UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ACTIMMUNE MARKETING LITIGATION

No. C 08-02376 MHP

MEMORANDUM & ORDER

Re: Motion to Dismiss Second Amended Complaint

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In this proposed nationwide class action, consumer plaintiffs Deborah Jane Jarrett ("Jarrett"), Nancy Isenhower ("Isenhower"), Jeffery Frankel ("Frankel"), Linda Rybkoski ("Rybkoski") and Joan Stevens ("Stevens"), along with third-party payor ("TPP") plaintiff Government Employees Health Association, Inc. ("GEHA") (collectively "plaintiffs"), allege that defendants InterMune, Inc. ("InterMune"), Dr. W. Scott Harkonen ("Harkonen") and Genentech, Inc. ("Genentech") (collectively "defendants") engaged in a fraudulent scheme to market and sell the drug Actimmune (interferon gamma-1b).

Plaintiffs initially asserted causes of action pursuant to the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)-(d); the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*; the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*; the consumer protection laws of 39 states other than California; and for unjust enrichment. On April 28, 2009, this Court dismissed plaintiffs' claims without prejudice, holding that plaintiffs lacked standing under Federal Rule of Civil Procedure 12(b)(1), failed to plead their claims of fraud with particularity under Federal Rule of Civil Procedure 9(b), and failed to state a claim upon which relief could be granted under Federal Rule of Civil Procedure 12(b)(6). *See In re*

Actimmune Marketing Litig., 614 F. Supp. 2d 1037 (N.D. Cal. 2009) ("*Actimmune I*"). In accordance with the court's order, plaintiffs filed an amended complaint seeking to remedy the infirmities identified by the court. In the amended complaint, filed on May 28, 2009, plaintiffs abandoned their claims arising under RICO, and added claims under the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.* Now before the court are motions from all three defendants to dismiss the amended complaint pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1) and 12(b)(6). Having considered the parties arguments and submissions and for the reasons set forth below, the court enters this memorandum and order.

BACKGROUND

The court discussed the procedural history and factual allegations of this action in great detail in *Actimmune I*, and so provides only a brief summary here. At base, plaintiffs contend that InterMune fraudulently marketed Actimmune to individuals afflicted with and to doctors who treat patients suffering from idiopathic pulmonary fibrosis ("IPF"), even though Actimmune was not approved by the Food and Drug Administration ("FDA") to treat IPF and defendants knew that Actimmune was not effective to treat IPF. In so doing, plaintiffs allege, defendants vastly increased sales of Actimmune beyond the extremely limited market available for its approved uses and injured plaintiffs by causing them to purchase an ineffective drug.

I. Procedural History

This action consolidated four separate actions: (1) a suit by Frankel, Isenhower, and Jarret against the three defendants, 08-2376; (2) a suit by Rybkoski against all three defendants, 08-2916; (3) a suit by Zurich American Insurance Company ("Zurich") against all three defendants, 08-3797 (which Zurich has since voluntarily dismissed, Docket No. 110); and (4) a suit by GEHA against all three defendants, 08-4531. The first three actions were related on September 5, 2008, and Frankel, Isenhower, Jarret, Rybkoski and Zurich filed a combined first amended complaint ("FAC") on September 21, 2008. Docket Nos. 60, 63. The defendants moved to dismiss the three related actions on October 20, 2008, before GEHA's suit, 08-4531, was related on December 12, 2008. Docket

Nos. 67, 69, 71, 80. In order to avoid duplicate efforts, the court then granted defendants' motion for the court to apply defendants' arguments for dismissal in the three related cases against GEHA's complaint. Docket No. 100. The primary substantive difference between the FAC and GEHA's initial complaint was that in GEHA's complaint, Genentech was only named as a defendant in the unjust enrichment cause of action.

In *Actimmune I*, the court dismissed without prejudice the claims of the plaintiffs in all four related actions. In an effort to comply with the court's order, Frankel, Isenhower, Jarret, Rybkoski and Zurich filed a second amended complaint ("SAC"), Docket No. 101, and GEHA filed its first amended complaint ("GEHA's FAC"), Docket No. 102. The SAC added Stevens as an additional plaintiff. The SAC and GEHA's FAC assert five identical claims: Count I, for violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq.*; Count II, for violations of California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500 *et seq.*; Count III, for violations of California's Consumer Legal Remedies ACT ("CLRA"), Cal. Civ. Code §§ 1750 *et seq.*; Count IV for violations of consumer protection statutes in 39 states other than California; and Count V for unjust enrichment. In the SAC, Frankel, Jarret, Isenhower and Rybkoski bring Counts I though IV against all three defendants and Count V against only InterMune and Genentech; in its FAC, GEHA bring Counts I through IV against only InterMune and Harkonen and Count V against InterMune and Genentech. Thus, again, the primary substantive difference between the complaints is that GEHA's FAC only names Genentech as a defendant in Count V for unjust enrichment. The factual allegations are identical. Therefore, the court cites only to the SAC unless otherwise noted.

II Factual Background

a. Development of Actimmune

Prior to 1990, Genentech, a biotechnology company, developed a synthetic form of interferon gamma 1-b, a protein that acts as a biologic response modifier through stimulation of the human immune system. SAC ¶ 19. In 1990, the FDA approved the product, carrying a brand name of Actimmune, for treatment of chronic granulomatous disease ("CGD"). *Id.* ¶ 21. CGD affects less

than 400 people annually in the United States. *Id.* ¶ 20. In 2000, Genentech also received FDA approval for Actimmune to treat severe, malignant osteopetrosis, another condition affecting less than 400 individuals per year in the United States. *Id.* ¶ 27.

In May 1998, Genentech licensed the marketing and development rights for Actimmune to Connetics Corporation ("Connetics"). *Id.* 27. Under the terms of the license, Connetics had the exclusive right "to use, sell, offer for sale and import (but not to make or have made)" Actimmune within the United States for "the treatment or prevention of CGD, severe malignant osteopetrosis and pulmonary fibrosis." *Id.* ¶ 28. The license contained a standard due diligence provision requiring Connetics to provide Genentech with annual reports about its sales and marketing efforts from the previous twelve months and its "planned development and marketing programs for the twelve . . . months" to come. *Id.* ¶ 29. Connetics was required to pay Genentech royalties on sales of Actimmune and a variety of milestone payments. SAC ¶ 30.

Between August 1998 and June 2000, Connetics entered into a number of sublicense agreements with InterMune, whereby InterMune assumed all of Connetics' rights and responsibilities under the Actimmune license with Genentech. *Id.* ¶ 31. InterMune is a pharmaceutical product marketing company, that specializes in acquiring rights to and then commercializing pharmaceutical products. *Id.* ¶ 32. Harkonen served as InterMune's CEO from February 1998 through at least June 30, 2003. After June 30, 2003, Harkonen became InterMune's Vice President of Sales and Marketing. *Id.* ¶ 33. Harkonen was also a member of InterMune's Board of Directors from February 1998 through September 2003. *Id.* ¶ 33.

b. Defendants' Marketing of Actimmune

Plaintiffs allege that in order to increase Actimmune's profitability, InterMune engaged in a fraudulent campaign to market Actimmune for the treatment of IPF. "IPF is characterized by progressive scarring, or fibrosis, of the lungs which leads to their deterioration and destruction. . . . The cause of IPF is unknown, and the survival rate is generally only two to three years." *Id.* ¶ 48. There are approximately 200,000 individuals in the United States who suffer from the disease, and 50,000 new cases are diagnosed each year. *Id.*

InterMune began to market Actimmune for the treatment of IPF in early 2000, which coincided roughly with the publication of a 1999 Austrian study of eighteen humans with mild IPF who were treated with Actimmune. The study, which was published in the *New England Journal of Medicine*, showed that the patients treated with Actimmune and corticosteroids experienced improved lung-capacity and blood-oxygen levels when compared with patients receiving only corticosteroids. *Id.* ¶ 52. Over the following few years, a great deal of debate erupted in the scientific community regarding whether physicians or patients should rely on the study's conclusions and prescribe Actimmune for the treatment of IPF. *Id.* ¶¶ 53-57. The debate aside, InterMune began touting the study's results, in a range of forums and in a variety of ways, to promote Actimmune for the treatment of IPF. *Id.* ¶ 59-66. InterMune claimed that the 1999 study demonstrated that IPF patients treated with Actimmune experience a "survival benefit", meaning prolonged life expectancy, and that Actimmune could "reverse and halt" the progression of the disease. *Id.* ¶¶ 58, 78.

Given the promising results of the 1999 study, in 2000, InterMune funded its own 330 patient Phase III trial to test Actimmune's efficacy in treating IPF. The trial was primarily designed to test whether IPF patients treated with Actimmune would experience progression-free survival, but also tested as secondary endpoints whether patients had improved lung function at rest, quality of life, and survival rates.

When the trial was complete in August 2002, it failed to establish its primary endpoint, progression-free survival, or any of the secondary endpoints, including improved survival benefit. *Id.* ¶ 68. Despite the failure of the trial, InterMune and Harkonen, in press releases and conference calls, repeatedly stated that the trial demonstrated that IPF patients treated with Actimmune, especially those in the early stages of the disease, experienced a significant survival benefit. *Id.* ¶¶ 71-74, 77, 86, 89. For example, on August 28, 2002, the day that the October 2000 study's results were released, InterMune distributed a press release proclaiming that the study showed that Actimmune "reduces morality by 70% in Patients with Mild to Moderate [IPF]" and that "[A]CTIMMUNE is the only available treatment demonstrated to have clinical benefit in IPF, with

improved survival data in two controlled clinical trials." *Id.* ¶ 71 (emphasis added). At the direction of InterMune, a specialty pharmacy faxed that same press release touting Actimmune's efficacy in reducing mortality to more than 2,000 pulmonologists. *Id.* ¶ 76. InterMune also directed the specialty pharmacy to mail a letter to patients already taking Actimmune, claiming that Actimmune reduced mortality for those with mild to moderate IPF, and that "ACTIMMUNE should be used early in the course of treatment of [IPF] in order to realize the most favorable long-term survival benefit." *Id.* ¶ 77.

Many independent scientific observers were critical of the manner in which InterMune and Harkonen interpreted the 2000 trial's results. *Id.* ¶¶ 80-86. At the same time, a January 2004 article published in the *New England Journal of Medicine*, written by one of the individuals involved in the 2000 study, claimed that "[w]e observed a trend toward enhanced survival in all randomized patients who were treated with [Actimmune] as compared with those receiving placebo . . . ." *Id.* ¶ 88. Another article, written by paid InterMune consultants and employees and published in the January 2005 issue of the journal *CHEST*, claimed that "the suggestion of benefit of [ACTIMMUNE] on both disease progression and mortality in almost all subgroups of lung function, while not reaching statistical significance in all, is promising and requires further exploration in larger and longer clinical trials of [ACTIMMUNE]." *Id.* ¶ 91.

In 2003 and again in 2005, InterMune enrolled patients in a Phase II trial of Actimmune in an attempt to prove that Actimmune benefitted individuals afflicted with IPF. In 2007, however, the FDA announced the early termination of the study after "an interim analysis showed that patients with IPF who received ACTIMMUNE did not benefit." *Id.* ¶ 102.

From 2001 until 2007, InterMune stated to its sales representatives that Actimmune provided a survival benefit to IPF sufferers and provided those representatives with financial incentives to market the drug off-label to pulmonologists. *Id.* ¶¶ 113-18. Because Actimmune was not approved for any indications relevant to pulmonologists, Actimmune sales representatives used other InterMune drugs that were approved for the treatment of pulmonology impairments to gain access to

pulmonologist offices. *Id.* ¶ 119. Once the representatives gained access, they were encouraged to and did promote Actimmune to pulomonologists for the treatment of IPF. *Id.* ¶¶ 120-124.

Plaintiffs also allege that defendants furthered their fraudulent marketing scheme by creating a publically accessible registry, operated by InterMune's sales and marketing staff, that collected information about patients taking Actimmune for the treatment of IPF, but in reality was used to promote the use of Actimmune to treat IPF, *id.* ¶¶ 126-27; by sponsoring meetings at which InterMune advocated the use of Actimmune to treat IPF, *id.* ¶¶ 129-33; and by creating a "bogus" IPF patient advocacy group that perpetuated, through the publication of a newsletter and the maintenance of a website, the false information that IPF patients benefitted from taking Actimmune, *id.* ¶¶ 134-47.

On October 26, 2006, after a two-year investigation, the United States Attorney for the Northern District of California filed a felony information charging InterMune with deceptive, fraudulent, and off-label marketing of Actimmune. *Id.* ¶¶ 148-49. To resolve the criminal charges against it, InterMune agreed to pay a $42.5 million penalty, and entered into a deferred prosecution agreement. *Id.* ¶ 150. On March 18, 2008, Harkonen was indicted by a grand jury in the Northern District of California for unlawfully promoting Actimmune. On September 29, 2009, a jury found Harkonen guilty of one count of wire fraud, 18 U.S.C. § 1343, based on his role in creating and disseminating the August 28, 2002 press release, and not guilty of mislabeling Actimmune pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. § 333(a)(2). *See United States v. Harkonen*, 08-0164, Docket No. 240 (Jury Verdict).

Plaintiffs allege that defendants' fraudulent conduct—actively marketing Actimmune for the treatment of IPF while knowing it was an inefficacious treatment for the disease—injured them by causing them to purchase an expensive drug that provided them with no benefit. The specific allegations as they relate to the individual consumer and TPP plaintiffs, as well as the holding in *Actimmune I*, are discussed in greater detail below.

LEGAL STANDARD

The same legal standards that applied to the initial motions to dismiss govern the court's analysis of the pending motions to dismiss.

I. Rule 12(b)(1), Standing

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) tests the subject matter jurisdiction of the court. *See, e.g.*, *Savage v. Glendale Union High Sch.*, 343 F.3d 1036, 1039-40 (9th Cir. 2003). Under Article III of the Constitution, federal judicial power extends only to "Cases" and "Controversies." U.S. Const., art. III, § 2, cl. 1. Article III standing is thus a threshold requirement for federal court jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-60 (1992). At a constitutional minimum, standing requires the party invoking federal jurisdiction to show that it has "suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, and that the injury can be traced to the challenged action and is likely to be redressed by a favorable decision." *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (citations and internal quotation marks omitted). To satisfy the injury in fact requirement, the alleged harm must be "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citations and internal quotation marks omitted). The party invoking federal jurisdiction bears the burden of establishing these elements. *Id.* at 561.

II. Rule 12(b)(6), Failure to State a Claim

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint may be dismissed against a defendant for failure to state a claim upon which relief can be granted against that defendant. A motion to dismiss under Rule 12(b)(6) "tests the legal sufficiency of a claim." *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Dismissal may be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). A motion to dismiss should be granted if a plaintiff fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 569 (2007). "The plausibility standard is not akin to a 'probability

requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 556). Allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337-38 (9th Cir. 1996). The court need not, however, accept as true pleadings that are no more than legal conclusions or the "formulaic recitation of the elements"of a cause of action. *Iqbal*, 129 S. Ct. at 1950; *see also Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001); *Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). "Determining whether a complaint states a plausible claim for relief . . . [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 129 S. Ct. at 1950.

III. Rule 9(b), Fraud-Based Claims

A plaintiff in federal court alleging claims grounded in fraud must satisfy a heightened pleading standard that requires that the circumstances constituting fraud be pled with particularity. Fed. R. Civ. P. 9(b). "Rule 9(b) demands that the circumstances constituting the alleged fraud 'be specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.' " *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)) (some quotation marks omitted). To satisfy Rule 9(b), plaintiffs must explicitly aver "the who, what, when, where, and how" of the alleged fraudulent conduct. *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997). In addition, plaintiffs must "set forth an explanation as to why [a] statement or omission complained of was false and misleading." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc); *see Fecht v. Price Co.*, 70 F.3d 1078, 1082 (9th Cir. 1995).

A plaintiff seeking to state a claim for fraud must also plead knowledge of falsity, or scienter. *See GlenFed*, 42 F.3d at 1546. The requirement for pleading scienter is less rigorous than that which applies to allegations regarding the "circumstances that constitute fraud" because "malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b).

Nonetheless, nothing in the Federal Rules of Civil Procedure relieves a plaintiff of the obligation to "set forth facts from which an inference of scienter could be drawn." *Cooper*, 137 F.3d at 628 (quoting *GlenFed*, 42 F.3d at 1546).

It is well settled in the Ninth Circuit that the Federal Rules of Civil Procedure, including Rule 9(b), "apply in federal court, 'irrespective of the source of the subject matter jurisdiction, and irrespective of whether the substantive law at issue is state or federal.' " *Kearns*, 567 F.3d at 1125 (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1102 (9th Cir. 2003)). Thus, plaintiffs' state law claims, at least to the extent they sound in fraud, must satisfy Rule (9)(b). *Id.*; *Vess*, 317 F.3d at 1102-05.

DISCUSSION

I. *Actimmune I*

In *Actimmune I*, the court dismissed plaintiffs' FAC in its entirety. The court held that plaintiffs' complaint was deficient in two primary ways. First, plaintiffs failed to specify how, or even if, defendants' alleged conduct injured any of the class representatives. In light of the elements of the RICO and state law causes of action, as well as Rule 9(b), plaintiffs complaint lacked sufficient details regarding "what specific information the individual plaintiffs or their physicians had about the drug [and] the extent to which they relied upon that information . . . ." *Actimmune I*, 614 F. Supp. 2d at 1052. The FAC was so deficient in this respect that it did not even allege that any of the named plaintiffs "suffered from IPF . . . took Actimmune® for that reason, or indeed if [Actimmune] was even prescribed at all or if plaintiffs obtained the drug by other means." *Id.* at 1051; *see id.* ("[N]o individual plaintiff has even alleged that their injuries resulted from defendants' purported fraud. Plaintiffs have not put forth any specific allegations that anyone—the doctors, the plaintiffs themselves, or any other third party—relied on defendants' purportedly fraudulent misrepresentations to cause the injury."); *id.* at 1052 ("The issue is whether the [scientific] studies themselves could have provided another basis for physician reliance, apart from the allegedly misleading representations by defendants to physicians. Plaintiffs fail to address this possibility and

therefore fail to sufficiently allege that the purportedly fraudulent practices of defendants fostered a belief that Actimmune® was effective in treating IPF and therefore caused physicians to prescribe Actimmune®, resulting in plaintiffs' harm.").

Second, seeing as the falsity of defendants' representations regarding Actimmune are at the center of all of plaintiffs' causes of action, plaintiffs' allegations did not provide a basis from which the court could infer that the statements made by defendants were false or something other than permissible, non-actionable "puffery." *Id.* at 1055; *see id.* at 1052 (holding that plaintiffs' complaint did not properly allege that "the information relied upon [by doctors and patients] was false, misleading or otherwise fraudulent"). In order to survive a motion to dismiss, the court held, plaintiffs' allegations of falsity require more than "summary assertions that defendants fraudulently misrepresented the scientific literature on Actimmune." *Id.*

Because of these two shortcomings in plaintiffs' FAC, the court dismissed all of the causes of action against defendants. The court did so, however, without prejudice, concluding that in accordance with the law of this Circuit, it was premature to dismiss with prejudice when there was a possibility that "plaintiffs [could] cure the aforementioned flaws in their pleading." *Id.* at 1053 (dismissing the RICO claims without prejudice); *id.* at 1055 (dismissing the state law claims without prejudice). As is discussed above, plaintiffs filed a SAC in an effort to remedy the deficiencies in the FAC. Docket Nos. 101-02. With *Actimmune I* in mind, the court now turns to plaintiffs SAC to determine if it can survive the instant motion to dismiss.

II. The Causes of Action Under California Law

In *Actimmune I*, the court devoted the bulk of its discussion to the substantive requirements of the plaintiffs' RICO claims. Because plaintiffs have since abandoned their RICO claims, the court must examine the contours of plaintiffs' state law claims more closely.

a. The California Unfair Competition Law

The California Unfair Competition Law ("UCL") prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . . ." Cal. Bus. & Prof. Code § 17200. Because section 17200 is written in the disjunctive, "a business act or

practice need only meet one of the three criteria—unlawful, unfair, or fraudulent—to be considered unfair competition under the UCL." *Daro v. Superior Court*, 151 Cal. App. 4th 1079, 1093 (2007). In their complaint, plaintiffs contend that defendants' conduct violated all three prongs of the UCL. the court addresses each in turn.

1. UCL fraudulent prong

To state a claim under the UCL for fraudulent marketing or advertising, a plaintiff need merely allege that "members of the public are likely to be deceived" by defendants' conduct. *Committee on Children's Television, Inc. v. General Foods Corp.*, 35 Cal. 3d 197, 211 (1983). In this sense, the UCL presents a substantively distinct standard from common law fraud. *See In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009). "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." *Id.* (internal quotation marks omitted). Instead, the UCL focuses primarily on "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." *Id.* "While the scope of conduct covered by the UCL is broad, its remedies are limited. A UCL action is equitable in nature; damages cannot be recovered." *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1144 (2003). A prevailing plaintiff's recovery is "generally limited to injunctive relief and restitution." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 179 (1999); *see also* Cal. Bus. & Prof. Code § 17203.

Although the UCL standard for fraudulent business practices is more easily met than its common law counterpart, class representatives in a UCL fraud action must still establish standing. Proposition 64, passed by the California voters in 2004, altered California Business and Professions Code section 17203 to narrow the types of plaintiffs who may assert claims on behalf of a class. Section 17203 now provides that "[a]ny person may pursue representative claims for relief on behalf of others only if the claimant meets the standing requirements of Section 17204 . . . ." Section 17204, in turn, states that an individual may bring suit for a violation of the UCL only if he or she

has "suffered injury in fact and has lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204.

The California Supreme Court recently held that, in the context of a fraudulent business practices claim under the UCL, the phrase "as a result of" in section 17204 mandates that a plaintiff demonstrate "actual reliance" upon a defendant's misrepresentation or omission. *Tobacco II*, 46 Cal. 4th at 327. Reliance can be established by showing that but-for the defendant's fraudulent conduct, "the plaintiff 'in all reasonable probability' would not have engaged in the injury-producing conduct." *Id.* at 326 (quoting *Mirkin v. Wasserman*, 5 Cal. 4th 1082, 1110-11 (1993) (Kennard, J., concurring in part & dissenting in part)). However, plaintiffs need not establish that defendants' conduct was the "only cause" of their alleged injury. *Id.* "It is enough that the representation . . . played a substantial part, and so has been a substantial factor, in *influencing*" the plaintiffs' behavior. *Engalla v. Permanente Med. Group, Inc.*, 15 Cal. 4th 951, 977 (1997). Further, under the UCL, plaintiffs do "not need to demonstrate individualized reliance on *specific* misrepresentations to satisfy the reliance requirement." *Tobacco II*, 46 Cal. 4th at 327 (emphasis added). In particular, "where . . . a plaintiff alleges exposure to a long-term advertising campaign, the plaintiff is not required to plead with an unrealistic degree of specificity that the plaintiff relied on particular advertisements or statements." *Id.* In sum, "a plaintiff must plead and prove actual reliance to satisfy the standing requirement of section 17204 but . . . is not required to necessarily plead and prove individualized reliance on specific misrepresentations or false statements where . . . those misrepresentations and false statements were part of an extensive and long-term advertising campaign." *Id.*

Although *Tobacco II* altered the pleading requirements for a UCL plaintiff seeking to represent a class of similarly situated individuals, it did not relieve class representatives from the burden of satisfying Rule 9(b) when their allegations "sound in fraud." *See Kearns*, 567 F.3d at 1125. As is discussed at length below, plaintiffs' claims under the fraudulent prong of the UCL—which are predicated entirely on misstatements made by defendants—unmistakably "sound in fraud" and thus must be pled with specificity.

Plaintiffs' allegations of fraud in the FAC were deficient in two primary respects: (1) plaintiffs did not identify any specific false or misleading representations made by defendants about Actimmune; and (2) plaintiffs did not allege that they relied upon any false or misleading statements in deciding to pay for Actimmune.

I. Falsity

The additional allegations included in plaintiffs' SAC adequately identify a number of false statements made by defendants that could serve as the foundation for plaintiffs' fraud-based UCL claim. Between 2000 and 2005, InterMune and Harkonen repeatedly stated that IPF patients treated with Actimmune experienced a statistically significant "survival benefit," meaning they lived longer than IPF sufferers not receiving Actimmune. The SAC specifies, by date and manner of communication, at least eleven instances where InterMune or Harkonen expressed the "survival benefit" theme. *See* SAC ¶ 62 (May 2, 2002 Press Release) ("Longterm follow-up data from a phase II clinical trial of Actimmune [demonstrated] a *mortality benefit* in IPF patients randomly assigned to Actimmune versus control treatment.") (emphasis added); *id.* ¶ 63 (July 18, 2002 Investor Conference Call) (Harkonen stated that follow-up data from 1999 Austrian study "demonstrates significant *survival benefit*" in IPF patients treated with Actimmune) (emphasis added); *id.* ¶ 71 (August 28, 2002 Press Release, discussing results of October 2000 study) ("InterMune Announces Phase II Data Demonstrating *Survival Benefit* of ACTIMMUNE in IPF; reduces morality by 70% in Patients with Mild to Moderate Disease. . . . ACTIMMUNE may extend the lives of patients suffering from this debilitating disease. . . . ACTIMMUNE is the only available treatment demonstrated to have clinical benefit in IPF, with *improved survival* data in two controlled clinical trials.") (emphasis added); *id.* ¶ 72 (August 28, 2002 Conference Call) (Harkonen states "[t]he results of this large study, basically confirming the *survival benefit*, are going to propel our sales growth demand by physicians and their patients for Actimmune.") (emphasis added); *id.* ¶ 73 (October 7, 2002 Press Release) ("[R]ecent Phase II clinical data suggesting *survival benefit* with Actimmune in IPF.") (emphasis added); *id.* ¶ 74 (January 6, 2003 Press Release) (quoting Harkonen as stating that "the preliminary *survival data* from the follow-up observation period continue to

support the hypothesis of a treatment benefit in IPF patients treated with Actimmune.") (emphasis added); *id.* (quoting Dr. James Pennington, Executive Vice President of Medical and Scientific Affairs at InterMune as stating "Actimmune is the first treatment with data from rigorous clinical trials that suggest a *survival benefit* in IPF patients. . . . We believe these results continue to indicate that early diagnosis of IPF and treatment with Actimmune may help patients achieve the most favorable long-term *survival benefit*.") (emphasis added); *id.* ¶ 77 (October 2002 letter drafted by InterMune sent to patients receiving Actimmune) ("ACTIMMUNE . . . showed a statistically significant *reduction in mortality* by 70% in patients with mild to moderate IPF. . . . These results indicate that ACTIMMUNE should be used early in the course of treatment of this disease in order to realize the most favorable long-term *survival benefit*.") (emphasis added); *id.* ¶ 86 (February 19, 2003 InterMune Conference Call) ("INSPIRE [t]rial suggested Actimmune provides a *survival benefit* for patients with mild to moderate impairment in lung function.") (emphasis added); *id.* ¶ 89 (August 4, 2004 presentation by Daniel Welsh, President and CEO of InterMune) ("However, in those patients who were less sick, . . . then you see a very powerful and very meaningful statistically important difference in *survival* when compared with placebo.") (emphasis added); *id.* ¶ 92 (Jan. 10, 2005 Press Release re: 2005 *CHEST* article) ("[n]early all patient subgroups defined by physiology had a tendency toward *prolonged survival* with Actimmune, therapy, and this effect was strongest in patients with baseline FVC of greater than or equal to 55%") (emphasis added); *id.* ¶ 98 (April 28, 2005 Conference Call re: INSPIRE study) (Welch stated "[t]here have been observations to be verified in INSPIRE that in some patients [Actimmune] does suggest an increased *survival benefit*.") (emphasis added).

Plaintiffs plainly allege that all of these statements were false. These representations regarding a survival benefit were primarily based upon the results of the 2000 clinical trial conducted by InterMune. Plaintiffs aver that the 2000 clinical trial "failed to show statistical significance as to any agreed upon secondary endpoint, *including overall survival rates*." *Id.* ¶ 64 (emphasis added). In so pleading, plaintiffs have satisfied the requirement that they allege fraudulent conduct with specificity. They have identified numerous instances in which defendants

stated that Actimmune provided a survival benefit and have also alleged that defendants knew that such assertions were objectively false. Whether the evidence in this case would bear out these contentions—that defendants did, in fact, make representations that Actimmune improved survival rates, and that the 2000 study did not show any survival benefit for IPF patients treated with Actimmune—is not for this court to decide at this time. It is enough that plaintiffs in the SAC have explained how and why specific representations by defendants about Actimmune were false or misleading.

Plaintiffs have also identified two additional instances in which defendants made allegedly false statements regarding the results of the 1999 Austrian pilot study that functioned as the springboard for defendants' marketing of Actimmune as a treatment for IPF. Defendants touted the study, claiming in InterMune's 2000 Securities and Exchange Commission filing that it "showed statistically significant evidence that interferon gamma-1b can halt and reverse the progression of idiopathic pulmonary fibrosis." *Id.* ¶ 58. Later, on an April 24, 2002, conference call, Dr. Harkonen echoed that sentiment, stating that the Austrian investigators found that Actimmune, especially when prescribed over a three to nine month period, had the ability to "reverse the disease." *Id.* ¶ 78. Plaintiffs concede that the 1999 study "showed some improvement in patients' lung capacity and blood oxygen level . . . ." *Id.* ¶ 54. They allege, however, that both of the above-identified statements were false because the 1999 study "did not show that ACTIMMUNE could halt and reverse the progression of IPF." *Id.* ¶ 54. Accordingly, InterMune's and Harkonen's statements about Actimmune's ability to "halt or reverse" IPF progression can satisfy the false, material representation element of plaintiffs' UCL fraudulent prong claim.

By presenting specific allegations of false statements made by defendants, plaintiffs have complied with the court's initial order dismissing the FAC. The court must now turn to plaintiffs' allegations of causation and reliance.

ii. Causation and reliance

Plaintiffs have not sufficiently amended their complaint to cure the causation and reliance deficiencies in their UCL fraudulent prong claim. This is not to say that plaintiffs' SAC was totally

unresponsive to the court's concerns. Whereas the FAC failed to even allege that plaintiffs "suffered from IPF . . . took Actimmune for that reason, or indeed if [Actimmune] was even prescribed at all or if plaintiffs obtained the drug by other means," *id.* at 1051, the SAC now adequately includes those details for each plaintiff. *See id.* ¶ 9 (Jarrett); *id.* ¶ 10 (Isenhower); *id.* ¶ 11 (Frankel); *id.* ¶ 12 (Rybkoski); *id.* ¶ 13 (Stevens); GEHA's FAC ¶¶ 9-10.

Plaintiffs have not, however, supplemented their complaint with any allegations of sufficient specificity from which the court could infer that any of above-alleged misrepresentations caused injury to plaintiffs by inducing them to pay for Actimmune. The allegations relating to plaintiffs Frankel and Isenhower are illustrative. Neither individual alleges with any degree of specificity that they or their doctors ever were actually the recipient of any of defendants' fraudulent representations. Instead, they merely allege that their doctors were exposed generally to the marketing of Actimmune because of their membership in various medical organizations and institutions and because they routinely received or had access to publications in which Actimmune was discussed. *Id.* ¶¶ 160-61. Such allegations clearly do not meet plaintiffs pleading burden. Plaintiffs do not identify any particular article, symposium, meeting, drug representative visit or any other vehicle for conveying information about pharmaceuticals from which they learned that Actimmune was an effective treatment for IPF. They do not specify the content of any misrepresentation, merely claiming that as a result of their generalized exposure to some information about Actimmune, they came to believe that it was "efficacious." Plaintiffs fail to allege that defendants were responsible for the information about Actimmune that the doctors received. And plaintiffs do not explain that the doctors relied upon the information they received about Actimmune when deciding to prescribe Actimmune for Frankel and Isenhower. Without some link connecting the doctors' alleged beliefs that Actimmune was efficacious for the treatment of IPF to some fraudulent representation or omission made by InterMune, the plaintiffs' allegations cannot satisfy Rule 12(b)(1), Rule 12(b)(6) or Rule 9(b).

The other consumer-plaintiffs' claims suffer from similar defects.[1] The SAC closely documents the professional affiliations of Dr. Jeffery Weiland, plaintiff Rybkoski's physician. The

plaintiffs claim that as a member of the American College of Chest Physicians ("CHEST"), Dr. Weiland had "access" to numerous articles and abstracts that contained false information about the Actimmune's usefulness in treating IPF. *Id.* ¶¶ 163-66. They also allege that "it is very likely" that Dr. Weiland relied upon inaccurate information about Actimmune provided by his colleague, Dr. James N. Allen, who provided a second opinion regarding Rybkoski's treatment. *Id.* ¶ 167. Dr. Allen, according to the complaint, was the beneficiary of significant research grants from InterMune and also was a principal investigator in one of the Actimmune clinical trials. *Id.* The SAC, however, completely fails to allege that Dr. Weiland ever believed that Actimmune was a useful treatment for IPF or that he relied upon that belief when he prescribed Actimmune for Rybkoski. Furthermore, a claim that an individual was "likely" exposed to fraudulent conduct and "likely" relied upon that conduct to their detriment cannot satisfy Rule 9(b).

Plaintiff Stevens' allegations come closest to stating a viable claim of fraud. The complaint asserts that prior to prescribing Actimmune to treat Stevens' IPF, her treating physician, Dr. Patrick Wolcott, was visited by an InterMune sales representative. *Id.* ¶ 168. According to the SAC, the representative informed Dr. Wolcott "that, based on clinical trials, ACTIMMUNE was promising in the treatment of IPF." *Id.* The SAC further alleges that "[b]ased upon the sales representative's statement, . . . Stevens and Dr. Wolcott agreed that [Stevens] would be treated for IPF with ACTIMMUNE." *Id.* ¶ 169. Stevens' allegations suffer from one primary shortcoming: claiming in 2001 that Actimmune appeared to be a "promising" treatment for IPF was not objectively false. According to the complaint, at the time Dr. Wolcott was visited by an InterMune sales representative, the only relevant clinical data available to defendants regarding Actimmune's efficacy as a treatment for IPF were the results of the 1999 Austrian study and an October 2000, InterMune-funded re-analysis of the Austrian study. As is discussed above, the Austrian investigators concluded that IPF patients treated with Actimmune "showed some improvement in their lung capacity and blood oxygen level at the end of 12 months." *Id.* ¶ 52. The 2000 re-analysis concluded that "patients with pulmonary fibrosis of unknown etiology who are resistant to an adequate trial of corticosteroids do improve with [ACTIMMUNE] and low dose prednisone

therapy." *Id.* ¶ 61. Given the results of those two studies, which plaintiffs have not alleged were incorrect, the InterMune representative who visited Dr. Wolcott did not proffer any objectively false or misleading representations about Actimmune; at the time, Actimmune was a "promising" treatment for IPF. Even if the statement was potentially misleading, the representative's comment that Actimmune was "promising" constitutes non-actionable puffery, in that it is not the type of "specific or absolute" statement of fact that can support a claim of fraud. *See Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1053 (9th Cir. 2008).

The allegations relating to the TPP plaintiff GEHA, also lack the details necessary to state a claim under California law and to satisfy Rule 9(b). GEHA claims that at least 50 pulmonologists who prescribed Actimmune for GEHA's members suffering from IPF also "worked directly with InterMune on ACTIMMUNE matters." GEHA's FAC ¶ 156. GEHA asserts that all of those doctors "relied on information they received from InterMune in making the decision to prescribe ACTIMMUNE for the treatment of IPF." *Id.* GEHA does not specify the content of the representations conveyed by InterMune to the prescribing doctors, nor does it allege that the doctors believed that Actimmune was an effective treatment for IPF. GEHA fails to allege whether any of its employees who ultimately decided whether or not to approve payment for Actimmune prescriptions were ever exposed to or relied upon any of defendants' misrepresentations. Without those averments, GEHA's claims sounding in fraud cannot survive defendants' motions to dismiss.

Plaintiffs argue that under the *Tobacco II* decision, their allegations are sufficient to defeat defendants' motions to dismiss. For at least three reasons, *Tobacco II* cannot rescue plaintiffs' claims under the UCL fraudulent prong. First, regardless of the substantive standard announced in *Tobacco II*, Rule 9(b) requires that plaintiffs allege fraud-based causes of action with particularity. Thus, while under certain circumstances *Tobacco II* may absolve plaintiffs in California courts from pleading the exact content, location, and timing of a representation that was part of a long-term fraudulent advertising campaign, Rule 9(b) mandates that the causation elements announced in *Tobacco II* be pled with specificity. *Vess*, 317 F.3d at 1103-04 ("[W]hile a federal court will

examine state law to determine whether the elements of fraud have been pled sufficiently to state a cause of action, the Rule 9(b) requirement that the circumstances of the fraud must be stated with particularity is a federally imposed rule."); *see also Marolda v. Symantec Corp.*, --- F.R.D. ----, 2009 WL 2252125, at *9 (N.D. Cal. 2009) (Patel, J.); *Germain v. J.C. Penney Co.*, No. CV 09-2847 CAS (FMOx), 2009 WL 1971336, at *4 (C.D. Cal. July 6, 2009) (holding post-*Tobacco II* that UCL claims sounding in fraud still must satisfy Rule 9(b)). None of the plaintiffs have met this burden. Stevens is the only plaintiff who alleges that he or her doctor were ever actually exposed to any representations made by defendants' about Actimmune. As is discussed above, her claim falls short because she does not allege that the statements upon which her doctor relied were false. All of the other plaintiffs allege only that it was "likely" that prescribing doctors were exposed to defendants' representations about Actimmune. Such an allegation is insufficient under *Tobacco II*. Further, with the exception of Stevens and GEHA, no plaintiffs allege that their doctors actually relied upon the information in defendants' marketing campaign when deciding to prescribe Actimmune to treat IPF. Accordingly, plaintiffs fail to plead the elements of a UCL fraudulent prong claim, as defined by *Tobacco II*, with the specificity required by Rule 9(b).

Secondly, it is not clear that *Tobacco II*'s relaxed actual reliance standard has any application in the instant case. Under the UCL fraudulent prong, only "where . . . a plaintiff alleges exposure to a long-term advertising campaign," is a plaintiff freed from pleading "individualized reliance on specific misrepresentations to satisfy the reliance requirement." *Tobacco II*, 46 Cal. 4th at 327. Here, plaintiffs have not alleged that defendants' marketing campaign was an "extensive and long-term advertising campaign." *Id.* at 328. Certainly, defendants' seven year effort to market Actimmune to approximately 7,000 pulmonologists and 200,000 individuals suffering from IPF pales in comparison to the decades-long, national, ubiquitous advertising campaigns embarked upon by cigarette manufacturers.

Finally, plaintiffs argued at the hearing on this motion that defendants "saturated" the market for information regarding Actimmune, and thus plaintiffs' doctors necessarily relied upon defendants' misrepresentations when choosing to prescribe Actimmune. This "saturation" argument

is nothing more than a repackaging of the "fraud on the market" theory the court rejected in *Actimmune I*. *Actimmune I*, 614 F. Supp. 2d at 1054 ("The court will not let plaintiffs escape their burden to plead and prove the element of reliance by using a market-based fraud theory to handwave the requirement that there be a connection between the misdeed complained of and the loss suffered under state law."). That plaintiffs' doctors had access or were potentially exposed to defendants' misrepresentations is not sufficient to establish causation; as defendants eloquently expressed at the hearing, "causation is not communicable." Even under *Tobacco II*, plaintiffs must allege that they relied upon defendants' misstatements of fact.

Accordingly the court concludes that none of the plaintiffs have stated a claim under the UCL's fraudulent prong with the specificity required under Rule 9(b). The plaintiffs' claims under the UCL fraudulent prong are therefore dismissed.

2. UCL unfair prong

"[T]here is some uncertainty about the appropriate definition of the word 'unfair' " in the UCL. *Camacho v. Automobile Club of Southern California*, 142 Cal. App. 4th 1394, 1400 (2006). Although the California Supreme Court provided a relatively clear definition of the term to apply in cases where a business competitor alleges anti-competitive practices, *see Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 187 (1999), "California courts have not yet determined how to define 'unfair' in the *consumer* action context . . . ." *Lozano v. AT & T Wireless Services, Inc.*, 504 F.3d 718, 736 (2007). Some courts apply the *Cel-Tech* test—which requires that "unfairness must 'be tethered to some legislatively declared policy or proof of some actual or threatened impact on competition.' " *Id.* at 735 (quoting *Cel-Tech*, 20 Cal. 4th at 186). Others adhere to an older balancing test established in *South Bay Chevrolet v. General Motors Acceptance Corp.*, 72 Cal. App. 4th 861, 886 (1999), which weighs the unfair practice's "impact on its alleged victim . . . against the reasons, justifications and motives of the alleged wrongdoer." Still others have created entirely different tests or blended the *Cel-Tech* and *South Bay* approaches. *See Lozano*, 504 F.3d at 736. In *Lozano*, the Ninth Circuit held that, "in the absence of further

clarification by the California Supreme Court," district courts may apply either or both the *Cel-Tech* or *South Bay* tests to determine if a defendant's conduct is "unfair." *Id.*

To the extent a plaintiff alleges that a defendant engaged in unfair business practices or acts that are not fraudulent, those allegations need not satisfy Rule 9(b). *See Vess*, 317 F.3d at 1103-04; *see id.* at 1105 ("[W]here fraud is not an essential element of a claim, only allegations ('averments') of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b)."). In both the SAC and their moving papers, however, plaintiffs' unfair prong claims overlap entirely with their claims of fraud. In their opposition to defendants' motion, plaintiffs explained "Defendants' conduct was unfair in that, for example, they fraudulently misrepresented that Actimmune was effective for the treatment of IPF when they had no reliable evidence to substantiate their claim, and induced physicians to prescribe Actimmune on the basis of these unfounded representations." *See* Docket No. 114 (Opp'n) at 28. Plaintiffs suggest no other theory by which defendants' conduct could be considered unfair, but non-fraudulent. Therefore, because plaintiffs' UCL unfair prong claims sound entirely in fraud, they must satisfy Rule 9(b)'s pleading requirement. For the reasons discussed above, plaintiffs have not pled defendants' fraudulent conduct with sufficient specificity. Accordingly, plaintiffs' claims under the unfair prong of the UCL must be dismissed as well.

3. UCL unlawful prong

"Under its 'unlawful' prong, the UCL borrows violations of other laws . . . and makes those unlawful practices actionable under the UCL." *See Berryman v. Merit Prop. Mgmt.*, 152 Cal. App. 4th 1544, 1554 (2007) (internal quotation marks and citation omitted; alteration in original). "Thus, a violation of another law is a predicate for stating a cause of action under the UCL's unlawful prong." *Id.*; *see Smith v. State Farm Mut. Auto. Ins. Co.*, 93 Cal. App. 4th 700, 717-18 (2001) (holding the unlawful prong forbids "anything that can be properly called a business practice and that at the same time is forbidden by law").

Plaintiffs contend that the SAC adequately alleges that defendants violated the California Legal Remedies Act ("CLRA") and the Food Drug and Cosmetics Act ("FDCA"), as well as "FTC [Federal Trade Commission] and FDA regulations." Opp'n at 29. For reasons discussed below,

plaintiffs have not stated a claim for relief under the CLRA, meaning the CLRA may not function as the basis for a claim under the unlawful prong of the UCL. With respect to the other laws from which plaintiffs seek to borrow, nowhere in their complaint do plaintiffs mention any specific sections of the FDCA or the FTC and FDA regulations that defendants violated, let alone the elements necessary to prove such violations. Under the UCL unlawful prong, it is not necessary that plaintiffs allege violation of the predicate laws with particularity; they must at a minimum, however, identify the statutory or regulatory provisions that defendants allegedly violated. Once again plaintiffs have couched their claims in fraud or deception only. For the reasons stated above under the other prongs, these allegations must fail. Because of this and the fact that their complaint does not point to specific provisions of the appropriate statutes, plaintiffs' claims under the unlawful prong of the UCL are also dismissed.

b. California False Advertising Law, Cal. Bus. & Prof. §§ 17500 et seq.

The California False Advertising Law ("FAL") provides that it is unlawful for an individual or entity to knowingly or unreasonably make or disseminate an untrue or misleading advertisement in an attempt to sell a product. Cal. Bus. & Prof. Code § 17500. Like the UCL, the FAL permits a private individual to bring suit to enjoin a specific illegal advertising practice. Cal. Bus. & Prof. Code § 17535. The California voters, via Proposition 64, also altered the standing requirements under the FAL, inserting into the FAL the exact same language that appears in the UCL. *Id.* Thus, the standing analysis under the UCL and FAL is identical. *See Buckland v. Threshold Enters, Ltd.*, 155 Cal. App. 4th 798, 819 (2007). Because the court has already held that plaintiffs have not alleged standing under the UCL, the court holds that plaintiffs cannot allege standing under the FAL. The plaintiffs' FAL claim is therefore dismissed.

c. California Legal Remedies Act

The California Legal Remedies Act ("CLRA") proscribes 24 specific "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770. "Any consumer who suffers any damage as a result of" any of the enumerated

types of unlawful conduct may bring an action for damages, restitution and injunctive relief. Cal. Civ. Code, § 1780(a). An individual filing suit under the CLRA, including one bringing suit on behalf of a class of similarly situated consumers, must establish standing under the statute. In comparison to the UCL and FAL, the CLRA has a more stringent standing requirement, in that a class representative must show actual causation and reliance. *See Wilens v. TD Waterhouse Group, Inc.*, 120 Cal. App. 4th 746, 755 (2003) ("[The CLRA] does not create an automatic award of statutory damages upon proof of an unlawful act. Relief under the CLRA is specifically limited to those who suffer damage, making causation a necessary element of proof."); *Massachusetts Mut. Life Ins. Co. v. Superior Court*, 97 Cal. App. 4th 1282, 1287 (2002). If the class representative can satisfy those requirements, the reliance of the class members may be inferred "if the trial court finds material misrepresentations were made to the class members." *Id.* at 1292-93.

Here, plaintiffs identify five provisions of the CLRA that defendants allegedly violated.[2] All five sound in fraud, meaning that plaintiffs' CLRA allegations must satisfy Rule 9(b). For reasons discussed at length above, plaintiffs have not adequately averred with the requisite specificity that they actually relied upon any of defendants' alleged misrepresentations. Accordingly, plaintiffs' CLRA claim fails and must also be dismissed.

d. Unjust Enrichment

Plaintiffs' final California cause of action, unjust enrichment, faces a number of insurmountable obstacles. In order to state a claim for unjust enrichment, a plaintiff must allege (1) that defendants received an unjust benefit and (2) and the unjust benefit was retained at plaintiffs' expense. *Peterson v. Cellco P'ship*, 164 Cal. App. 4th 1583, 1593 (2008). "The theory of unjust enrichment requires one who acquires a benefit which may not justly be retained, to return either the thing or its equivalent to the aggrieved party so as not to be unjustly enriched." *Otworth v. Southern Pac. Trans. Co.* 166 Cal. App. 3d 452, 460 (1985). Restitution is not ordinarily available to a plaintiff unless "the benefits were conferred by mistake, fraud, coercion or request; otherwise, though there is enrichment, it is not unjust." *Nibbi Bros., Inc. v. Home Federal Sav. & Loan Assn.*, 205 Cal. App. 3d 1415, 1422 (1988) (quoting 1 *Witkin Summary of Cal. Law*, Contracts, § 97, at 126

(9th ed. 1987)). Plaintiffs have not alleged that they paid InterMune for doses of Actimmune as a result of mistake, coercion or request. Accordingly, plaintiffs' only basis for their unjust enrichment claim would, like their other claims, sound in fraud, and be subject to Rule 9(b)'s particularity requirement. *See, e.g., Ramapo Land Co., Inc. v. Consolidated Rail Corp.*, 918 F. Supp. 123, 128 (S.D.N.Y. 1996) (holding that where unjust enrichment claim is founded on fraudulent conduct, pleadings must conform with Rule 9(b)). As is discussed above, plaintiffs have not specifically pled that defendants engaged in any "unjust" fraudulent conduct. Furthermore, courts routinely dismiss unjust enrichment claims where a plaintiff cannot assert any substantive claims against a defendant. *Oestreicher v. Alienware Corp.*, 544 F. Supp. 2d 964, 975 (2008) (Patel, J.) (dismissing unjust enrichment claim because plaintiff's "fraud-based claims have been dismissed") *aff'd* 322 Fed. Appx. 489 (9th Cir. 2009). Plaintiffs cannot maintain any of their substantive actions. Thus, their unjust enrichment claim must be dismissed.

II. Other state law claims

Plaintiffs also assert claims under the consumer protection statutes of 39 states in addition to California. In *Actimmune I*, the court suggested that plaintiffs "focus on state law claims in this state and the other states where the named plaintiffs reside." *Actimmune I*, 614 F. Supp. 2d at 1056. "A class cannot assert a claim on behalf of an individual that they cannot represent." *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1027 (N.D. Cal. 2007) (Alsup, J.). "Where, as here, a representative plaintiff is lacking for a particular state, all claims based on that state's laws are subject to dismissal." *In re Flash Memory Antitrust Litig.*, --- F. Supp. 2d ----, 2009 WL 1096602, at *25 (N.D. Cal. 2009) (Armstrong, J.). Plaintiffs' claims brought under the consumer protection statutes in states for which they do not have a representative—Alaska, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Maryland, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin—are dismissed.

Named consumer-plaintiffs Jarret, Isenhower, Frankel, Rybkoski and Stevens reside in Georgia, Indiana, Pennsylvania, Ohio and California, respectively. TPP-plaintiff GEHA has standing to sue under the consumer protection statutes in the state in which it is incorporated and operated, which is Missouri, and wherever it alleges it paid for Actimmune prescriptions, which is only California. GEHA's FAC ¶ 9.

Plaintiffs do not assert any claims under Indiana or Pennsylvania law, but do allege violations of Ohio, Missouri, and Georgia's consumer protection statutes. *See* SAC ¶¶ 199, 211, 215 (alleging violations of Ohio Rev. Code Ann. § 4165.01 *et seq.*, Mo. Rev. Stat. § 407.010 *et seq.*, Ga. Code Ann. § 10-1-393 *et seq.* and Ga. Code Ann. § 10-1-370 *et seq.*). Georgia and Ohio's consumer protection statutes clearly require that a plaintiff allege that a defendant's conduct caused the plaintiff an injury. *See Regency Nissan, Inc. v. Taylor*, 194 Ga. App. 645, 647 (1990) ("A private [Fair Business Practices Act, Ga. Code Ann. § 10-1-393,] claim has three essential elements: a violation of the act, *causation* and injury.") (emphasis added); *Friedlander v. HMS-PEP Products, Inc.*, 226 Ga. App. 123, 125 (1997) (holding that "[a]t the very minimum," an individual suing under Georgia's Uniform Deceptive Trade Practices Act, Ga. Code Ann. § 10-1-370 *et seq.*, "must show some *causal connection* between something [defendant] has done and [plaintiff's] own nonspeculative damages in order to receive relief") (emphasis added); *HER, Inc. v. RE/MAX First Choice, LLC*, 468 F. Supp. 2d 964, 979 (S.D. Ohio 2007) (holding that claim of false or misleading advertising [under Ohio Deceptive Trade Practices Act, Ohio Rev. Code Ann. § 4165.01 *et seq.*,] requires that plaintiffs allege the existence of "some *causal link* between the challenged statements and harm to the plaintiff") (emphasis added). For the reasons discussed above, plaintiffs in this action have not met that burden, and thus the Ohio and Georgia causes of action are dismissed.

GEHA's FAC does, however, appear to state a claim under Missouri's Merchandising Practices Act (MPA). Missouri courts have interpreted the MPA in the broadest conceivable manner, absolving plaintiffs of any showing of reliance on a defendant's unfair practice.[3] To establish a violation of the MPA, "a plaintiff must show that he purchased a product that was falsely represented in violation of the Act, and that as a result of such purchase transaction he received a

product that would have been worth more if it in fact had truly been as represented." *Collora v. R.J. Reynolds Tobacco Co.*, No. 002-00732, 2003 WL 23139377, at *2 (Mo. Cir. Ct. Dec. 31, 2003); *see also Plubell v. Merck & Co., Inc.*, 289 S.W.3d 707, 714 (Mo. Ct. App. 2009) ("The MMPA does not require that an unlawful practice cause a 'purchase.' . . . [A] plaintiff's loss should be a result of the defendant's unlawful practice, but the statute does not require that the purchase be caused by the unlawful practice. Therefore, [plaintiffs] are not . . . required to show what they would or would not have done had the product not been misrepresented and the risks known."). Here, GEHA's FAC alleges that it purchased a misrepresented product, Actimmune, and that as a result of that purchase, it received a product that would have been worth more if it in fact had been truly represented. In other words, Actimmune would have been more valuable if it had, as defendants represented, been an efficacious treatment for IPF. It should be noted that GEHA asserts this claim only against InterMune and Harkonen.

The court's preliminary conclusion that the GEHA's FAC states a claim for relief under the MPA has been reached without the benefit of briefing from the parties. Rather than deny defendants' motion to dismiss the MPA cause of action, the court requests additional briefing. Within fifteen (15) days, GEHA, InterMune and Harkonen are ordered to file supplemental briefs addressing (1) whether GEHA's FAC does, in fact, state a claim for relief under the MPA, and (2) if the MPA is the sole surviving claim, why the court should not transfer this action to a district in Missouri. Each brief shall not exceed seven (7) pages in length.

IV. Dismissals: with or without prejudice

Having held that all of plaintiffs' claims, with the exception of GEHA's MPA cause of action against InterMune and Harkonen, should be dismissed, the court must decide whether to dismiss with or without prejudice. Plaintiffs' claims under the UCL's fraudulent prong, the FAL, the CLRA and for unjust enrichment are dismissed with prejudice. Jarrett, Isenhower, Frankel, Rybkoski and Stevens's claims under all of the consumer protection statutes from states in addition to California are also dismissed with prejudice. The facts needed to adequately state claims under these statutory and common law provisions have always been within plaintiffs' and their treating physicians'

knowledge. The court provided plaintiffs with an opportunity to gather and allege the requisite facts. Their failure to do so justifies dismissing the claims with prejudice.

Plaintiffs' claims under the UCL's unfair and unlawful prongs are dismissed without prejudice. Plaintiffs may file an amended complaint within thirty (30) days. If plaintiffs do file an amended complaint, it must (1) state a claim under the unfair prong, clearly identify the "legislatively declared policy" that defendants' conduct contravened, and, (2) state a claim under the unlawful prong, clearly identify the specific statutory and/or regulatory provisions they allege that InterMune and Harkonen violated. Plaintiffs must also allege exactly how they were injured "as a result of" InterMune and Harkonen's unfair and/or unlawful conduct. They shall not, however, couch their UCL claims on a theory of fraud; all such claims are dismissed from this action with prejudice. To establish aiding and abetting liability with respect to Genentech, plaintiffs should carefully aver how Genentech had "actual knowledge" of and provided "substantial assistance" to InterMune and Harkonen's unfair or unlawful conduct.[4] *Schulz v. Neovi Data Corp.*, 152 Cal. App. 4th 86, 93 (2007).

CONCLUSION

Defendants' motion to dismiss is GRANTED in part.

Plaintiffs' claims under the UCL's fraudulent prong, the FAL, the CLRA, the consumer protection statutes of Alaska, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Maryland, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and for unjust enrichment are dismissed with prejudice.

Jarrett, Isenhower, Frankel, Rybkoski and Stevens's claims under Missouri's MPA are also dismissed with prejudice.

Plaintiffs' claims under the UCL's unfair and unlawful prongs are dismissed without prejudice. Plaintiffs may file an amended complaint within thirty (30) days of the date of this order

and in accordance with this order. Prior to ruling on whether GEHA's FAC states a claim for relief under Missouri's MPA, the court orders simultaneous supplemental briefing from GEHA, InterMune and Harkonen in accordance with this order. The briefs shall be filed within fifteen (15) days of the date of this order and shall not exceed seven (7) pages in length.

IT IS SO ORDERED.

Dated: November 6, 2009

MARILYN HALL PATEL
United States District Court Judge
Northern District of California

ENDNOTES

1. It should be noted that the SAC contains no allegations regarding how or when plaintiff Jarret or her physician were ever exposed to any of defendants' alleged misrepresentations.

2. In their moving papers, plaintiffs claim that defendants violated the following provisions of the CLRA:

- representing that the goods have source, sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have (Cal. Civil Code § 1770(a)(2) and § 1770(a)(5));

- representing that the goods have a particular affiliation, connection, or association with, or certification by another, which they do not have (Id. § 1770(a)(3));

- representing that the goods have a particular representation or designation of geographic origin in connection with the goods, which they do not have (Id. § 1770(a)(4));

- representing that the goods are of a particular standard, quality, or grade when they are of another (Id. § 1770(a)(7)); and

- advertising goods with intent not to sell them as advertised (Id. § 1770(a)(9)).

3. The term "unlawful practices," though not defined in the statute, *see* Mo. Rev. Stat. § 407.020, is defined very broadly in the regulations promulgated by the Missouri Attorney General to effectuate the MPA. *See* Mo. Code Regs. Ann. tit. 15, § 60-8.020(1) ("An unfair practice is any practice which: (A) Either: 1. Offends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or 2. Is unethical, oppressive or unscrupulous; and (B) Presents a risk of, or causes, substantial injury to consumers.")

4. Genentech asserts that it should be dismissed from this case entirely by pointing the court to a number of cases rejecting various plaintiffs' attempts to assert aiding and abetting liability over a defendant for violation of the UCL. *See Perfect 10, Inc. v. Visa Intern. Service Ass'n*, 494 F.3d 788 (9th Cir. 2007); *In re Jamster Marketing Litig.*, No. 05cv0819 JM(CAB), 2009 WL 1456632 (S.D. Cal. 2009); *Emery v. Visa Internet. Service Ass'n*, 95 Cal. App. 4th 952 (2002). These cases make clear that mere passive business interactions with an entity that might be violating the UCL is not sufficient to establish aiding and abetting liability. Along those lines, the court continues to hold that Genentech's license agreement with InterMune, by itself, cannot function as a basis for establishing aiding and abetting liability. *See InterMune I*, 614 F. Supp.2d 1 at 1056.

However, without the benefit of an amended complaint that identifies with greater specificity how InterMune and Harkonen acted unfairly or unlawfully under the UCL, it simply is not possible for the court to determine whether Genentech aided and abetted the unfair or unlawful conduct. To this point in this case, the parties have focused almost exclusively on whether plaintiffs adequately alleged that defendants engaged in fraudulent conduct. This order dismisses all fraud-based claims with prejudice. Plaintiffs are entitled to one final opportunity to allege a violation of the UCL's unfair and unlawful prongs and Genentech's legally actionable relationship to that violation. If on their third try plaintiffs fail to plead sufficient facts to satisfy that burden, plaintiffs' UCL unfair and unlawful prong claims will be dismissed with prejudice with respect to all defendants.