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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MUTUAL PHARMACEUTICAL COMPANY, INC., a Pennsylvania corporation, AR SCIENTIFIC, INC., a Delaware corporation, and AR HOLDING COMPANY, INC., a Delaware corporation,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., a Nevada corporation, WESTWARD PHARMACEUTICAL CORP, a Delaware corporation, GENERICS BIDCO I, LLC dba QUALITEST PHARMACEUTICALS, a Delaware corporation, VISION PHARMA, LLC, a New Jersey corporation; and EXCELLIUM PHARMACEUTICAL, INC., a New Jersey corporation,

Defendants.

CASE NO. CV 09-05700 PA (RCx)

The Honorable Percy Anderson

NOTICE OF MOTION AND MOTION OF DEFENDANTS WATSON PHARMACEUTICALS, INC., EXCELLIUM PHARMACEUTICAL, INC., AND VISION PHARMA LLC TO DISMISS PLAINTIFFS' COMPLAINT OR, IN THE ALTERNATIVE, TO DISMISS THE FOURTH CAUSE OF ACTION AND TO STRIKE ALLEGATIONS AND REQUESTS FOR DAMAGES

[Fed. R. Civ. P. 12(b)(6), 12 (f)]

Hearing:
Date: October 19, 2009
Time: 1:30 p.m.
Courtroom: 15

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT, on October 19, 2009 at 1:30 p.m. or at such date and time as the Court may establish, Defendants Watson Pharmaceuticals, Inc., Vision Pharma, LLC, and Excellium Pharmaceutical, Inc. (collectively, "Defendants") will and hereby do move before the Honorable Percy Anderson for an Order dismissing with prejudice the entire complaint of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively, "Plaintiffs") pursuant to Fed. R. Civ. P. 12(b)(6), on the ground it is an improper attempt to usurp the primary jurisdiction of the U.S. Food and Drug Administration, or in the alternative, (1) dismissing Plaintiffs' Fourth Cause Of Action for Common Law Unfair Competition pursuant to Fed. R. Civ. P. 12(b)(6) and (2) striking the following portions of Plaintiffs' Complaint pursuant to Fed. R. Civ. P. 12(f):

1. Paragraph L of the Prayer For Relief (page 37, lines 10-14) on the ground that the damages sought in that paragraph are not recoverable as a matter of law under section 17200, *et seq*., and section 17500, *et seq.*, of the California Business and Professions Code;

2. The words "and unfair" in Paragraph 152 (page 30, line 19), the words "and unfairly" in Paragraph D of the Prayer For Relief (page 36, line 15), and the words "competed unfairly against Plaintiffs by" in Paragraph E of the Prayer for Relief (page 36, lines 18-19), on the ground that Plaintiffs' allegations in those paragraphs improperly attempt to assert a claim under the "unfair" prong of California Business and Professions Code section 17200, *et seq*.

This Motion is based on this Notice of Motion and Motion, including the Memorandum of Points and Authorities set forth below, the pleadings and papers on file with the Court, any reply memorandum and points and authorities filed by

Defendants, all matters of which the court may take judicial notice, and any further evidence presented at or prior to the hearing on this motion.

This motion is made following the conference of counsel pursuant to Local Rule 7-3, which took place via e-mail on August 25, 2009 and telephonically on September 1, 2009, and September 9, 2009.

DATED: September 23, 2009

KEVIN E. GAUT
PATRICIA H. BENSON
MITCHELL SILBERBERG & KNUPP LLP

By: /s/ Patricia H. Benson
Patricia H. Benson
Attorneys for Defendant
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DATED: September 23, 2009

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DATED: September 23, 2009

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. ("Plaintiffs") have sued Moving Defendants Watson Pharmaceuticals, Vision Pharma, LLC, and Excellium Pharmaceutical, Inc. ("Defendants") because they sell colchicine, a therapeutic compound that has been extracted and used for more than one hundred years. Plaintiffs claim that the recent approval by the U.S. Food and Drug Administration ("FDA") of Plaintiffs' colchicine product, COLCRYS, for two specific and limited treatment purposes precludes the marketing of colchicine by any other company for any other purpose. Plaintiffs are incorrect as a matter of law.

First, FDA approval of Plaintiffs' limited-use drug has no effect on the Defendants' ability to distribute their broader-use drugs. Second, Plaintiffs are asking this Court to displace the FDA and to ban the sale of a drug that may be lawfully dispensed in the United States and that is currently reimbursed by both Medicare and Medicaid. *See* Social Security Act §§ 1860D-1 *et seq*., 1927, respectively. Such a court-ordered ban would not only usurp the FDA's exclusive enforcement authority and interfere with these federal health care programs, but also would endanger the public health by removing from the market all colchicine drug products labeled to prevent various symptoms associated with gout. Plaintiffs' drug–COLCRYS–has not been approved to prevent symptoms, but only to treat certain symptoms, once they appear. The FDA has not taken steps to ban the sale of Defendants' oral colchicine, and Defendants' arguments provide the Court with no basis to do so.

Congress has delegated to the FDA the discretion to remove – or not remove – unapproved products from the market (even assuming Defendants' products are unlawfully marketed). There is no private right of action under the Food, Drug,

and Cosmetic Act ("FDCA"). *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); 21 U.S.C. § 337(a).

Recognizing that they have no private right of action to enforce the FDCA, Plaintiffs now seek to circumvent *Buckman* and the exclusive jurisdiction of the FDA by instituting this private action under the Lanham Act and California state unfair competition law. Plaintiffs allege that Defendants violated the Lanham Act and California law because their products have not been approved by the FDA and therefore, their product labels and inserts, as well as their general marketing efforts, are false and misleading. Plaintiffs also claim that due to the asserted unapproved nature of Defendants' drugs, Defendants misrepresent their products' safety and effectiveness by providing incomplete information on their labels, and that they misrepresent their products' regulatory status by the simple act of using the customary marketing system for prescription drugs.

Plaintiffs' claims fail as a matter of law. First, Plaintiffs' attempt to stop Defendants from selling colchicine through standard sales channels is an impermissible effort to bring a private action for enforcement of the FDCA and the Orphan Drug Act ("ODA"). This end run around the regulatory process raises legal and policy questions – including, but not limited to, whether Defendants' products are lawfully on the market and, if not, whether the public health requires that they not be abruptly removed – that are within the primary jurisdiction of the FDA. The entire complaint, therefore, should be dismissed. Second, Plaintiffs' Fourth Cause of Action for common law unfair competition should be dismissed because California common law unfair competition only extends to claims for "passing off," which Plaintiffs do not and cannot allege. Third, Plaintiffs' claim for damages under sections 17200 and 17500 of the Cal. Bus. & Prof. Code should be stricken because compensatory damages are simply not available under those statutes. Fourth, Plaintiffs' allegations that Defendants have engaged in conduct prohibited by the "unfair" prong of Section 17200 should be stricken because

between competitors, "unfair" conduct must be based on incipient antitrust violations, none of which has been or can be alleged here.

II. BACKGROUND

Colchicine is an alkaloid derived from the *colchicum autumnale* plant. Use of colchicum for medical purposes began two thousand years ago, and colchicum was used for the treatment of gout pain as early as the 6th century A.D. Oral dosage colchicine became available in the 19th century, and has been used safely, effectively and continuously to treat and prevent symptoms of gout for more than one hundred years. As Plaintiffs note in their Complaint, "[t]he active pharmacological component of the plant, colchicum, was isolated in 1820 and, in 1883, a fairly pure colchicum was extracted and subsequently called colchicine." Compl. ¶ 59.

A. Overview of FDA Regulation of Drugs

Pursuant to the FDCA, Pub. L. No. 75-717, 52 Stat. 1040 (June 25, 1938), as amended, the FDA has jurisdiction over the distribution, manufacturing, and labeling of drugs in commerce. The FDCA prohibits anyone from distributing a "new drug" unless that drug has been affirmatively approved by the FDA. *See* FDCA § 505(a), 21 U.S.C. § 355(a). Many drugs are lawfully marketed without FDA approval because they are not "new drugs" within the meaning of the FDCA. Oral colchicine, which has been marketed continuously since before 1938, is such a drug. The regulation of drugs in the United States is divided into three time periods–(i) before June 25, 1938, (ii) between June 25, 1938 and October 9, 1962, and (iii) after October 9, 1962. Before the enactment of the FDCA on June 25, 1938, drugs could be marketed as long they were not misbranded or adulterated. *See* Federal Food and Drugs Act of 1906, Pub. L. 59-384, 34 Stat. 768 (June 10, 1906). The FDCA, enacted in 1938, required manufacturers to submit evidence

that their drugs were safe for their intended use. A drug could then be lawfully marketed as long as the FDA did not object; there was no formal FDA approval, but rather drugs were simply deemed "effective." In addition, any drug that was identical, related or similar ("IRS") to a drug that had been cleared by the FDA could be marketed without submitting anything to the FDA.

The Drug Amendments of 1962, Pub. L. No. 87-871, 76 Stat. 780 (Oct. 10, 1962), required for the first time that all new drugs must be shown by adequate studies to be both safe and effective for their intended uses, and that before a new drug could be marketed, the FDA had to affirmatively approve the application. For those drugs for which safety information had been submitted under the 1938 Act (*i.e.*, drugs that were first marketed between June 25, 1938 and October 9, 1962), the Amendments require the FDA to conduct only a retrospective literature review of the effectiveness of the drugs. *See id.* at § 107, 76 Stat. at 788. Where the FDA believes that such a drug is not effective, it will initiate a process to revoke marketing authorization. If the authorization is revoked, any drug that is IRS to that drug also may no longer be marketed.

The FDA has reviewed 3,400 products in this process, known as the DESI review. *See Weinberger v. Hynson, Westcott & Dunning, Inc*., 412 U.S. 609 (1973) (discussing the DESI process). Drugs for which DESI review has not been completed may be lawfully marketed and are in fact reimbursed under both Medicare and Medicaid. *See* Social Security Act § 1861D-1 *et seq*.; SSA §§ 1927(d) and 1927(k); 42 C.F.R. § 441.25. The DESI Review, however, does not apply to drugs marketed on or before June 24, 1938 ("grandfathered" drugs) or those that are generally recognized as safe and effective (collectively, "old drugs"). These drugs are not new drugs and may continue to be marketed without either FDA approval or DESI Review. *See* FDCA § 201p)(1) and (2), 21 U.S.C. § 321(p)(1) and (2). Colchicine is one of these drugs.

B. Drugs Are Determined by Their Intended Uses

Drugs are described by their chemical composition, their intended uses, their dosage form, strength, route of administration and patient population. *See* 73 Fed. Reg. 63491, 63492 (Oct. 24, 2008). Thus, the FDA regulates two drug compounds differently, even if they are chemically identical, if their intended uses are different. Here, Plaintiffs are marketing two colchicine drugs – one for treating FMF and another for treating acute gout flares. Compl. ¶¶ 81-83. Both of these drugs have different labeled uses than the colchicine marketed by Defendants, which is also indicated to prevent gout flares. Therefore, the drug products at issue are different.

C. Drug Approvals under the FDCA Today

Not all drug approvals are comparable. The FDA recognizes three broad categories of new drug approvals: (i) traditional New Drug Application ("NDA"); (ii) Abbreviated New Drug Application ("ANDA"); and (iii) so-called "paper NDAs" under Section 505(b)(2) of the FDCA. The traditional NDA is for entirely new drugs and usually requires the sponsor to conduct three sets of clinical trials usually taking five or more years to complete. An ANDA is used to bring a generic drug to market, and the application relies on the clinical studies conducted by the pioneer drug company. A paper NDA relies heavily on published literature and may also involve some limited new clinical trials. Usually, any such trial is relatively short and far less expensive than the trials underlying the traditional NDA. A paper NDA is commonly filed where the chemical compound has been approved for other indications and the sponsor wishes to expand its use to include a new indication. Here, the Plaintiffs sought and received paper NDA approvals under section 505(b)(2) rather than traditional full fledged NDAs.

D. The FDA's Authority to Remove Drugs From the Market

If the FDA determines that a drug is not being legally marketed, it has "complete discretion . . . to decide how and when" to exercise its enforcement authority. *Shering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (quoting *Heckler v. Chaney*, 470 U.S. 821, 822 (1985)) (emphasis added). Although the FDA has long known that thousands of unapproved drugs remain on the market, and has from time to time issued guidance regarding its approach to such drugs, it has taken no enforcement action against the majority of them. *See, e.g.*, FDA Compliance Policy Guide ("CPG") § 7132c.02 (1981).

In 2006, the FDA adopted a comprehensive enforcement policy. Expressly noting the dangers to the public health of abruptly removing products from the market, the FDA announced that it "intends to evaluate on a case-by-case basis whether justification exists to exercise enforcement discretion to allow continued marketing for some period of time after the FDA determines that a product is being marketed illegally." CPG § 440.100, at 5 (2006). As the FDA has implemented this policy, it has made clear that its approach is a flexible one, intended to bring products into compliance in a manner that protects the public health.

In its comprehensive policy, the FDA announced that it would take steps to phase unapproved drugs out of the market in a measured way that takes into account the potential for serious adverse public health consequences. CPG § 440.100, at 1. The FDA's established process for removing unapproved products from the market is designed to bring products into compliance "without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market." CPG § 440.100, at 2 (emphasis added). When a new drug, like COLCRYS, is approved, the FDA takes into account "the implications of enforcement actions on the marketplace and on consumers who are accustomed to using the marketed products." *Id.* at 5. Thus, the FDA does not ordinarily take enforcement actions to halt immediately the marketing of unapproved drugs.

Rather, the FDA generally establishes a grace period, *id.*, to permit patients using the unapproved products to transition to the newly approved drug, and to prepare for the impact of such a transition. The FDA's determination as to the appropriate length for the grace period involves a complex set of factors, including "the effects on the public health of proceeding immediately to remove the illegal products from the market," the burden on the affected parties, and any special circumstances. *Id.* at 6.

E. FDA's Regulation of Oral Colchicine

The FDA is well aware of the unapproved oral colchicine products on the market – but has taken no steps to remove them from the marketplace. Each of the colchicine products of the Defendants has been assigned a National Drug Code ("NDC") number[1] listed with the FDA in the NDC Directory for prescription drugs in compliance with section 510 of the FDCA, 21 U.S.C. § 360.[2]

As recently as February 2008, the FDA made clear its determination that removing oral colchicine products from the market was not an enforcement priority. FDA recently took enforcement action against injectable colchicine products, and, in doing so, the agency specifically recognized the existence of oral colchicine products – such as those at issue here – and declined to take enforcement action against them. Drug Products Containing Colchicine for Injection; Enforcement Action Dates, 73 Fed. Reg. 7565, 7566 (Notice) (Feb. 8, 2008) [hereinafter "Colchicine Notice"].

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[1] Watson's colchicine product is listed under Schein Pharmaceuticals, Inc., a pharmaceutical company that Watson acquired in 2000.

[2] Pursuant to section 510 of the FDCA, all drug product manufacturers are required to register annually and to list each of their drug products with FDA. 21 U.S.C. § 360. The National Drug Code Directory is a universal product identifier maintained by FDA that contains the human drug products listed under the statute. *See U.S. Food and Drug Administration: National Drug Directory* (Sept. 23, 2009) available at http://www.fdagov/Drugs/InformationOnDrugs/ucm145438.htm.

On July 29, 2009, the FDA approved Mutual's COLCRYS colchicine product for the treatment of familial Mediterranean fever ("FMF") and granted Mutual "orphan drug" status for that product under section 526 of the FDCA, 21 U.S.C. § 360bb. Under the Orphan Drug Act, 21 U.S.C. § 360aa-ee, orphan drugs are drug products that treat rare diseases or conditions affecting fewer than 200,000 Americans. Through grants of orphan drug status, the FDA provides a period of exclusivity for seven years, during which time the FDA will not approve another new drug application for the same drug for treatment of the same rare condition, in this case FMF. On July 30, 2009, the FDA also approved COLCRYS for treatment of acute gout flares, giving Mutual a three-year exclusivity period.[3]

Less than one week later, Plaintiffs filed the complaint in this case seeking to remove from the market Defendants' colchicine products. The FDA has made no determination as to how and whether to exercise its enforcement authority against oral colchicine products, including Defendants' products.

III. ARGUMENT

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal of a lawsuit for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "A district court should grant a motion to dismiss if plaintiffs have not pled 'enough facts to state a claim to relief that is plausible on its face.'" *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Here, Plaintiffs' claims fail as a matter of law and should be dismissed.

[3] The ODA does not provide true market exclusivity, but rather prevents the FDA from approving a new drug with the same indication during the period of "exclusivity." ODA does not preclude other companies already marketing similar drugs for the same indication from continuing to do so.

A. Plaintiffs' Claims Should Be Dismissed Because They Are Within The FDA's Primary Jurisdiction And Amount To An Impermissible Private Right Of Action Under The FDCA.

Recognizing that there is no private right of action to bring their claims under the FDCA, Plaintiffs have instead asserted that Defendants have violated the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and California state law. Plaintiffs' action attempts to make an end run around Section 310(a) of the FDCA, 21 U.S.C. § 337(a), which precludes a private right of action to remove Defendants' colchicine products from the marketplace immediately. Because all of Plaintiffs' claims fall squarely within the primary jurisdiction of FDA, they should not go forward.

Plaintiffs' claims, if permitted to proceed, would interfere with the "proper relationships between the courts and administrative agencies charged with particular regulatory duties," thus requiring application of "the doctrine of primary jurisdiction." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956). "The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). In weighing whether to dismiss a case under the doctrine,[4] courts "have traditionally employed such factors as (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 781 (9th Cir. 2002). "[T]he doctrine of primary jurisdiction is committed to the sound discretion of the court when

4 "Normally, if the court concludes that the dispute which forms the basis of the action is within the agency's primary jurisdiction, the case should be dismissed without prejudice so that the parties may pursue their administrative remedies." *Syntec Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 782 (9th Cir. 2002).

'protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme.'" *Id.* (quoting *United States v. General Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987)).

Here, Plaintiffs seek to usurp FDA's authority to make two determinations – whether Defendants' products require approval, and whether, notwithstanding FDA's approach to its prosecutorial discretion, Defendants' products should be immediately removed from the market. Because Plaintiffs' claims and requested relief are fundamentally at odds with FDA's comprehensive regulatory scheme, they should be dismissed.

1. Plaintiffs Have Not Alleged Any Facts to Support Their Naked Allegation that Defendants' Drugs Are Unlawfully Marketed, and any Such Determination Is Within the FDA's Primary Jurisdiction.

Plaintiffs' Complaint hinges on their bald allegation, repeated innumerable times, that the Defendants are unlawfully marketing their drug products because they have not been approved by the FDA. *See e.g.*, Complaint ¶ 16 ("illegal colchicine products"), ¶ 17 ("Defendants' unlawful marketing"), ¶ 18 ("unlawful marketing"), ¶ 19 (Defendants "illegal colchicine"). As noted above, however, it is only unlawful to market an unapproved "new drug." *See* FDCA § 505(a). It is not unlawful to market an unapproved old drug. Nowhere in their Complaint have Plaintiffs alleged that Defendants' products are "new drugs." Thus, the legal predicate necessary to support Plaintiffs' claim of unlawful marketing, namely that the product is an "unapproved new drug," is absent from this Complaint. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.").

To the extent any uncertainty exists over the regulatory status of Defendants' products, moreover, it is not for this Court to resolve in the first instance. *See*

Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) ("We decline to find and do not believe that the district court had to find . . . that which the FDA, with all of its scientific expertise, has yet to determine."); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) ("[T]he FDA has not yet determined whether or not the re-imported Summit devices need further approval at all. . . . Plaintiff's Lanham Act cause of action would thus 'usurp[ ] the FDA's discretionary role in the application and interpretation of its regulations.'") (citation omitted). Determining whether an old drug requires FDA approval involves the FDA's technical and scientific judgment. This is uniquely a judgment entrusted to the FDA. FDCA § 201(p)(1) and (2), 21 U.S.C. § 321(p)(1) and (2). Plaintiffs should not be permitted to remove this determination from the expert agency to which it was delegated.

2. It Is Within the FDA's Primary Jurisdiction to Remove Unapproved Products from the Market.

When new drugs are marketed without prior review, the FDA must decide whether and how to initiate enforcement proceedings. The enforcement provisions of the FDCA "authorize, but do not compel the FDA to undertake enforcement activity; they 'commit complete discretion to the Secretary to decide how and when they should be exercised.'" *Shering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (quoting *Heckler v. Chaney*, 470 U.S. 821, 822 (1985) (emphasis added).

Here, even assuming Defendants' drugs are "new drugs," the FDA has decided not to take enforcement action to remove Defendants' products from the market. In 2008, when the FDA announced that it would take action against unapproved injectable colchicine products, it affirmatively noted that it was *not* exercising its enforcement discretion to "affect the legal status of products containing colchicine in oral dosage forms." Colchicine Notice, 73 Fed. Reg. at 7566<SoftRt>. The Court should not ignore the FDA's decision.

It is telling that Plaintiffs themselves have acknowledged the primacy of the FDA. They have filed a Citizens Petition, which is currently pending, asking the FDA to find that, in the absence of additional studies, oral colchicine is not effective for preventing symptoms associated with gout. *See* Mutual Pharmaceutical Co., *Citizen Petition* (Aug. 7, 2008), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064806b1d8e; 5 U.S.C. § 553(e); 21 C.F.R. pt. 10. On February 6, 2009, the FDA responded: "FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. . . . We will respond to your petition as soon as we have reached a decision on your request." FDA/CDER, *Interim Response to Mutual Pharmaceutical Co., Inc. - Letter* (Feb. 5, 2008), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064 80847d33 (emphasis added). Plaintiffs have been continuously supplementing the record before the FDA.

By this lawsuit, however, Plaintiffs attempt to sidestep the FDA's primary jurisdiction. Though their bid to have the Court stand in for the FDA is couched in the "false advertising" language of the Lanham Act and California unfair competition law, Plaintiffs actually are seeking this Court's assistance to privately regulate the availability and labeling of prescription drugs. This ill conceived effort to skirt the FDA's exclusive authority should be rejected.

This Court should exercise its discretion by dismissing this case under the primary jurisdiction doctrine. *See Far East Conf. v. United States*, 342 U.S. 570, 574 (1952); *Writers Guild of Am., West, Inc. v. Am. Broadcasting Co.*, 609 F.2d 355, 366 (9th Cir. 1979) ("Deferral to the FCC is, we believe, essential to further the purposes of the delicately balanced system of broadcast regulation."). "The primary jurisdiction doctrine properly acknowledges 'the advantages of allowing an agency to apply its expert judgment,' and also recognizes that this expertise

does not merely involve issues of technical complexity, 'but extends to the policy judgments needed to implement an agency's mandate.'" *Dial A Car, Inc. v. Transp., Inc.*, 82 F.3d 484, 490 (D.C. Cir. 1996) (Edwards, J., concurring) (quoting *Allnet Commc'ns. Serv., Inc. v. Nat'l Exch. Carrier Ass'n*, 965 F.2d 1118, 1120 (D.C. Cir. 1992)). These policy judgments, in turn, extend to the discretionary enforcement decisions delegated to the agency. *See id.* ("[O]ne might imagine that the [regulatory] authorities, who have primary jurisdiction over enforcement of the [regulations], might decide (for any of a number of reasons) that certain types of violations ought not be prosecuted.").

This case effectively requires this Court to make two determinations that are at the heart of the FDA's authority: (1) whether Defendants' products are being marketed legally, *see supra* Part III.A.1, and (2) whether Defendants' products should be immediately removed from the market or subject to the FDA's standard grace period. *Cf. Ricci v. Chicago Mercantile Exch.*, 409 U.S. 289, 299-300 (1973) (noting that a primary jurisdiction issue arises "when conduct seemingly within the reach of the antitrust laws is also at least arguably protected or prohibited by another regulatory statute enacted by Congress" (emphases added)).

Whether and when a drug should be removed from the marketplace requires a policy-bound enforcement decision that "has been placed by Congress within the jurisdiction of" the FDA "pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority." *Syntek*, 307 F.3d at 781; *see* 21 U.S.C. § 337(a); 21 C.F.R. § 10.25(b) ("FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate . . . .").

Delicate policy matters are implicated by the FDA's decision-making involving a nationwide phase-out of thousands of drugs. *See* CPG § 440.100, at 2 (estimating that "as many as several thousand drug products" are marketed without approval). Consequently, an orderly approach to enforcement regarding these drugs "require[s] expertise or uniformity in administration," *Syntek*, 307 F.3d at

781, not enforcement under the Lanham Act or California state law by a private company competing with companies making the same drug that it seeks to exclude from the marketplace.

Even when the FDA determines that an unapproved new drug is being unlawfully marketed and should be removed from the marketplace, the FDA usually establishes a one-year grace period and does not demand immediate cessation of marketing or seizure of the product. *See* CPG § 440.100, at 6. Tellingly, in the *Ivax* case on which Plaintiffs so heavily rely, *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925 (C.D. Cal. 2006), the FDA announced a grace period for the drug at issue after the *Ivax* court's decision – which Plaintiffs fail to bring to this Court's attention. Drug Products Containing Quinine; Enforcement Action Dates, 71 Fed. Reg. 75,557, 75,559-60 (Notice) (Dec. 15, 2006) (announcing enforcement action against unapproved quinine products effective December 15, 2006, but permitting continued manufacturing of unapproved products through February 13, 2007, and continued distribution through June 13, 2007). Plaintiffs' one-sided portrayal of the issues at stake clouds the detailed technical and scientific nature of FDA's enforcement task.

Courts have routinely dismissed private attempts to enforce the FDCA dressed up as Lanham Act claims. *See, e.g.*, *Summit Tech.*, 922 F. Supp. at 306 ("Plaintiff's Lanham Act cause of action would thus 'usurp[] the FDA's discretionary role in the application and interpretation of its regulations.' It would force this Court to rule on the legality of Defendants' conduct before the FDA has done so. . . . As such, this would use the Lanham Act as a vehicle for enforcing the requirements of the FDCA." (citation omitted)). The Fourth Circuit, in a decision this Court has termed "extremely persuasive," *id.*, rejected a similar claim to the one Plaintiffs make here:

> We agree with the defendants that permitting Mylan to proceed on the theory that the defendants violated § 43(a)

> merely by placing their drugs on the market would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated thereunder. An attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted.

Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993); *see also Sandoz*, 902 F.2d at 232 (finding that "the issue of whether an ingredient is properly labeled 'active' or 'inactive' under FDA standards is not properly decided as an original matter by a district court in a Lanham Act case"); *cf. IQ Prods. Co. v. Pennzoil Prods. Co.*, 305 F.3d 368, 372-74 (5th Cir. 2002) (rejecting Lanham Act claim that omission of the word "flammable" falsely represented compliance with the Federal Hazardous Substances Act, where the agency with discretion to enforce the Act "was aware of [the defendant's] alleged labeling deficiencies but took no action").

Plaintiffs' basic contention is that Defendants, by marketing their drugs, are falsely representing that their products have received FDA approval. No doubt aware that private enforcement of the FDCA under the guise of the Lanham Act is forbidden, Plaintiffs add a thinly veneered layer to try to cover-up the true character of their claims. Rather than relying on the fact that Defendants market their products, Plaintiffs assert that Defendants' misrepresentation is achieved by "by listing their . . . colchicine products on the Price Lists, Wholesaler Ordering Systems, and other advertising channels." Compl. ¶ 115. In essence, since the Lanham Act does not permit a claim for falsely implying FDA approval by the act of lawfully marketing a product, Plaintiffs cast their claim as the false implication of FDA approval by the act of marketing a product <u>through conventional industry channels</u>. Plaintiffs' effort to distinguish impermissible attempts to enforce the FDCA and bona fide false advertising claims cannot survive close scrutiny.

Plaintiffs' requested relief speaks volumes. Plaintiffs ask this Court to enjoin Defendants from marketing their products on <u>all</u> price lists, wholesaler

ordering systems, and "pharmacy and drug store computer systems," "including but not limited to" specific databases mentioned in the complaint. Compl. at 34 (emphasis added). The relief Plaintiffs seek is nothing less than the immediate removal of Defendants' products from the market, something the FDA has declined to do.

Nor is this case controlled by *Ivax*, as Plaintiffs contend. *See, e.g.*, *Pls.' Mot. for Prelim. Inj.* at 14. The *Ivax* Court drew a line between claims premised simply on marketing an unapproved drug and those asserting an actual misrepresentation of FDA approval. *See id.*; *see also Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 944 (E.D. Wis. 2008) ("When and if a false advertising claim strays 'too close to the exclusive enforcement domain of the FDA,' it cannot stand.") (citation omitted), appeal pending, Nos. 09-1438, 09-1462, 09-1601 (7th Cir. submitted Sept. 15, 2009). Asserting that Defendants actually misrepresent their approval status by using the industry's customary forms of marketing, however, is simply a clever way of saying that Defendants impermissibly market their products. Such a claim is not viable under *Ivax,* or any other precedent.

The recent guidance announced by the FDA reinforces the importance of dismissing claims that boil down to general allegations of marketing an unapproved drug. The *Ivax* Court did not address the FDA's practice of establishing grace periods or those provisions of the FDCA that permit continued marketing of a pre-1962 or pre-1938 drug. The FDA's recently announced enforcement strategy makes clear that Lanham Act claims that effectively seek the removal of drugs from the market interfere with that strategy. Given the FDA's carefully balanced enforcement agenda and the express public health concerns underlying it, a Lanham Act claim (or parallel state law claim) purporting to target specific marketing strategies, but in effect targeting the marketing of drugs in general, should be dismissed.

In short, this case is simply a thinly veiled attempt to bring a private right of action under the FDCA and runs headlong into the FDA's primary jurisdiction to take enforcement actions to remove unapproved drugs from the marketplace when the FDA has declined to do so. Accordingly, the complaint should be dismissed as a matter of law.

B. Plaintiffs' Fourth Cause Of Action For Violation Of California Unfair Competition Law Should Be Dismissed Because Plaintiff Cannot Allege "Passing Off"

Dismissal of a claim "can 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. 1990). Where, as here, Plaintiffs attempt to plead a cause of action under California law, the court looks to the state law for the substantive requirements of the cause of action. *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 726 (1966). Because California common law does not permit Plaintiffs to state a claim for "Unfair Competition" based on the conduct Plaintiffs allege or can allege, Plaintiffs' Fourth Cause Of Action should be dismissed.

Under California law, common law unfair competition claims do not extend to anything beyond claims for "passing off" the goods of the Defendant as those of the Plaintiff. *See*, *e.g.*, *Bank of the West v. Superior Court*, 2 Cal. 4th 1254, 1263 (1992) ("The common law tort of unfair competition is generally thought to be synonymous with the act of 'passing off' one's goods as those of another."). The narrow common law definition of unfair competition, for which damages may be available, cannot be equated with the broader statutory definition of unfair competition, for which damages are not available. *See Bank of the West*, 2 Cal. 4th at 1264-1266. Thus, federal courts have repeatedly held that a plaintiff cannot state a claim for California common law unfair competition where the claim does

not amount to "passing off." *See Sybersound Records, Inc. v. UAV Corp.*, 517 F.3d 1137, 1153 (9th Cir. 2008) (claim for common law unfair competition properly dismissed because plaintiff did not allege passing off); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1147 (9th Cir. 1997) (same).

In *Southland Sod Farms*, the plaintiff presented sufficient evidence to withstand summary judgment on its false advertising claim, but the Ninth Circuit held that that evidence would not support a claim for common law unfair competition because allegations of false advertising (including false comparative advertising) do not amount to allegations of "passing off." *See* 108 F.3d at 1147. Here, Plaintiffs' Fourth Cause of Action is founded on the allegation that "Defendants have implicitly and explicitly made false and misleading misrepresentations… that their colchicine products are FDA approved and/or comparable or equivalent to Plaintiffs'… product." Compl., ¶ 165 (p. 32, ll. 15-19). These are precisely the type of averments the Ninth Circuit found insufficient for common law unfair competition purposes in *Southland Sod Farms*. Accordingly, Plaintiffs' Fourth Cause Of Action for common law unfair competition should be dismissed. *See Sybersound Records*, 517 F.3d at 1153; *Southland Sod Farms*, 108 F.3d at 1147.

C. Plaintiffs' Claim For Damages Under Sections 17200 and 17500 Should Be Stricken Because Damages Are Not Available Remedies Under Those Statutes

"A motion to strike may be used to strike a prayer for relief where the damages sought are not recoverable as a matter of law." *Friedman v. 24 Hour Fitness USA, Inc.*, 580 F. Supp. 2d 985, 990 (C.D. Cal. 2008) (request for punitive damages stricken where not supported by statute), citing *Bureerong v. Uvawas*, 922 F. Supp. 1450, 1479, n. 34 (C.D. Cal. 1996). Paragraph L of the "Prayer For Relief" in the Complaint improperly seeks damages under California Business and

Professions Code Sections 17200 and 17500, "including exemplary damages provided by § 17206." Plaintiffs cannot obtain damages under any of these provisions, and therefore these claims for damages should be stricken.

A private plaintiff may not obtain damages under section 17200, *et seq.*, of the California Business and Professions Code. *See Korea Supply Co. v. Lockheed Martin*, 29 Cal. 4th 1134, 1144; 1148 (2003) ("damages cannot be recovered" under section 17200, *et seq.*, including under section 17206; punitive damages also not available); *Cel-Tech Cmmc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 179 (1999) ("Plaintiffs may not receive damages" under statutory unfair competition law). Nor may a private plaintiff receive damages under section 17500. *See Chern v. Bank of Am.*, 15 Cal. 3d 866, 875 (1976) (section 17500, *et seq.*, "do[es] not authorize recovery of damages by private individuals"). Accordingly, federal courts routinely dismiss claims for damages under these statutes. *See Little Oil Co., Inc. v. Atl. Richfield Co.*, 852 F.2d 441, 445 (9th Cir. 1988) (trial court properly dismissed claims for damages under section 17200, *et seq.*, and section 17500, *et seq.*, because private individuals cannot recover damages under those statutes); *Lee Myles Assocs. Corp. v. Paul Rubke Enters., Inc.*, 557 F. Supp. 2d 1134, 1144 (S.D. Cal. 2008) (motion to strike claim for damages under section 17200 granted); *Brown v. Allstate Ins. Co.*, 17 F. Supp. 2d 1134 (S.D. Cal. 1998) (claim for damages under section 17500 dismissed without leave to amend). Because Plaintiffs' claim for damages under California Business and Professions Code Sections 17200 and 17500"[5] are clearly barred as a matter of law, these claims should be stricken.

[5] Plaintiffs' claimed damages under "common law" (Paragraph L, p. 37, l. 13) should also be stricken because Plaintiffs cannot allege a violation of common law unfair competition, as discussed in Section III B, *supra*.

D. Plaintiffs' Allegations Under "Unfair" Prong Of Section 17200 Should Be Stricken Because Plaintiff Cannot Allege An Antitrust Violation

Under section 17200 of California's Business and Professions Code, "unfair" competition among competitors means "conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition." *Cel-Tech*, 20 Cal. 4th at 187. Thus, federal courts have properly dismissed claims under the "unfair" prong of section 17200 that were not based on allegations constituting antitrust violations. *See Sybersound Records, Inc. v. UAV Corp.*, 517 F.3d 1137, 1153 (9th Cir. 2008) (claim for unfair competition properly dismissed where plaintiff has not "pled an act that would be an incipient violation of antitrust law, as required under *Cel-Tech* for claims against competitors"); *Carter v. Variflex, Inc.*, 101 F. Supp. 2d 1261, 1270 (C.D. Cal. 2000) (summary judgment dismissing unfair competition claim where plaintiff's evidence could not establish an antitrust violation).

Here, Plaintiffs' claims against Defendants are based on alleged false advertising, not anything even remotely approaching an antitrust violation. *See*, *e.g.*, Compl., ¶ 150 (p. 30, ll. 9-12) ("Defendants have made… misleading statements, representations and advertisements… thereby misrepresenting the nature… of their colchicine products…"). Therefore, the portions of the Complaint alleging a violation of the "unfair" prong of section 17200 should be stricken. *See Sybersound Records*, 517 F.3d at 1153 (alleged misrepresentations do not constitute an antitrust violation; claim for unfair competition dismissed).

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss Plaintiffs' entire Complaint as an improper attempt to usurp the primary

jurisdiction of the FDA. In the alternative, Defendants respectfully request that the Court dismiss Plaintiffs' Fourth Cause of Action for Common Law Unfair Competition with prejudice, and that the Court strike from Plaintiffs' Complaint their prayer for compensatory damages under California Business and Professions Code sections 17200, *et seq.*, and 17500, *et seq.*, and their allegations and prayer regarding the "unfair" prong of section 17200.

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