complaints, and granted defendants' motions to seal portions of the record. Plaintiffs have filed timely appeals from the judgments of dismissal.[2] For the reasons stated below, we affirm.

I. Federal Regulation of Medical Devices

In enacting the Medical Device Amendments of 1976 (MDA) (21 U.S.C. § 360c et seq.) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), Congress sought to "'to provide for the safety and effectiveness of medical devices intended for human use.'" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 474 (*Medtronic*).) The MDA divides medical devices into three classifications: Class I, Class II, and Class III. (21 U.S.C. § 360c(a)(1).) A Class III device, such as the Ancure Device, receives the most federal oversight, and requires premarket approval by the FDA.[3] (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. __, __ [128 S.Ct. 999, 1003-1004] (*Riegel*).) This "rigorous" process requires an applicant to submit "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should

---

[1] EVT designed, manufactured, and distributed the Ancure Device. Guidant is the parent corporation of EVT. Advanced Cardiovascular Systems, Inc. had some involvement in the design and testing of the Ancure Device. Some employees of Origin Medsystems may have been involved in the design or testing of the Ancure Device.

[2] This court has denied the parties' stipulated request to consolidate the appeals. However, on its own motion, this court will consider the cases together for purposes of briefing, oral argument, and decision.

[3] There are two statutory exceptions to the premarket approval requirement for Class III devices not relevant here. They are the "grandfathering provision" (21 U.S.C. § 360e(b)(1)(A)), and the "substantially equivalent" provision (21 U.S.C. § 360e(b)(1)(B)).

reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of proposed labeling. (§ 360e(c)(1).)" (*Riegel*, at p.__ [128 S.Ct. at p. 1004].)

The FDA spends an "average of 1,200 hours" on each premarket approval application. (*Medtronic*, *supra*, 518 U.S. at p. 477.) In determining whether to grant premarket approval of a Class III device, the FDA must, among other things, "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." (21 U.S.C. § 360c(a)(2)(C).) The FDA will also "rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance" of the device's "safety and effectiveness." (21 U.S.C. § 360e(d)(1)(A).) In the event that the FDA grants premarket approval, it may condition its approval on adherence to various requirements. (21 U.S.C. §§ 360e(d), 360j(e)(1).) After approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." (*Riegel*, *supra*, 552 U.S. at p. __ [128 S.Ct. at p. 1005].)

II. Statement of Facts[4]

In the spring of 1999, defendants filed a premarket approval application for the Ancure Device. On September 28, 1999, the FDA approved the Ancure Device for commercial distribution, subject to certain conditions and requirements.

---

[4] The statement of facts is based on undisputed facts and evidence presented by plaintiffs in opposition to the motion for summary judgment.

Within the first year after the premarket approval of the Ancure Device, several serious problems arose. They included: a limited recall of some units due to a "monofilament" problem; non-unique serial numbers; "Figure 8" problem involving wire controls; the Cassini Project involving several changes to the device; off-label promotion to the Medical Services Group; jacket retraction problem; handle breaking technique to be used to retract device if it became stuck after the graph was implanted; need for medical device report (MDR) policy; aneurysm rupture; non-validated processes; and labeling mix-ups. In October 2000, several employees informed Guidant about these problems. In response, Guidant initiated both an internal investigation and one by outside auditors.

As of December 14, 2000, Guidant was informed of "significant weaknesses in the quality systems" by the outside auditor. Outside counsel also gave its opinion to Guidant that the Ancure Devices "currently being manufactured" were "at least 'technically' adulterated" under federal law, presented "a potential risk to the public health," and Guidant's "continued distribution of certain devices … expose[d] the devices, the Company and responsible individuals to potential FDA regulatory action."

Guidant assembled a team of employees under the supervision of Steve Wirkus to investigate the safety of the Ancure Device. The team reviewed Ancure case experience forms (E-Forms), voice mail, and complaints. Over 7,600 patients were implanted with the Ancure Device, and approximately 4,400 E-Forms were submitted. Though the E-Forms contained check boxes for equipment malfunctions and comments, they did not contain a check box for injuries except where death was an outcome. According to Wirkus, other injuries could be listed in the comment box, but the data in the comment box was sometimes missing due to the limited size of the box.[5] No one on the team contacted anyone with knowledge of the complaints. In summarizing the data, Wirkus

[5] A new E-Form was issued in September 2001, but it had no check boxes or questions about injuries.

initially acknowledged that the "E-Form data may be under-reported," but a later report stated that the data might be "skewed."

After Guidant became aware of an FDA investigation, outside counsel to Guidant wrote a memo indicating that Guidant would stop shipment of the Ancure Device and recall the product due to "deficiencies in the GES regulatory submission and communications with FDA." On March 16, 2001, defendants recalled the Ancure Device.

On March 23, 2001, Guidant provided evasive, if not false, information to the FDA. In response to the FDA's request for an audit report, Guidant also sent a report, which stated that it had "found nothing that indicated any intent or desire to hide information from FDA."

The FDA subsequently reviewed several MedWatch reports and approved premarket approval supplements. On August 17, 2001, the FDA reapproved the Ancure Device.

In the fall of 2001, the Department of Justice began an investigation and subpoenaed the independent auditor reports. Guidant's motion to quash was denied in July 2002. The trial court noted Guidant's use of these reports "for the purpose of influencing the FDA." The trial court also cited the declaration of an FDA representative, who stated that the existence of the reports persuaded the FDA "not to pursue additional regulatory measures beyond those proposed by the company."

In April 2002, the FDA approved an aortoiliac version of the Ancure Device, and approved and required additional language pertinent to its use.

Though Guidant played a central role in the fraudulent conduct, EVT entered into a plea agreement in June 2003. EVT pleaded guilty to nine counts of shipping misbranded medical devices (21 U.S.C. §§ 331(a), 333(a)(2)) arising from the shipping of nine devices between November 3, 1999 and September 24, 2000, and one count of making false statements (18 U.S.C. § 1001), arising from the provision of incomplete

information to an FDA inspector in July 2000. The plea agreement also states: "From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632 Devices into interstate commerce. [¶] Between September 30, 1999 and March 16, 2001, defendant filed 172 MDRs [Medical Device Reports] for the delivery system of the Ancure Device. [¶] On or about March 23, 2001, defendant disclosed to [the] FDA the existence of approximately 2,628 additional MDRs concerning the delivery system of the Ancure Device that had not been previously reported to [the] FDA, as required by law. . . . [¶] On or about March 23, 2001, defendant informed [the] FDA that it had failed to seek prior approval to amend its instruction for use to include the Handle Breaking Technique as legally required." The plea agreement required EVT to forfeit $10.9 million as well as pay a criminal fine of $32.5 million and a civil settlement of $49 million.

As of June 23, 2003, the Ancure Device "was no longer available."

III. Statement of the Case

In August 2004, McGuan filed a complaint in which he alleged that he suffered severe injuries after he was implanted with the Ancure Device on February 8, 2002. His complaint alleged eight causes of action: strict product liability (failure to warn); strict product liability (Restatement Second of Torts § 402A); negligence; breach of express warranty; breach of implied warranty; fraudulent concealment; punitive damages; and violations of the Consumer Legal Remedies Act. In June 2005, Johnson filed a first amended complaint in which she alleged that she suffered severe injuries after she was implanted with the Ancure Device on May 17, 2002. Her complaint alleged the same causes of action as those alleged in McGuan's complaint. However, her complaint also added a cause of action for fraud and misrepresentation. Plaintiffs' complaints focus on defects in the design, testing, and manufacture of the Ancure Device, the failure to warn

of all possible adverse side effects, and the fraudulent concealment of the dangers and defects of the product. The complaints do not refer to violations of federal law.

On September 22, 2005, defendants filed a motion for summary judgment on the ground that plaintiffs' claims were preempted by federal law. Plaintiffs were granted leave to conduct discovery. On May 5, 2008, plaintiffs filed opposition to the summary judgment motion. The day after defendants filed their reply, plaintiffs brought motions to amend their complaints.

The trial court granted defendants' motions for summary judgment on the ground that plaintiffs' claims were preempted by 21 U.S.C. section 360k(a) of the MDA. The trial court also ruled that plaintiffs could not avoid preemption by arguing that defendants engaged in fraud-on-the-FDA because this claim was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341 (*Buckman*). The trial court subsequently denied plaintiffs' motions to amend their complaints, and granted defendants' motions to seal audit reports. Following judgments of dismissal, plaintiffs filed timely notices of appeal.

IV. Discussion

A. Motion for Summary Judgment

1. Standard of Review

In bringing a motion for summary judgment, a party bears the "burden of persuasion" that there are no triable issues of material fact and that the moving party is entitled to judgment as a matter of law. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850 (*Aguilar*).) A defendant may be entitled to judgment as a matter of law where there is "an affirmative defense to that cause of action." (Code Civ. Proc., § 437c, subd. (o)(2).) After the defendant meets the burden of establishing all elements of the affirmative defense, the burden shifts to the plaintiff to show that a genuine issue of material fact exists as to that defense. (Code Civ. Proc., § 437c, subd. (p)(2).) "There is

a triable issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof." (*Aguilar*, at p. 850, fn. omitted.) Our review of a ruling on a summary judgment motion is de novo. (*County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 316.)

2. Federal Preemption

Congress has the power under the supremacy clause of article VI of the federal Constitution to preempt state law. "[S]tate law that conflicts with federal law is 'without effect.'" (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516, quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746.) As the United States Supreme Court has explained, federal law preempts state law in three circumstances. "First, Congress can define explicitly the extent to which its enactments pre-empt state law. [Citation.] Pre-emption fundamentally is a question of congressional intent, [citation] and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one. [¶] Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. . . . [¶] Finally, state law is pre-empted to the extent that it actually conflicts with federal law." (*English v. General Electric Co.* (1990) 496 U.S. 72, 78-79.)

The preemption provision of the MDA states in relevant part: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." (21 U.S.C. § 360k(a).)

The United States Supreme Court considered the scope of this preemption provision in *Riegel*, *supra*, 552 U.S. __ [128 S.Ct. 999]. In *Riegel*, the plaintiffs alleged

that the defendant's catheter, a Class III device, was "designed, labeled, and manufactured in a manner that violated" state common law, and that these defects caused severe injuries. (*Riegel*, at p. __ [128 S.Ct. at p. 1005].) The plaintiffs' complaint stated claims for "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." (*Riegel*, at p. __ [128 S.Ct. at p. 1006].) At issue was whether the preemption provision in the MDA barred common law claims that challenged the safety and effectiveness of Class III devices which had received premarket approval by the FDA. (*Riegel*, at p. __ [128 S.Ct. at p. 1002].) In resolving this issue, the court articulated a two-part test: (1) "whether the Federal Government has established requirements applicable to" the defendant's catheter, and (2) if so, whether the "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." (*Riegel*, at p. __ [128 S.Ct. at p. 1006].)

The court first found that premarket approval imposes federal requirements because it is granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness" and because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." (*Riegel*, *supra*, 552 U.S. at p. __ [128 S.Ct. at p. 1007.) Turning to the second question, the court, relying on *Medtronic*, *supra*, 518 U.S. at p. 512, concluded that tort duties under common law impose "'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." (*Riegel*, at p. __ [128 S.Ct. at p. 1007].) As the court explained, "excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation

adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." (*Riegel*, at p. __ [128 S.Ct. at p. 1008].) Accordingly, the court held that the plaintiffs' common law claims were preempted by federal law. (*Riegel*, at pp. __ [128 S.Ct. at pp. 10057-1008].)

Here, though plaintiffs' complaints are based, in part, on alleged defects in the design, testing, and manufacture of the Ancure Device as well as the failure to warn of all possible adverse side effects, they do not allege that defendants violated FDA regulations. Since the FDA reapproved the Ancure Device prior to plaintiffs' surgeries, the FDA gave its approval of the device's design, testing, intended use, manufacturing methods, performance standards, and labeling. Thus, to the extent that plaintiffs' complaints allege that the Ancure Device was unsafe and its warnings were inadequate, they are seeking to impose requirements that are "'different from, or in addition to'" the MDA. Consequently, the state law claims for strict product liability, negligence, breach of express warranty, breach of implied warranty, and violations of the Consumer Legal Remedies Act are preempted under the MDA.

Plaintiffs, however, focus on defendants' alleged fraudulent conduct after March 2001. They argue that their "causes of action are not preempted, by virtue of fraud on the FDA" or, alternatively, their "cause of action for fraud and misrepresentation is not preempted."[6] Defendants counter that plaintiffs have failed to plead fraud-on-the-FDA claims and that any such claims are "not legally cognizable."

---

[6] Plaintiffs identify the "main issue" on appeal as whether preemption should apply when "re-approval for the device was obtained by [defendants'] fraud on the FDA, proven by the FDA with severe consequents on defendant[s]." Plaintiffs argue that their

We first note that McGuan's complaint does not allege a cause of action for fraud-on-the-FDA or fraud and misrepresentation. It states a cause of action for "fraudulent concealment," which alleges that defendants "had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the Ancure Device product; that is, that said product was dangerous, defective, and likely to cause serious consequences to users, including injuries as herein occurred." This cause of action does not refer to the FDA's reapproval of the Ancure Device. Nor does it allege that defendants violated any federal regulations or provided inaccurate information to the FDA in the premarket approval supplements submitted prior to the reapproval. In order for McGuan to prevail on the cause of action for fraudulent concealment, the jury would be required to find that the warnings, which were approved by the FDA, were inadequate. Thus, this cause of action would impose "requirements" that are "'different from, or in addition to'" those imposed by the FDA, and consequently would be preempted. (*Riegel*, *supra*, 552 U.S. at p. __ [128 S.Ct. at p. 1011].)

We next consider Johnson's first amended complaint. Though this complaint does not specifically refer to a fraud-on-the-FDA claim, it alleges that, after the FDA's reapproval of the Ancure Device in August 2001, defendants "withheld from the FDA, surgeons and public, reports of serious failures and resulting problems caused by" the device. The complaint also states a cause of action for fraud and misrepresentation that alleges defendants failed to disclose to her and her physicians that the Ancure Device was "dangerous, defective, and likely to cause serious consequences to users" and that

---

"claims all stem from the fraudulent conduct of Defendants during 2001 in the context of the recall and reapproval of Ancure." They further contend that defendants "violated several key FDA regulations, such as the PMA conditions and regulations requiring thorough investigations and reporting of injuries" and these "violations of FDA reporting and other regulations and criminally fraudulent conduct led to the FDA's reapproval of Ancure and marketing of Ancure while still violating the investigating and reporting regulations that preceded" plaintiffs' surgeries.

defendants "made material misrepresentations that were calculated to deceive the medical community, *governmental agencies*, and Plaintiff . . . ." (Italics added.)

For purposes of argument, we will assume that plaintiffs have, or could have, stated causes of action for fraud-on-the-FDA. We conclude, however, that these claims are preempted under *Buckman*, *supra*, 531 U.S. 341).

In *Buckman*, the plaintiffs suffered injuries after orthopedic bone screws were implanted in their spines. (*Buckman*, *supra*, 531 U.S. at p. 343.) The plaintiffs then brought state tort law claims in which they alleged that the defendant made fraudulent representations to the FDA in obtaining approval to market these CLASS III devices, and they would not have been injured if these representations had not been made. (*Ibid.*) The *Buckman* court began its discussion by observing that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' [citation]" and thus the nature of the plaintiffs' claims was insufficient to warrant a presumption against preemption. (*Buckman*, at p. 347.) The court based this conclusion on the principle that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." (*Ibid.*)

Based on this "analytical framework," the court held that the state law fraud-on-the-FDA claims conflicted with, and thus, were impliedly preempted by federal law. (*Buckman*, *supra*, 531 U.S. at p. 348.) As the court explained, "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." (*Ibid.*) After reviewing the extensive disclosure requirements of the MDA and the provisions governing the detection, deterrence and punishment of false statements made during the approval process, the court concluded that state tort law fraud-on-the-FDA

claims would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (*Buckman*, at pp. 349-350.) Since the court held that the claims were impliedly preempted, it did not consider whether the claims were expressly preempted under 21 U.S.C. § 360k. (*Buckman*, at p. 348, fn. 2.)

Plaintiffs attempt to distinguish the present case from *Buckman* on the ground that the "FDA had not investigated the Buckman defendant for any alleged wrongdoing." They point out that "the FDA took strong action against" defendants and that Justice Stevens' concurring opinion in *Buckman* is "an invitation, as it were, to bring a case involving fraud 'policed' by the FDA."

In the concurring opinion, Justice Stevens suggested that *Buckman* would be "a different case" if "the FDA had determined that petitioner had committed fraud during the § 510(k) process and had taken the necessary steps to remove the harm-causing product from the market." (*Buckman*, *supra*, 531 U.S. at p. 354.) However, neither requirement is present in the case before us. Though defendants were prosecuted and entered into a plea agreement for fraudulent conduct that occurred before March 2001, the FDA took no action against defendants for their conduct in seeking reapproval in August 2001. Instead, the FDA continued to allow the Ancure Device to be marketed, and even approved a premarket approval supplement in April 2002. Since the FDA failed to take action against defendants for any alleged fraudulent conduct after March 2001, *Buckman* is controlling. Accordingly, plaintiffs' state law tort claims for fraud-on-the-FDA are preempted by federal law.

Plaintiffs next argue that *Buckman* does not apply to causes of action for fraud on patients and their physicians. In *Riegel*, the court noted that the MDA preemption provision did "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than

add to, federal requirements."[7] (*Riegel, supra*, 552 U.S. at p. __ [128 S.Ct. at p. 1011].) Thus, they assert that their state fraud claims are not different from or in addition to federal requirements.

Here, though plaintiffs' fraud claims are premised on violations of FDA regulations, that does not resolve the issue. In contrast to *Riegel*, *Buckman* was not interpreting the MDA preemption provision. Instead, *Buckman* relied on implied preemption principles. (*Buckman, supra*, 531 U.S. at pp. 348-353.) Those same principles apply with equal force to claims involving defendants' misrepresentations to plaintiffs and their physicians after March 2001. It is undisputed that the FDA found no violations of federal regulations after March 2001. Thus, if plaintiffs were allowed to proceed with their state law fraud claims, a finding of liability would also "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (*Buckman*, at p. 350.)

Plaintiffs next rely on *Altria Group, Inc. v. Good* (2008) __ U.S. __ [129 S.Ct. 538] (*Altria*), and argue that "a state law fraud claim must now be considered under Altria." In *Altria*, the plaintiffs brought state law claims against cigarette manufacturers, alleging that they fraudulently advertised that their light cigarettes had less tar and nicotine than regular brands. (*Altria*, at p. __ [129 S.Ct. at p. 541].) After considering the scope of the express preemption provisions of the Cigarette Labeling and Advertising Act, the court held that the plaintiffs' state law fraud claims were not preempted by federal law. (*Altria*, at pp. __ [129 S.Ct. at pp. 544-549].) *Altria* is distinguishable from the present case on two grounds. First, as the *Altria* court acknowledged, the language in the MDA's preemption provision was "much broader" than that in the statute before it. (*Altria*, at p. __ [129 S.Ct. at p. 549].) Second, the *Altria* court rejected the defendants'

---

[7] In *Riegel*, the court declined to consider whether the plaintiffs had stated parallel claims because the issue was not raised before the Second Circuit or in their petition for review. (*Riegel, supra*, 552 U.S. at p. __ [128 S.Ct. at p. 1011].)

argument that the plaintiffs' claim was impliedly preempted because, if allowed, it would frustrate the FTC's policy of promoting the consumption of low tar cigarettes. (*Ibid.*) The court reasoned that "[e]ven if such a regulatory policy could provide a basis for obstacle pre-emption, [the defendants'] description of the FTC's actions in this regard are inaccurate." (*Ibid.*) In contrast to *Altria*, *Buckman* acknowledged the FDA's role in detecting, deterring, and punishing fraud. Thus, *Altria* does not compel a different conclusion in the present case.

B. Motion to Amend Complaint

Plaintiffs next contend that the trial court erred in denying their motions to amend their complaints. They purport to incorporate by reference the same authorities and arguments submitted to support their motions in the trial court.

California Rules of Court, rule 8.204(a)(1)(B) requires that appellate briefs "support each point by argument and, if possible, by citation of authority." "[I]t is well settled that the Court of Appeal does not permit incorporation by reference of documents filed in the trial court. (*Colores v. Board of Trustees* (2003) 105 Cal.App.4th 1293, 1301, fn. 2. ['[I]t is not appropriate to incorporate by reference, into a brief, points and authorities contained in trial court papers, even if such papers are made a part of the appellate record'].)" (*Soukup v. Law Offices of Herbert Hafif* (2006) 39 Cal.4th 260, 295, fn. 20.) A Court of Appeal may refuse to consider arguments incorporated by reference. (*Parker v. Wolters Kluwer United States, Inc.* (2007) 149 Cal.App.4th 285, 290-291 (*Parker*).) Thus, we have not considered these arguments. Since plaintiffs have failed to submit any other arguments or authorities, the issue has been waived.

In any event, plaintiffs' contentions have no merit. Plaintiffs sought to amend their complaints by adding causes of action for fraud-on-the-FDA as well as fraud on plaintiffs and their physicians based on defendants' failure to comply with federal regulations by providing accurate information to the FDA. Courts are liberal in allowing

the amendment of pleadings at any stage of the proceedings where the amendment does not cause prejudice to the rights of other parties. (*Hayutin v. Weintraub* (1962) 207 Cal.App.2d 497, 505.) We review the trial court's determination on this issue under the abuse of discretion standard. (*Id.* at pp. 505-506.) However, a trial court does not abuse its discretion in denying leave to amend "if it appears from the complaint that under applicable substantive law there is no reasonable possibility that an amendment could cure the complaint's defect." (*Heckendorn v. City of San Marino* (1986) 42 Cal.3d 481, 486.) Here, as previously discussed, plaintiffs' proposed amendments could not cure the complaints' defects. Accordingly, the trial court did not abuse its discretion in denying plaintiffs' motions to amend the complaints.

C. Motion to Seal Records

Plaintiffs also argue that the trial court erred in granting defendants' motion to seal documents. Plaintiffs purport to incorporate by reference the same authorities and arguments filed in opposition to defendants' motions in the trial court. As previously discussed, we refuse to consider authorities and arguments incorporated by reference. (*Parker, supra,* 149 Cal.App.4th at pp. 290-291.) Even if we were to consider plaintiffs' arguments, we would reject them.

In the present case, the trial court found that the records "contain trade secrets and are protected from disclosure under federal law. The Court further finds that in weighing the public's right to access against the Defendant's right to maintain the confidentiality of its trade secrets, the right to privacy clearly outweighs the public's right. This overriding interest supports sealing the records in question. The Court further finds that the [proposed] sealing of records is narrowly tailored and no less restrictive means exists to achieve the overriding interest."

The trial court "may order that a record be filed under seal only if it expressly finds facts that establish: [¶] (1) There exists an overriding interest that overcomes the

right of public access to the record; [¶] (2) The overriding interest supports sealing the record; [¶] (3) A substantial probability exists that the overriding interest will be prejudiced if the record is not sealed; [¶] (4) The proposed sealing is narrowly tailored; and [¶] (5) No less restrictive means exist to achieve the overriding interest." (California Rules of Court, rule 2.550(d).) Courts have found that the protection of trade secrets is an interest that can support sealing records in a civil proceeding. (*In re Providian Credit Card Cases* (2002) 96 Cal.App.4th 292, 298-299, & fn. 3 (*Providian*).) "'Trade secret' means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: [¶] (1) Derives independent economic value, actual or potential from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and [¶] (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." (Civ. Code, § 3426.1, subd. (d).) We review the trial court's decision to order the documents sealed under the abuse of discretion standard, and any factual determinations made in connection with that decision will be upheld if they are supported by substantial evidence. (*Providian*, at p. 299.)

Here, the trial court made the requisite findings and these findings are supported by substantial evidence. Defendants submitted the declaration of Kristen Honl, Guidant's director of global compliance, in support of their motion. Honl stated that the records discuss the details of defendants' "quality system procedures, complaint handling procedures, device tracking procedures, process validation procedures, and corrective action procedures." According to Honl, these records "would have economic value to many medical device manufacturers, including Defendants' competitors, because they reveal the business methods and processes Defendants have developed to comply with the requirement of very technical FDA regulations." She further noted that the "value and utility of this information is not completely dependent on the specific design of the device being manufactured, but could have application across a range of different Class

III medical devices . . . [and that these records] are maintained as confidential and disseminated within Defendants' organization on a limited basis." Thus, the trial court did not abuse its discretion in granting defendants' motion to seal records.

V. Disposition

The judgments are affirmed.

_____
Mihara, J.

WE CONCUR:

_____
Elia, Acting P. J.

_____
McAdams, J.