UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ROBERT PEREZ, NANCY ART and BRETT HARBACH, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

NIDEK CO. LTD., et al.,

Defendants.

CASE NO. 08cv1261 BTM(JMA)

ORDER GRANTING MOTIONS TO DISMISS, DENYING MOTION TO STRIKE AS MOOT, AND GRANTING IN PART AND DENYING IN PART MOTION FOR LEAVE TO AMEND

Defendant Nidek Incorporated ("Nidek") has filed a motion to dismiss and/or strike portions of Plaintiffs' Second Amended Complaint ("SAC"). Defendants Estate of Glenn A. Kawesch, M.D., Gary Kawesch, M.D. Farzad Yaghouti M.D., and John Kownacki, M.D., have filed separate motions to dismiss the SAC. Defendants Manoj V. Motwani, M.D., Keith Liang, M.D., William Ellis, M.D., Randa Garrana, M.D., Joseph Lee, M.D., Linda Vu, M.D., Michael Rose, M.D., and Thomas S. Tooma, M.D., have filed notices of joinder in the motions to dismiss/strike. Plaintiffs have filed a motion for leave to file a Third Amended Complaint. For the reasons discussed below, Defendants' motions to dismiss are **GRANTED** and the motion to strike is **DENIED** as moot. Plaintiff's motion for leave to file a Third Amended Complaint is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

On October 2, 2008, Plaintiffs filed the SAC. The original complaint and First Amended Complaint had not been served on Defendants.

Plaintiffs bring this action on behalf of themselves and a purported class of similarly situated individuals, consisting of persons who underwent Hyperopic Laser in Situ Keratomilesis ("LASIK") and/or Hyperopic PhotoRefractive Keratectomy ("PRK") with a NIDEK EC-5000 Excimer Laser System (the "Laser") on or about February of 1996 until the date of October 11, 2006, and did not consent to and were not included in an approved FDA clinical trial. (SAC ¶ 1.)

Under the Federal Food, Drug, and Cometic Act ("FDCPA"), as amended by the Medical Device Amendments of 1976, the Laser is a Class III device. Generally, premarket approval ("PMA") is required before a Class III device may be marketed. 21 U.S.C. § 360e(a).

Commencing in 1998, Nidek obtained various PMAs for the Laser for PRK and Lasik for myopia. According to Plaintiffs, the PMAs did not approve use of the Laser for hyperopia. Plaintiffs allege that despite the lack of FDA approval, Nidek and the defendant physicians conspired to perform hyperopic corrections with the Laser and achieved this goal by modifying the device with illegal hardware and software. (SAC ¶ 55.)

On December 20, 2002, the FDA sent Nidek a letter in which the FDA expressed concern regarding the replacement of chips in previously distributed Laser units with chips that enable the device "for unapproved applications, such as hyperopia." (SAC ¶ 56.) The FDA stated that there had been allegations that NIDEK employees had been providing the chips and that at least one employee had been terminated for providing this service. (Id.)

On July 11, 2001, the FDA sent certain physicians a Warning Letter that informed them that the Nidek Laser they were using for hyperopia was manufactured prior to the issuance of the PMA. (SAC ¶ 57.) The letter explained that the Laser used by the physicians contained software version 2.2.5 dhc, which was not approved for commercial distribution in the United States. (Id.) The letter further explained, "Because an approved

PMA or an approved IDE does not cover this laser, it is adulterated within the meaning of the Act. Therefore, you should not be using this laser to treat patients." (Id.)

On July 26, 2001, the FDA sent a second Warning Letter, which reiterated the information in the first Warning Letter and added that the modified Lasers needed to be certified as in compliance with the Federal laser product performance standard pursuant to 21 C.F.R. § 1040.10(I). (SAC ¶ 58.) The FDA also pointed out that it had not received product reports for the modified Lasers as required by 21 C.F.R. § 1002. (Id.)

Plaintiffs allege that despite the FDA warnings, Nidek and the defendant physicians continued to sell, distribute, lease, use, service, and market the modified Lasers in the United States. Plaintiffs allege that Defendants did not inform them or the other members of the class that underwent Lasik or PRK for hyperopic corrections that the modified Laser was not approved by the FDA. (SAC ¶¶ 10-11.) Plaintiffs do not allege that they or the other members of the class suffered personal injury as a result of the procedures.

The SAC asserts the following causes of action (1) violation of the Human Subjects in Medical Experimentation Act, Cal. Health & Safety Code § 24176; (2) unfair or deceptive acts or practices in violation of the Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq. ("CLRA"); (3) violation of the Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, based upon the FDCA; (4) violation of the UCL based upon FDA regulations and the Cal. Health & Safety Code; (5) violation of the UCL based upon Cal. Health & Safety Code § 24176; (6) civil conspiracy. The SAC seeks statutory damages, injunctive relief, restitution, disgorgement, and punitive damages. (SAC, Prayer for Relief.)

II. DISCUSSION

A. Jurisdiction

The SAC asserts that this Court has federal-question jurisdiction over the action because Plaintiffs' claims concern Defendants' alleged violations of the FDCA. (SAC ¶ 44.) The SAC also states that the Court has diversity jurisdiction over the action pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1332(d). (Id.) Some of the

Defendants dispute that the Court has subject-matter jurisdiction. Although the Court concludes that it lacks federal-question jurisdiction, the Court finds that Plaintiffs have satisfied their initial burden of establishing diversity jurisdiction under CAFA.

Plaintiffs' allegations that Defendants violated the FDCA and regulations promulgated thereunder do not give rise to federal question jurisdiction. Section 337(a) of the FDCA provides that "all proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States." Courts have interpreted this provision to mean that there is no private right of action to enforce the Act's provisions. See, e.g., Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994); Milan Laboratories, Inc. v. Matcher, 7 F.3d 1130, 1139 (4th Cir. 1993); Summit Tech., Inc., v. High-Line Med. Instruments Co., Inc., 922 F. Supp. 299, 305 (C.D. Cal. 1996). When there is no private right of action under a federal statute such as the FDCA, "the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804, 814 (1986). Accordingly, federal question jurisdiction is not created by the fact that Plaintiffs' state law claims under the CLRA and UCL hinge upon alleged violations of the FDCA and its regulations.

Plaintiffs argue that substantial federal issues have been raised by Defendants' argument that Plaintiffs' claims are preempted by the FDCA. However, "[t]he fact that a defendant might ultimately prove that a plaintiff's claims are preempted . . . does not establish" federal jurisdiction. Caterpillar v. Williams, 482 U.S. 386, 398 (1987). Preemption gives rise to federal question jurisdiction only when an area of state law has been completely preempted by federal law. Id. at 393. The FDCA does not completely preempt state law. See, e.g., Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804 (1986) (holding that the Medical Devices Amendments to the FDCPA do not preempt all state law claims pertaining to devices governed by the federal statute); In re Orthopedic "Bone Screw" Products Liability Litig., 132 F.3d 152 (3d Cir. 1997) (discussing remand of MDL actions which had been removed under the Medical Devices Amendments to the FDCPA because the statute did not

completely preempt state law). Therefore, the preemption issue raised by Defendants does not confer federal-question jurisdiction.

Plaintiffs claim that the Court also has diversity jurisdiction over this action pursuant to CAFA. Under CAFA, diversity jurisdiction exists where the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and the action is a class action in which any member of a class of plaintiffs is a citizen of a state and any defendant is a citizen or subject of a foreign state. 28 U.S.C. § 1332((d)(2)(C). The SAC alleges that Plaintiffs are citizens of California and that Nidek Co., Ltd. and TLC Vision Corporation are citizens of a foreign country. (SAC ¶¶ 10-12, 31.) The SAC also alleges that the aggregate amount in controversy is over $5,000,000. (SAC ¶ 44.)

Under CAFA, the initial burden of establishing removal jurisdiction under § 1332(d)(2) rests on the party invoking jurisdiction. Abrego Abrego v. The Dow Chemical Co., 443 F.3d 676, 685 (9th Cir. 2006). The Court finds that Plaintiffs have satisfied this burden. Based on the allegations of the SAC, there is diversity of citizenship as required by 28 U.S.C. § 1332(d)(2)(C). As for the amount-in-controversy requirement, without reaching the merits of Plaintiffs' claims, it appears that the requirement is easily met based on the scope of the purported class and the remedies sought – i.e., statutory damages of $10,000 for each willful violation of the Human Subjects in Medical Experimentation Act and restitution under the UCL.[1]

Defendants do not dispute that Plaintiffs have satisfied CAFA's requirements of diversity of citizenship and an amount in controversy in excess of $5,000,000, but argue that this case falls within CAFA's "local controversy exception." The "local controversy exception" provides:

> A district court shall decline to exercise jurisdiction . . .
>
> > (A)(i) over a class action in which --
> >
> > > (I) greater than two-thirds of the members of all proposed

[1] Defendants challenge the propriety of the class as defined by Plaintiffs. However, issues pertaining to the propriety of the class and whether Plaintiffs are adequate class representatives are better dealt with on a motion for class certification.

> plaintiff classes in the aggregate are citizens of the State in which the action was originally filed;
>
> (II) at least 1 defendant is a defendant --
>
> (aa) from whom *significant relief* is sought by members of the plaintiff class;
>
> (bb) whose alleged conduct forms a *significant basis* for the claims asserted by the proposed plaintiff class; and
>
> (cc) who is a citizen of the State in which the action was originally filed; and
>
> (III) Principal injuries resulting from the alleged conduct or any related conduct of each defendant were incurred in the State in which the action was originally filed; and
>
> (ii) during the 3-year period preceding the filing of that class action, no other class action has been filed asserting the same or similar factual allegations against any of the defendants on behalf of the same or other persons . . . .

28 U.S.C. § 1332(d)(4) (emphasis added).

Defendants contend that Plaintiffs bear the burden of establishing that the exception does *not* apply. Defendants are mistaken. The Ninth Circuit has held that once the proponent of federal jurisdiction satisfies its initial burden of establishing jurisdiction under section 1332(d)(2), the party objecting to federal jurisdiction bears the burden of proof as to any express statutory exception under sections 1332(d)(4)(A) and (B). Serrano v. 180 Connect, Inc., 478 F.3d 1018, 1024 (9th Cir. 2007). Serrano involved a case that was removed. Therefore, once the removing defendants satisfied their initial burden of establishing jurisdiction under CAFA, the plaintiff had the burden of proving the applicability of the local controversy exception. Id. at 1024. Here, in contrast, Plaintiffs are the proponents of federal jurisdiction. Accordingly, Defendants bear the burden of establishing that the local controversy exception applies. See Beye v. Horizon Blue Cross Blue Shield of New Jersey, 568 F. Supp. 2d 556, 573 (D.N. J. 2008) (explaining that defendants in a case that was commenced in federal court had the burden of showing that an exception to CAFA applied).

Defendants have not carried their burden of establishing that the local controversy

exception applies. Defendants have not shown that greater than two-thirds of the members of the proposed plaintiff class are citizens of California, as required by section 1332(d)(4)(A)(i)(I). Although the members of the proposed class underwent hyperopic surgery in California, there is no evidence that 2/3 of them actually resided and continue to reside in California. Therefore, the Court finds that it has subject matter jurisdiction under CAFA.[2]

B. Motions to Dismiss

Defendants seek to dismiss the SAC in its entirety for failure to state a claim. The Court agrees that Plaintiffs have failed state a claim for the specific reasons discussed below.

1. Cal. Health & Safety Code § 24176

Plaintiffs allege that Defendants are liable for statutory damages under Cal. Health & Safety Code § 24176, because Defendants subjected Plaintiffs and the other members of the class to medical experiments without first obtaining their informed consent, as required by Cal. Health & Safety Code § 24175.

Section 24175(a) provides: "Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained." The term "medical experiment," as used in section 24175(a), is defined as:

> (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting [sic] the subject.
>
> (b) The investigational use of a drug or device as provided in Sections 111590 and 111595.
>
> (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

Cal. Health & Safety Code § 24174.

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[2] The Court need not reach whether Defendants have met their burden of proof with respect to the remaining requirements of the local controversy exception.

The "informed consent" required by section 24175(a) must meet the detailed requirements set forth in section 24173. Under section 24173, a written consent form must be signed and dated, and the subject must be informed both verbally and within the written consent form of certain enumerated facts regarding the proposed medical experiment. Section 24173 "makes significant specific procedural additions to the general common law requirements" for informed consent. Daum v. Spinecare Medical Group, Inc., 52 Cal. App. 4th 1285, 1309 (1997).

Defendants contend that the laser surgeries performed on Plaintiffs do not fall within the definition of a "medical experiment, " and that, therefore, Defendants were not required to give the detailed "informed consent" prescribed by section 24173. The Court agrees.

Under section 24174(a), to qualify as a "medical experiment," the use of a device must be "in the practice or research of medicine *in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting [sic] the subject*." (Emphasis added.) Here, the use of the Laser to correct farsightedness was reasonably related to improving the health of the subject. See Trantafello v. Medical Center of Tarzana, 182 Cal. App. 3d 315, 320 n. 2 (1986) (explaining that section 24174(a) deals with experiments on human subjects in the course of pure research and did not apply to an innovative procedure that had a therapeutic purpose). Therefore, the laser surgeries at issue do not qualify as "medical experiments" under section 24174(a).

Under section 24174(b), the investigational use of a drug or device as provided in sections 111590 and 111595 constitutes a "medical experiment." Section 111590 refers to investigations conducted in accordance with the requirements of section 505(i) or section 520(g) of the FDCPA (21 U.S.C. §§ 352, 355(i), 360) and the regulations adopted pursuant to the FDCPA. Similarly, section 111595 refers to investigational use under specified conditions. Plaintiffs do not allege the investigational use of the Laser within the parameters of section 111590 or 111595. Indeed, the SAC specifies that the class does not include individuals who participated in an approved FDA clinical trial. Because there was no "investigational use" of the device under section 24174(b), Defendants were not required to

provide informed consent under section 24173. See Huntman v. Danek Medical, Inc., 1998 WL 663362, at * 7 (S.D. Cal. July 24, 1998) (dismissing negligence per se claim to the extent it was based on allegations that defendant was required to obtain informed consent under section 24173 and federal regulations, because there was no evidence that Plaintiff was part of any Investigational Device Exemption ("IDE") clinical trial).

Section 24174(c) concerns the withholding of medical treatment and is inapplicable here.

The laser surgeries at issue do not satisfy any of the statutory definitions of "medical experiment." Therefore, Plaintiffs' claim under section 24176 is dismissed for failure to state a claim.

2. CLRA and UCL Claims

Plaintiffs' CLRA and UCL claims are premised on violations of the FDCA and its regulations.[3] As discussed below, Plaintiffs' CLRA and UCL claims are dismissed because they impermissibly seek private enforcement of the FDCA. Furthermore, Plaintiffs' UCL claims are time-barred.

a. No Private Right of Action Under FDCA

Section 337(a) of the FDCA provides that "all proceedings for the enforcement , or to restrain violations of [the Act] shall be by and in the name of the United States." Courts have interpreted section 337(a) as prohibiting private rights of action under the FDCA and have dismissed state law claims that seek to enforce the FDCA or its regulations.

In Summit Tech. Inc. v. High-Line Med. Instruments Co., Inc., 922 F. Supp. 299 (C.D. Cal. 1996) ("Summit I"), the plaintiff asserted a Lanham Act claim based on the defendants' alleged failure to disclose that their re-imported excimer laser systems were materially different from the FDA-approved systems and were not actually approved by the FDA. The

[3] Plaintiffs' Fifth Cause of Action pleads a UCL claim premised upon Cal. Health & Safety Code § 24176. As discussed above, Plaintiffs have failed to state a claim under Cal. Health & Safety Code § 24176.

court dismissed plaintiff's Lanham Act claim, explaining that because the FDA had not completed its investigation into whether the defendants had violated FDA regulations by marketing the re-imported machines, plaintiff's claim would require the court to usurp the FDA's authority to enforce the FDCA:

> A Lanham Act cause of action cannot stand if it alleges that a defendant has failed to disclose the fact of FDA non-approval, when the FDA has not yet determined whether or not the product in question has been approved. Simply put, the Lanham Act does not allow a federal court to "determine preemptively how a federal agency will interpret and enforce its own regulations." Id.

Id. at 306 (quoting Sandoz Pharm. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990)).

Similarly, in Photomedex, Inc. v. RA Med. Sys. Inc., 2007 WL 3203039 (S. D. Cal. Oct. 29, 2007), the court dismissed plaintiff's claims under the Lanham Act and Cal. Bus. & Prof. Code §§ 17200, 17500, because the claims rested upon whether the design changes made by defendants to their laser required defendants to file additional documents with the FDA to obtain further FDA pre-market clearance. The court held that the determination of whether the defendants were improperly marketing a laser that was not FDA-approved required application of FDA regulations and the FDA's expertise. See also In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litig., __ F. Supp. 2d __, 2008 WL 5335062 (C.D. Cal. Dec. 17, 2008) (dismissing plaintiffs' RICO and Cal. Bus. & Prof. Code § 17200 claims because they were primarily based on allegations that the defendants promoted a prescription drug for off-label uses, causing the drug to be "misbranded" in violation of the FDCA).

In Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir. 1990), the Third Circuit affirmed the dismissal of a Lanham Act claim that the defendant engaged in false labeling of its over-the-counter cough medicine by listing demulcents (locally-acting inert sugary liquids which operate directly on cough receptors in the throat and respiratory passages) as "inactive." The Third Circuit explained that the FDA had not yet found conclusively whether demulcents must be labeled as "active" within the meaning of 21 C.F.R. § 210.3(b)(7), and that it was not proper for a district court to "usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." Id. at 231.

See also Braintree Lab., Inc. v. Nephro-Tech, Inc., 1997 WL 94237 (D. Kan. Feb. 26, 1997) (granting motion to dismiss Lanham Act and common law unfair competition claims because the crux of the claims was that defendants had failed to receive FDA approval for a "dietary supplement," resulting in misbranding under the FDCA); Healthpoint, Ltd. v. Ethex Corp., 273 F. Supp. 2d 817 (W.D. Tex. 2001) (dismissing claims requiring a determination of whether drugs were on the market lawfully under the FDCA).

Of course, not all claims that touch upon subject matter regulated by the FDCA are preempted. For example, literally false or misleading statements made to promote drugs or devices are actionable if they do not depend on a determination by the court whether the FDCA has been violated. See, e.g., In re Epogen, 2008 WL 5335062 at *9; Healthpoint, 273 F. Supp. 2d at 846; Summit Tech., Inc, v. High-Line Med. Instruments, Co., 933 F. Supp. 918 (C.D. Cal. 1996) ("Summit II").

Here, Plaintiffs' CLRA and UCL claims rest upon allegations that (1) Defendants permitted the use, sale, lease, distribution and/or service of Lasers that were modified to perform hyperopic corrections in violation of the PMA, resulting in the device being "adulterated" within the meaning of the FDCA; (2) Defendants failed to re-certify and re-identify the modified Lasers as required by 21 C.F.R. § 1040.10; and (3) Defendants failed to inform patients that the modified Lasers were not approved by the FDA and were not properly certified.

Plaintiffs' claims require the Court to make determinations regarding the scope of the PMA, whether the modified Lasers were "adulterated" under section 501(f)(1)(B) of the FDCA, and whether re-certification was required under 21 C.F.R. § 1040.10. These matters should be decided by the FDA in the first instance. Although the FDA issued Warning Letters regarding the modified Laser's lack of pre-market approval and Defendants' failure to re-certify and re-identify the Lasers pursuant to 21 C.F.R. § 1040.10, such letters do not constitute a final decision by the FDA. Summit I, 922 F. Supp. at 306.

The Court will not permit Plaintiffs to privately enforce the FDCA and its regulations under the guise of state law claims. Accordingly, the Court dismisses Plaintiffs' CLRA and

UCL claims.[4]

b. UCL Statute of Limitations

Plaintiffs' UCL claims are dismissed on the additional ground that they are barred by the applicable statute of limitations.

Cal. Bus. & Prof. Code § 17208 provides: "Any action to enforce any cause of action pursuant to this chapter shall be commenced within four years after the cause of action accrued." The Ninth Circuit has interpreted this provision to mean that claims under Cal. Bus. & Prof. Code § 17200 "are subject to a four-year statute of limitations which [begins] to run on the date the cause of action accrue[s], not on the date of discovery." Karl Storz Endoscopy-America, Inc. v. Surgical Tech., Inc., 285 F.3d 848, 857 (9th Cir. 2002).

One published California Court of Appeal case has similarly held that the "discovery rule" does not apply to unfair competition actions. Snapp & Assoc. Ins. Services, Inc. v. Robertson, 96 Cal. App. 4th 884, 891 (2002). However, another published California Court of Appeal case, Massachusetts Mutual Life Ins. Co. v. Superior Court, 97 Cal. App. 4th 1282, 1295 (2002), stated that the statute of limitations for a claim under Bus. & Prof. Code § 17208 would "probably" run from the time a reasonable person would have discovered the basis for the claim. Massachusetts Mutual did not provide any reasoning in support of its conclusion. The California Supreme Court has not yet decided whether the "discovery rule" applies to unfair competition claims and has noted that the matter is not settled under California law. Grisham v. Philip Morris U.S.A., Inc., 40 Cal. 4th 623, 635 n. 7 (2007).

Absent a clear indication from the California courts that the Ninth Circuit's interpretation of Cal. Bus. & Prof. Code § 17208 was incorrect, this Court must follow Karl Storz. See Jones-Hamilton Co. v. Beazer Materials & Services, Inc., 973 F.2d 688, 696 n. 4 (9th Cir. 1992) (explaining that an additional intermediate appellate court decision on one

[4] Plaintiffs cite to Evraets v. Intermedics Intraocular, Inc., 29 Cal. App. 4th 779 (1994), in support of their position that their state law claims need not be dismissed. However, Evraets concerned preemption under the FDCA's *express* preemption clause (21 U.S.C. § 360k). The court did not analyze whether the state law claims required the court to resolve matters under the FDCA that should be decided by the FDA in the first instance.

side of a clear split was not the kind of indication that the Ninth Circuit's past interpretation of California law was incorrect that would cause the Ninth Circuit to revisit its prior holding). See also Endres v. Wells Fargo Bank, 2008 WL 344204 (N.D. Cal. Feb. 6, 2008) (citing Karl Storz and explaining that the UCL limitations period begins to run at the time of the alleged misrepresentation, not on the date of discovery by the plaintiff).

Plaintiffs' UCL claims are premised on Defendants' use of the modified Laser on them to perform hyperopic surgery. Plaintiffs' surgeries took place in 2000-2002. (Robert Perez underwent surgery on August 15, 2002 and September 12, 2002; Nancy Art underwent surgery on September 28, 2000; and Brett Harbach underwent surgery on September 28, 2000 and May 23, 2001). Therefore, the four-year statute of limitations on all of Plaintiffs' UCL claims expired prior to the filing of this lawsuit on July 14, 2008.[5]

c. Conspiracy

In light of the dismissal of Plaintiffs' substantive claims, Plaintiffs' conspiracy claim is dismissed as well. See Oregon Laborers-Employers Health & Welfare Trust Fund v. Philip Morris Inc., 185 F.3d 957, 969 (9th Cir. 1999). The Court notes that although Defendants argue that Plaintiffs must allege the conspiracy itself with particularity under Fed. R. Civ. P. 9(b), the Ninth Circuit has held that "under federal law a plaintiff must plead at a minimum, *the basic elements of a civil conspiracy* if the object of the conspiracy is fraudulent." Wasco Products, Inc. v. Southwall Tech., Inc., 435 F.3d 989, 991 (9th Cir. 2006).

[5] The Estate of Glenn A. Kawesch argues that all of Plaintiffs' claims against it are barred by Cal. Civ. Proc. Code § 366.2, which provides: "If a person against whom an action may be brought on a liability of the person, whether arising in contract, tort, or otherwise, and whether accrued or not accrued, dies before the expiration of the applicable limitations period, and the cause of action survives, an action may be commenced within one year after the date of death, and the limitations period that would have been applicable does not apply." Plaintiffs do not dispute that Dr. Kawesch died on March 14, 2007, and that this action was not commenced until July 14, 2008. However, Plaintiffs' claims may be timely under Cal. Civ. Proc. Code § 366.2(b)(2), because it appears that Plaintiffs timely filed their claims in probate proceedings - Plaintiffs were served with a Notice to Creditors on or about July 17 2008, and filed their claims shortly thereafter (Exs. 2-3 to Thale Decl.). See Levine v. Levine, 102 Cal. App. 4th 1256, 1261 (2002) (explaining that if a claim is timely filed in probate proceedings, it remains timely filed even though the claim is allowed, approved, or rejected outside the limitations period set forth in Cal. Civ. Proc. Code § 366.2).

d. Abatement

In their motions to dismiss, Defendants argue that this action must be abated due to Williams v. Nidek, Case No. GIC 842089, an action pending in state court which, according to Defendants, involves some of the same parties, similar class allegations, and similar causes of action.

Whether a federal court should stay a case due to the pendency of a state court proceeding is governed by Colorado River Water Conserv. Dist. v. United States, 424 U.S. 800, 817-19 (1976). Under Colorado River, federal courts may under "exceptional circumstances" stay or dismiss a case in deference to pending state proceedings. Abstention is not appropriate unless the state and federal actions are "substantially similar." Nakash v. Marciano, 882 F.2d 1411, 1416 (9th Cir. 1989).

Here, it appears that the federal action and state action are not substantially similar. As pointed out by Plaintiffs, although four of the defendants are the same, the plaintiffs and potential classes are different. In addition, the state case seeks individual damages for physical injury suffered by class members as a result of hyperopic surgery using the modified Laser. The federal case does not seek damages for physical injury, but, rather, seeks restitution and statutory penalties.

Even if the cases were "substantially similar," Defendants have not shown that abstention is warranted by "exceptional circumstances." In assessing whether Colorado River abstention is appropriate, federal courts should consider the following factors: (1) whether either court has assumed jurisdiction over a *res*; (2) the relative convenience of the forums; (3) the desirability of avoiding piecemeal litigation; (4) the order in which the forums obtained jurisdiction; (5) whether state or federal law controls; (6) whether the state forum will adequately protect the interests of the parties; and (7) whether the parties have engaged in forum shopping. Colorado River, 434 U.S. at 817-818; Travelers Indemnity Co. v. Madonna, 914 F.2d 1364, 1367-68 (9th Cir. 1990). The aforementioned factors are not a "mechanical checklist." Moses H. Cone Memorial Hosp. v. Mercury Const. Corp., 460 U.S. 1, 16 (1983). Rather, the decision whether to abstain in favor of parallel state-court litigation

rests on a "careful balancing of the important factors as they apply in a given case, *with the balance heavily weighted in favor of the exercise of jurisdiction*." Id. (emphasis added). Defendants did not discuss any of the aforementioned factors.

Therefore, the Court denies Defendants' request to stay the case pending the litigation of Williams v. Nidek.

C. Motions to Strike

Nidek has filed a motion to strike portions of the prayer for relief and allegations regarding an agency relationship between Nidek and the defendant physicians. Nidek's motion to strike is denied as moot in light of the dismissal of Plaintiffs' SAC.

D. Motion for Leave to Amend

Plaintiffs have filed a motion for leave to amend complaint and have submitted a proposed Third Amended Complaint. The proposed Third Amended Complaint adds a cause of action for "aiding and abetting," adds allegations against a Defendant Doctor Class, and pleads additional facts regarding Defendants' alleged intentional omissions regarding the lack of FDA approval for the Laser. The proposed Third Amended Complaint also drops Defendant Paul C. Lee, M.D., because he did not perform the surgical procedures at issue during the Class Period.

Leave to amend a complaint should be freely given when justice so requires. Fed. R. Civ. P. 15(a)(2). However, "[l]iberality in granting a plaintiff leave to amend is subject to the qualification that the amendment not cause undue prejudice to the defendant, is not sought in bad faith, and is not futile." Bowles v. Reade, 198 F.3d 752, 758 (9th Cir. 1999).

Here, the proposed Third Amended Complaint suffers from the same defects as the SAC and would be dismissed for the same reasons.[6] Therefore, the Court denies Plaintiffs'

[6] The Third Cause of Action for violations of the Unfair Competition Law adds allegations that in addition to violating the FDCA, Defendants violated California's Sherman Food, Drug, and Cosmetics Laws, including Cal. Health & Safety Code §§ 111295, 111300, and 111305, by adulterating a device and/or by manufacturing, selling, delivering, holding, or offering for sale an adulterated device. However, Plaintiffs do not claim that the device

motion to file the proposed Third Amended Complaint. However, the Court will give Plaintiffs one more chance to state claims against Defendants in a new Third Amended Complaint.

III. CONCLUSION

For the reasons discussed above, Defendants' motions to dismiss are **GRANTED**. Defendant Nidek's motion to strike is **DENIED AS MOOT**. The Second Amended Complaint is **DISMISSED** for failure to state a claim. Plaintiffs' motion for leave to amend the complaint is **GRANTED IN PART** and **DENIED IN PART**. The Court denies Plaintiffs' request to file the proposed Third Amended Complaint submitted with its papers. However, the Court will allow Plaintiffs to file a new Third Amended Complaint. If Plaintiffs choose to file a new Third Amended Complaint, Plaintiffs must do so within 20 days of the filing of this order.

IT IS SO ORDERED.

DATED: August 31, 2009

Honorable Barry Ted Moskowitz
United States District Judge

in question was "adulterated" under an independent standard set forth in the California statute, but, rather, that the device was "adulterated" because it was used to perform hyperopic corrections in violation of the PMA. (Proposed Third Amended Complaint, ¶¶ 81-84). Therefore, even though Plaintiffs cite to violations of California law, this cause of action would be dismissed because it seeks to privately enforce violations of the FDCA and its regulations. At any rate, as discussed above, Plaintiffs' UCL claims are barred by the applicable statute of limitations.