

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA**

ORGANIC PASTURES DAIRY COMPANY, LLC,

Plaintiff,

KATHLEEN SEBELIUS, et al.,

Defendants.

| Case No. 1:12-cv-02019-SAB

ORDER RE MOTIONS

ECF NOS. 29, 36, 38

and

ORDER SETTING FURTHER SCHEDULING CONFERENCE

Date: June 18, 2013

Time: 11:00 a.m.

Courtroom: 9

Currently pending before the Court are three related motions. On March 26, 2013, Plaintiff Organic Pastures Dairy Company, LLC (“Plaintiff”) filed a motion to strike certain affirmative defenses in the answer filed by Defendants Kathleen Sebelius, United States Department of Health and Human Services, Margaret A. Hamburg, and United States Food and Drug Administration (“Defendants”). (ECF No. 29.) On April 17, 2013, Defendants filed a motion for judgment on the pleadings, based on the same affirmative defenses Plaintiff sought to strike. (ECF No. 36.) On April 18, 2013, Plaintiff filed a motion to amend its complaint to address issues raised in Defendants’ motion for judgment on the pleadings. (ECF No. 38.)

All parties have consented to the jurisdiction of a United States Magistrate Judge for all purposes. (ECF Nos. 33, 34.)

The Court, having reviewed the record, finds this matter suitable for decision without oral argument. See Local Rule 230(g). Accordingly, the previously scheduled hearing on May 15, 2013 will be vacated and the parties will not be required to appear at that time.

For the reasons set forth below, the Court grants Plaintiff's motion to amend. Plaintiff's motion to strike and Defendants' motion for judgment on the pleadings will be denied as moot.

I.

BACKGROUND

Plaintiff initiated this action by filing a petition for a writ of mandamus on December 12, 2012. (ECF No. 1.) Plaintiff initially sought a writ of mandamus to compel Defendant United States Food and Drug Administration (“FDA”) to take final action on a citizen petition submitted by Plaintiff to the FDA on December 22, 2008. Plaintiff’s citizen petition to the FDA sought a modification of 21 C.F.R. § 1240.61, which prohibits the sale of unpasteurized milk (also known as “raw milk”) across state lines.¹ Plaintiff requested an exemption that permitted the sale of raw milk in other states so long as the sale was legal in both the seller’s state and the destination state. According to Plaintiff, at the time Plaintiff filed its petition for writ of mandamus, the FDA had not responded to Plaintiff’s citizen petition for over four years.

On March 7, 2013, Plaintiff filed its First Amended Complaint. (ECF No. 25.) Plaintiff's first amended complaint alleged that the FDA responded to Plaintiff's citizen petition on February 26, 2013. The FDA denied Plaintiff's citizen petition. Plaintiff sought judicial review of the FDA's actions pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701, et seq. Plaintiff's First Amended Complaint alleged that the FDA's denial was arbitrary and capricious. Plaintiff sought an injunction requiring the FDA to modify 21 C.F.R. § 1240.61 in accordance with

¹ The regulation at issue states, in pertinent part:

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

21 C.F.R. § 1240.619(a).

1 Plaintiff's citizen petition.

2 Defendants filed their answer to Plaintiff's First Amended Complaint on March 20, 2013.
3 (ECF No. 28.) Defendants raised three affirmative defenses by their answer. Defendants alleged
4 that Plaintiff lacks standing, that Plaintiff's claims are not yet ripe and that Plaintiff's First
5 Amended Complaint fails to state a claim upon which relief can be granted.

6 On March 26, 2013, Plaintiff filed a motion to strike Defendants' affirmative defenses.
7 (ECF No. 29.) Plaintiff argues that the affirmative defenses based upon standing, ripeness and
8 failure to state a claim are insufficient and should be stricken from Defendants' answer.

9 On April 17, 2013, Defendants filed a motion for judgment on the pleadings. (ECF No.
10 36.) Countering the arguments raised in Plaintiff's motion to strike, Defendants argued that
11 judgment is warranted because Plaintiff lacks standing and Plaintiff's claims are not ripe for
12 adjudication. Defendants argued that Plaintiff lacked standing because the company does not
13 currently sell unpasteurized milk across state lines and did not allege that it intends to do so in the
14 future if their citizen petition were granted. (Mem. in Supp. of Defs.' Mot. for J. on the Pleadings
15 and in Opp'n to Pl.'s Mot. to Strike 6:1-9.) Defendants argued that Plaintiff's claims were not
16 ripe because Plaintiff asked for a modification of the 21 C.F.R. § 1240.61 permitting interstate
17 distribution of milk that is "tested, state inspected, state regulated, carries a 'government warning
18 statement' and labeled for retail sale in one state," but the "FDA is aware of no such standards or
19 testing protocols for unpasteurized milk in California or elsewhere." (Mem. in Supp. of Defs.'
20 Mot. for J. on the Pleadings and in Opp'n to Pl.'s Mot. to Strike 10:3-18.) Defendants also
21 argued that Plaintiff's claims are not ripe because Plaintiff intends to abandon the claims
22 currently before the Court and raise a new challenge to the FDA's response to a future citizen
23 petition that Plaintiff has yet to file. (Mem. in Supp. of Defs.' Mot. for J. on the Pleadings and in
24 Opp'n to Pl.'s Mot. to Strike 10:27-11:2.)

25 On April 18, 2013, Plaintiff filed a motion to amend the First Amended Complaint. (ECF
26 No. 38.) Plaintiff sought to amend the complaint to add allegations addressing Defendants'
27 arguments pertaining to standing and ripeness. Plaintiff filed a proposed Second Amended
28 Complaint on April 19, 2013. (ECF No. 40.)

II.

PLAINTIFF'S MOTION TO AMEND²

3 Plaintiff's motion to amend is governed by Federal Rule of Civil Procedure 15(a)(2),
4 which states that "a party may amend its pleading only with the opposing party's written consent
5 or the court's leave." Defendants do not consent to any amendment and filed an opposition on
6 May 1, 2013. (ECF No. 43.)

A. Legal Standards for Motions to Amend

8 “After a party has amended a pleading once as a matter of course, it may only amend
9 further after obtaining leave of the court, or by consent of the adverse party.” Eminence Capital,
10 LLC v. Aspeon, Inc., 316 F.3d 1048, 1051 (9th Cir. 2003) (citing Fed.R.Civ.P. 15(a)). “The court
11 should freely give leave when justice so requires.” Fed.R.Civ.P. 15(a)(2). “This policy is ‘to be
12 applied with extreme liberality.’” Eminence Capital, LLC, 316 F.3d at 1051 (quoting Owens v.
13 Kaiser Found. Health Plan, Inc., 244 F.3d 708, 712 (9th Cir. 2001)).

Leave to amend must be given unless reasons exist to deny leave “such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc....” Foman v. Davis, 371 U.S. 178, 182 (1962) see also AmerisourceBergen Corp. v. Dialysist West, Inc., 465 F.3d 946, 951 (9th Cir. 2006)). “Not all of the factors merit equal weight.... [I]t is the consideration of prejudice to the opposing party that carries the greatest weight.” Eminence Capital, LLC, 316 F.3d at 1052. “Absent prejudice, or a strong showing of any of the remaining Foman factors, there exists a presumption under Rule 15(a) in favor of granting leave to amend.” Id. (emphasis in original).

B. Analysis of Plaintiff's Motion to Amend

24 Defendants contend that amendment would be futile and that Plaintiff's proposed
25 amendment can be characterized as "gamesmanship," i.e., bad faith. Defendants do not argue that
26 amendment would cause undue delay or that it would cause undue prejudice to Defendants.

²⁷ Since granting leave to amend will moot the remaining motions (to strike Defendants' answer and for judgment on the pleadings), the Court will address Plaintiff's motion for leave to amend first.
²⁸

1 Since prejudice carries the greatest weight, the Court notes that Defendants have not identified
2 any undue prejudice resulting from Plaintiff's request to amend. Moreover, the Court finds no
3 undue delay as this matter has not yet gone beyond the pleading stage. Plaintiff's request for
4 amendment was prompt, as the conduct at issue in Plaintiff's claims took place in February 2013.
5 Moreover, as discussed below, the Court intends to proceed without delay in scheduling this
6 action. See discussion, infra, Part IV. Repeated failure to cure deficiencies is not a factor in this
7 case, since Plaintiff's prior amendment merely re-characterized the claims brought in this action
8 in light of Defendants response to Plaintiff's citizen petition.

9 1. Futility of Amendment

10 Defendants argue that Plaintiff's proposed Second Amended Complaint is futile because
11 Plaintiff's claims remain unripe for adjudication. Defendants contend that Plaintiff's Second
12 Amended Complaint is not ripe for adjudication because Plaintiff's requested exception to the
13 regulations is premature because it calls for permissible sale of raw milk under state standards and
14 testing protocols which do not yet exist. Defendants also contend that Plaintiff's claims are not
15 ripe because Plaintiff expressed its intention to file a second citizen petition seeking modification
16 of the FDA's response to the first petition. The Court will also address the standing arguments
17 raised in Defendants' motion for judgment on the pleadings.

18 a. Ripeness

19 “Ripeness is a justiciability doctrine designed ‘to prevent the courts, through avoidance of
20 premature adjudication, from entangling themselves in abstract disagreements over administrative
21 policies, and also to protect the agencies from judicial interference until an administrative
22 decision has been formalized and its effects felt in a concrete way by the challenging parties.’”
23 National Park Hospitality Ass'n v. Department of Interior, 538 U.S. 803, 807-808 (2003) (quoting
24 Abbott Laboratories v. Gardner, 387 U.S. 136, 148-149 (1967)). “Determining whether
25 administrative action is ripe for judicial review requires us to evaluate (1) the fitness of the issues
26 for judicial decision and (2) the hardship to the parties of withholding court consideration.” Id. at
27 808 (citing Abbott Laboratories, 387 U.S. at 149); see also Oklevueha Native American Church
28 of Hawaii, Inc. v. Holder, 676 F.3d 829, 837 (9th Cir. 2012). In evaluating the “fitness of the

1 issues for judicial decision”, courts consider whether judicial intervention would inappropriately
2 interfere with further administrative action and whether the courts would benefit from further
3 factual development of the issues presented. Public Lands for the People, Inc. v. U.S. Dept. of
4 Agriculture, 733 F. Supp. 2d 1172, 1184 (E.D. Cal. 2010) (citing Ohio Forestry Ass’n, Inc. v.
5 Sierra Club, 523 U.S. 726, 733 (1998)).

6 With respect to challenges to agency regulations, the Supreme Court in National Park
7 Hospitality Association stated:

8 “Absent [a statutory provision providing for immediate judicial
9 review], a regulation is not ordinarily considered the type of agency
10 action ‘ripe’ for judicial review under the [Administrative
11 Procedure Act (APA)] until the scope of the controversy has been
12 reduced to more manageable proportions, and its factual
components fleshed out, by some concrete action applying the
regulation to the claimant’s situation in a fashion that harms or
threatens to harm him.”

13 Id. at 808 (quoting Lujan v. National Wildlife Federation, 497 U.S. 871, 891 (1990)).

14 Both the First Amended Complaint and the Second Amended Complaint allege that
15 Plaintiff filed a citizen petition pursuant to 21 C.F.R. §§ 10.25, et seq., requesting the FDA to
16 amend its regulations to incorporate an exception to the raw milk prohibition. Judicial review of
17 the FDA’s final decision on the citizen petition is expressly permitted by 21 C.F.R. § 10.45. As
18 provided by 21 C.F.R. § 10.45(d), “the Commissioner’s final decision constitutes final agency
19 action (reviewable in the courts under 5 U.S.C. 701 et seq. ...) on a petition submitted under §
20 10.25(a)...” There is no dispute that the FDA’s February 26, 2013 denial constituted final agency
21 action in response to Plaintiff’s citizen petition.

22 Turning to the ripeness factors, the Court finds that the issues are fit for judicial decision
23 and Plaintiff would suffer hardship if the Court withheld consideration of the issues. The issues
24 are fit for judicial decision because judicial intervention would not interfere with further
25 administrative action. The FDA’s regulations make clear that the February 26 denial constitutes
26 final agency action. Defendants do not identify any other interference with further administrative
27 action in their opposition. Moreover, the Court would not benefit from further factual
28 development of the issues presented. If this case were dismissed on ripeness grounds, it is

1 unclear how the facts would be further developed. Finally, the Court notes that Plaintiff suffers
2 hardship if the Court withholds consideration of the issues because Plaintiff would continue to be
3 prohibited from selling raw milk in markets outside of California.

4 Defendants argue that Plaintiff's claims are not ripe because Plaintiff's requested
5 exception to the prohibition on raw milk is premised on hypothetical circumstances that do not
6 yet exist. Defendants point out that Plaintiff's requested exception would permit the sale of raw
7 milk which is tested, state inspected, and state regulated. Defendants argue that "FDA is aware of
8 no such standards or testing protocols for unpasteurized milk in California or elsewhere." (Defs.'
9 Opp'n to Pl.'s Mot. to Amend 4:19-21.) Thus, Defendants argue that Plaintiff's claim is not yet
10 ripe because the exception requested by Plaintiff is based upon hypothetical circumstances that do
11 not yet exist. In other words, Plaintiff has not suffered concrete injury from the FDA's actions
12 because the requested exception does not apply to Plaintiff's situation.

13 Defendants' argument relies on matters outside the pleadings. The non-existence of state
14 certification programs is not alleged in Plaintiff's complaint and is not a matter subject to judicial
15 notice. The Court will not deny leave to amend based upon a factual assertion unsupported by the
16 pleadings. Notably, in its reply, Plaintiff contends that there are several state standards pertaining
17 to raw milk. (Pl.'s Reply to Defs.' Opp'n to Pl.'s Mot. to Amend 3:18-4:4.) Therefore, the
18 existence or non-existence of the state certification programs alluded to in Plaintiff's requested
19 exception appears to be a factual issue outside the pleadings that is more appropriately resolved
20 on a motion for summary judgment.³

21 In their motion for judgment on the pleadings, Defendants cite Pfizer Inc. v. Shalala, 182
22 F.3d 975 (D.C. Cir. 1999) for the proposition that an agency's final action may still be unripe for
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24 ³ The FDA's response to the citizen petition appears to acknowledge that state standards and testing protocols for raw
25 milk exist, but are inadequate in the eyes of the FDA. (See Defs.' Mot. for J. on the Pleadings, Ex. B, at pg. 3
26 ("Certain states that permit the sale of raw milk to consumers require that such milk meet the same or similar *quality*
27 standards as pasteurized milk.... These quality indicators do not provide any information as to the presence or
28 absence of harmful bacteria," italics and underlining in original)). However, Plaintiff's citizen petition did not ask
for an exception based upon standards and testing protocols that the FDA deemed adequate. Plainly, Plaintiff's
citizen petition seeks an exception permitting them to sell raw milk outside of California so long as the raw milk
could lawfully be sold under the laws of the state California and could lawfully be sold under the laws of the
destination state.

1 judicial review, such as when it issues a declaratory order that has not yet crystallized into an
2 actual case or controversy with threat of significant and immediate impact on the plaintiff. (Mem.
3 in Supp. of Defs.’ Mot. for J. on the Pleadings and in Opp’n to Pl.’s Mot. to Strike 9:19-10:2.)
4 However, this case is distinguishable because Plaintiff contends that state certification programs
5 exist and that it suffered actual injury from the FDA’s action because the FDA’s denial of
6 Plaintiff’s petition prevents Plaintiff from selling raw milk outside of the state.

7 Defendants also argue that Plaintiff’s claims are not ripe because Plaintiff intends to file a
8 second citizen petition seeking modification of the FDA’s denial of the first citizen petition, then
9 proceed solely on claims based upon the FDA’s response to the second citizen petition.
10 Defendants premise their argument on Plaintiff’s statement in the Joint Scheduling Report,
11 wherein Plaintiff indicated that it would file a new citizen petition to the FDA seeking a
12 modification of the FDA’s prior denial and seek leave to file an amended complaint after the
13 FDA responds to Plaintiff’s future citizen petition. (See Joint Scheduling Report, 3:27-4:21.)

14 Defendants’ argument pertains to the ripeness of claims arising from the second citizen
15 petition, which Plaintiff has not yet attempted to assert in this action. Defendants do not
16 demonstrate how Plaintiff’s intended course of conduct impacts the ripeness of the claims in the
17 proposed second amended complaint, which are unrelated to the yet-to-be-filed second citizen
18 petition. Moreover, there is no suggestion that “Plaintiff clearly does not intend to litigate over
19 the existing Response [to the first citizen petition] that the FDA issued on February 26, 2013.”
20 (Defs.’ Opp’n to Pl.’s Mot. to Amend 5:3-6.) Defendants do not consider the possibility that
21 Plaintiff litigates the FDA’s responses to both citizen petitions, as Plaintiff indicated in their
22 reply. (See Pl.’s Reply to Defs.’ Opp’n to Pl.’s Mot. to Amend 4:5-18.) As discussed below, the
23 Court intends to proceed without delay on Plaintiff’s proposed second amended complaint.
24 Plaintiff’s ability to assert new and additional claims in this action based on the FDA’s response
25 to the second citizen petition will be contingent on Plaintiff’s ability to demonstrate grounds to
26 amend at that time. See discussion, infra, Part IV.⁴

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28 ⁴ To the extent that Plaintiff should seek further amendments, the court will be mindful of
Defendants’ present arguments as to undue delay and abandonment of issues.

Based upon the foregoing, the Court finds that Defendants have not demonstrated that Plaintiff's requested amendment would be futile.

b. Standing

In their motion for judgment on the pleadings, Defendants argue that Plaintiff lacks standing. However, those arguments are raised with respect to the claims asserted in Plaintiff's first amended complaint and Defendants' opposition to Plaintiff's motion to amend contains little discussion of the standing issue. Instead, in the opposition, Defendants wrote that "even if the [proposed second amended complaint] could now withstand a challenge on standing, Plaintiff's claim is still unripe." (Defs.' Opp'n to Pl.'s Mot. to Amend 4:2-3.)

Plaintiff's proposed second amended complaint alleges that, in the past, Plaintiff sold raw dairy products across state lines. (See Second Am. Compl. [Proposed] ¶ 21.) Plaintiff no longer sells raw dairy products across state lines due to the regulations prohibiting such sales. Plaintiff's allegations appear sufficient to establish standing. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (standing requires (1) injury in fact, (2) a causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision). Defendants do not demonstrate that Plaintiff's proposed second amended complaint would be futile based upon Plaintiff's lack of standing.

2. Bad Faith in Amendment

Although Defendants do not explicitly raise any bad faith arguments, Defendants contend that Plaintiff is engaging in “gamesmanship” by seeking to submit a second citizen petition, asserting claims based upon the FDA’s response to the second citizen petition and abandoning the present claims based upon the response to the first citizen petition. Defendants essentially contend that Plaintiff seeks to amend in bad faith, which is one of the factors considered by the Court in determining whether leave to amend should be granted. See Foman, 371 U.S. at 182.

However, as discussed above, any bad faith argument is premature because Plaintiff has yet to express an intention to abandon any claims. Without expressing an opinion on the merits

1 of Defendants' argument, the argument would be more appropriately raised after Plaintiff
2 attempts to abandon his claims or there is more concrete evidence of an intention to abandon his
3 claims or otherwise cause undue delay.

4 **C. Plaintiff Should Be Given Leave To Amend**

5 As discussed above, there is no suggestion of undue delay, bad faith, repeated failure to
6 cure deficiencies by amendment, undue prejudice, or futility. Accordingly, the Court concludes
7 that Plaintiff's motion to amend should be granted.

8 **III.**

9 **PLAINTIFF'S MOTION TO STRIKE AND DEFENDANTS' MOTION FOR JUDGMENT
10 ON THE PLEADINGS**

11 In light of the Court's conclusion that Plaintiff should be granted leave to file its Second
12 Amended Complaint, Plaintiff's motion to strike and Defendants' motion for judgment on the
13 pleadings are moot, as they arise from the superseded First Amended Complaint and Defendants'
14 answer thereto. Accordingly, Plaintiff's motion to strike and Defendants' motion for judgment on
15 the pleadings will be denied as moot.

16 **IV.**

17 **SCHEDULING CONFERENCE**

18 On April 16, 2013, a scheduling conference was held. The Court set the deadline for
19 filing the presently resolved dispositive motion. In light of this order, the Court will schedule a
20 further scheduling conference.

21 The Court will set a further scheduling conference to take place on June 18, 2013 at 11:00
22 a.m. The Court notes that, in the Joint Scheduling Report submitted by the parties on April 1,
23 2013, Plaintiff expressed its intention to file a second citizen petition and seek leave to amend its
24 complaint within 30 days after the FDA responds. The FDA has 180 days to respond to the
25 second citizen petition.

26 Based upon the information presently before it, the Court is not inclined to delay this
27 action to accommodate possible future claims arising out of the second citizen petition. There are
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1 too many uncertainties surrounding those future claims to justify delay in the adjudication of the
2 claims presently before the Court. For example, the FDA may issue a favorable response to the
3 second citizen petition or the FDA may take longer than 180 days to issue a final reviewable
4 response as it allegedly did with respect to the first citizen petition. To the extent that Plaintiff
5 intends to litigate claims based upon the FDA's response to the second citizen petition, Plaintiff is
6 forewarned that its ability to assert those claims via a request to amend will be contingent on
7 Plaintiff's ability to demonstrate sufficient grounds for the Court to grant leave to amend at that
8 time.

9 Accordingly, it is the Court's inclination to schedule dates for the submission of the
10 administrative record and the filing of dispositive motions. The parties shall prepare and file a
11 Second Joint Scheduling Report by June 11, 2013. The Second Joint Scheduling Report shall
12 have the same form and content requirements as set forth in the Court's December 13, 2012 Order
13 Setting Mandatory Scheduling Conference. (ECF No. 9.)

14 **V.**

15 **CONCLUSION AND ORDER**

16 Based upon the foregoing, it is HEREBY ORDERED that:

- 17 1. The hearing on this matter scheduled for May 15, 2013 is VACATED and taken
18 off calendar. The parties shall not appear at that time;
- 19 2. Plaintiff's motion to amend is GRANTED (ECF No. 38);
- 20 3. Plaintiff is directed to file a copy of its Second Amended Complaint within seven
21 (7) days;
- 22 4. Plaintiff's motion to strike and Defendants' motion for judgment on the pleadings
23 are DENIED as moot;
- 24 5. The parties shall appear for a further scheduling conference on June 18, 2013 at
25 11:00 a.m. before United States Magistrate Judge Stanley A. Boone, in Courtroom
26 9 at the United States Courthouse, 2500 Tulare Street, Fresno, CA 93721; and

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1 6. The parties shall file a Joint Scheduling Report by June 11, 2013. The Joint
2 Scheduling Report shall be e-mailed, in Word format, to
3 saborders@caed.uscourts.gov.

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7 IT IS SO ORDERED.
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10 Dated: May 10, 2013

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UNITED STATES MAGISTRATE JUDGE

