THE HONORABLE BENJAMIN H. SETTLE

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of an article of food, cheese, labeled in part, "*** ESTRELLA FAMILY CREAMERY *** Red Darla ***" and all other articles of food, cheese, in any size and type of container, including in-process and finished products, labeled and unlabeled, which are held anywhere on the premises of Estrella Family Creamery, 659 Wynoochee Valley Road, Montesano, Washington, Defendants.	NO. 3:10-cv-5772 BHS DEFENDANTS' MOTION TO BIFURCATE ISSUES OF LIABILITY AND REMEDY AND MEMORANDUM IN SUPPORT NOTE ON MOTION CALENDAR: September 7, 2012

Pursuat to Fed.R.Civ.Proc. 42(b), Defendants Kelli Estrella, Anthony Estrella (respectively, "the Estrellas"), and Estrella Family Creamery (the "Company"), collectively Defendants, hereby file their Motion to Bifurcate the Issues of Liability and Remedy. A memorandum in support is attached hereto and is incorporated as if rewritten herein.

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Dated this 16th day of August, 2012

Respectfully submitted,

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MEMORANDUM IN SUPPORT

I. Background

This case was filed by the federal Food and Drug Administration ("FDA") on October 21, 2010. An amended complaint was filed on January 6, 2012. Since September 2011, Defendants have obtained the services of their current counsel and these counsel have been in settlement negotiations with the FDA surrounding the issues in this case. Those settlement discussions generated several drafts of a Consent Decree. Unfortunately, the parties were not able to agree on the terms and conditions of a Consent Decree and FDA ultimately filed its motion for summary judgment. Attached to FDA's motion for summary judgment is a proposed consent decree that is onerous, burdensome, draconian and not based in reality. Specifically, the order proposed by FDA presumes that Defendants will resume cheese making operations in order to engage in interstate commerce. Nothing could be further from the truth. Instead, the Defendants have been abused by FDA to such an extent that Defendants are willing to forego

their right to engage in interstate commerce, to never again have to deal with FDA, and to instead engage solely in intrastate commerce free from the draconian methods of FDA.

As part of settlement discussions, the Defendants offered to be bound by an injunction that would prohibit them from engaging in or affecting interstate commerce. The parties were successful in some respects in defining what constitutes "affecting" interstate commerce. (*See* Exhibits A, B and C attached hereto, correspondence via counsel for the parties on what constitutes "interstate commerce" or "affecting" interstate commerce.). Essentially, it became apparent that Defendants would be engaged in or would affect interstate commerce (1) any time Defendants obtained an ingredient for their cheese that came from out of state or (2) whenever any of Defendants' products crossed state lines, whether or not that product was sold.[1] Ultimately, Defendants agreed to an injunction enjoining them from engaging in or affecting interstate commerce and agreed to engage in purely intrastate sales of their cheese. A copy of Defendants' proposed consent decree is attached hereto as Exhibit D.

However, FDA took the position that *even if* Defendants were not engaged in or affected interstate commerce, FDA had the right to monitor compliance with the terms of any Consent Decree entered in this case and demanded the right to do so via unfettered access to Defendants' facility. Consequently, a settlement impasse occurred whereby Defendants believed that since they would be enjoined from engaging in or affecting interstate commerce, FDA would lack any regulatory authority to conduct inspections of Defendants' facility. FDA believed otherwise and suggested that even if Defendants were *not* engaged in or affecting interstate commerce, FDA

[1] *See also* FDA's motion for summary judgment at page 12, wherein FDA suggests that the receipt of one ingredient from out of state, e.g., rennet, constitutes interstate commerce.

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still had authority to conduct inspections of Defendants' facility to determine for itself whether the terms of the Consent Decree were being complied with.

In an effort to achieve a compromise, Defendants offered to allow FDA to conduct inspections of Defendants' facility to ensure compliance with the terms of any Consent Decree yet sought conditions on the limit of those inspections.[2] FDA refused to agree to the conditions and instead insisted on complete and unfettered access to Defendants' facility, even though FDA would lack jurisdiction over Defendants' conduct. Defendants also offered, via counsel, to provide FDA with documents such as purchase orders, shipping invoices and other documents to demonstrate that they were not engaging in or affecting interstate commerce yet FDA refused to consider this as well.

Therefore, and because Defendants will not contest FDA's request for a summary judgment in this case[3], Defendants believe that good cause exists to bifurcate the remedy portion of this case because evidence is necessary to allow the Court to determine the scope and extent of FDA's remedy in this case.

The reason why an evidentiary hearing on the scope and extent of FDA's remedy is necessary is more fully explained below.

II. Argument

Fed.R.Civ.Proc. 42(b) provides, in part, that a court "may order a separate trial of one or more separate issues, claims, cross claims, counterclaims, or third-party claims." When

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[2] Those conditions were that some type of advance notice be given; the inspection could only occur when Kelli Estrella, the corporate representative, was present; and inspections could not be done while Ms. Estrella was making cheese because the inspection would interfere with her ability to make cheese and she could not do both at the same time. *See, e.g.,* ¶9 of Defendant's proposed consent decree.

[3] Defendants will, however, deny some of the factual allegations contained in FDA's motion for summary judgment, even though they will not contest FDA's request for a summary judgment.

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reviewing a motion to bifurcate, a reviewing court "considers factors such as convenience, prejudice, judicial economy and whether the issues are clearly separable." *McCoy v. Liberty Mut. Fire Ins. Co.*, 2009 WL 5215760, *4 (J. Settle) (W.D. Wash. 2009) (attached hereto as Exhibit E). If the issues are "so intertwined" as to "create confusion and uncertainty" then it is inappropriate to bifurcate. *Id*. Bifurcation "is within the sound discretion of the court." *See PacTool Intern. Ltd. V. Kett ToolCo., Inc*., 2012 WL 13686 (J. Settle) (W.D. Wash. 2012) (attached hereto as Exhibit F).

In this case, liability is not contested.[4] The question, however, is the scope and extent of FDA's remedy. Thus, the issues of liability and remedy are clearly separable and thus would not serve as an impediment to bifurcation. However, to merely afford FDA the remedy it requests (i.e., unfettered access to Defendants' facility when they are not engaged in or affecting interstate commerce) simply because it prevails on its summary judgment motion would be prejudicial to Defendants. Therefore, and as explained below, the extent and scope of FDA's remedy needs to be examined carefully and should be based on the evidence adduced at a separate hearing, thus necessitating a bifurcation of the issues.

For example, FDA is taking the position that it should be allowed unfettered access to Defendants' facility and that Defendants should be forced to pay for the costs of these inspections. *See, e.g.,* ¶¶14 and 16 of FDA's proposed summary judgment order. However, FDA lacks any jurisdiction over an entity that does not engage in or that affects interstate commerce. *See* 21 U.S.C. 321(b) that defines interstate commerce. Thus, an evidentiary hearing is necessary to determine whether Defendants' operation impacts or even affects interstate

[4] Again, Defendants will dispute certain of FDA's factual allegations but in essence Defendants will not contest FDA's request for a summary judgment.

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commerce. If the evidence demonstrates that Defendants would *not* engage in or affect interstate commerce, then FDA would lack any jurisdiction over Defendants' operation.

Moreover, FDA is taking the position that documentation of Defendants' operation, alone, is not sufficient for FDA to determine whether Defendants are or are not engaged in or affecting interstate commerce. To the contrary, FDA has suggested that Defendants may "doctor" or "fabricate" a false set of production records in an effort to demonstrate that Defendants are not engaged in or affecting interstate commerce. Thus, an evidentiary hearing is necessary on this issue as well because if Defendants can document they are not engaging in or affecting interstate commerce, then FDA's inspection authority over Defendants' operation would not even be necessary.

In this case, Defendants make cheese. Part of the cheese production process involves such ingredients as salt, rennet and cultures. Defendants have decided that they will make their own rennet, will make their own cultures, and will use salt only from sources that are located within the State of Washington. This has been communicated to FDA. *See* Exhibit G. By sourcing all of their ingredients from the state of Washington, Defendants have chosen to engage in only *intrastate* sales of cheese. Significantly, FDA has suggested during settlement discussions that if Defendants use ingredients that come from sources located solely within the State of Washington, then Defendants *would not be* engaged in nor affecting interstate commerce. Defendants have also decided that they will sell their cheese only within the State of Washington. Thus, Defendants are committed to engaging in intrastate sales only.

As a result, it is important for the Court to take evidence of whether or not FDA would even have jurisdiction over Defendants' operations before the Court could provide FDA with a remedy that would include unfettered access to Defendants' operations.

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Moreover, it is important to note that Defendants have offered to provide to FDA on a routine basis all of their invoices, shipping orders and purchase orders for their ingredients to allow FDA to determine whether Defendants are engaged in or affecting interstate commerce. FDA, however, has suggested that because Defendants have fed spoiled cheese to pigs in "defiance of this Court's authority" that Defendants cannot be "trusted" to demonstrate compliance via records alone.[5] If FDA believes that Defendants are "bad actors" because they fed spoiled cheese to their pigs without a court order, then Defendants are entitled to show why they fed spoiled cheese to pigs and why they are not the "bad actors" FDA would have this Court believe. Thus, it is important for the Court to also take evidence on this issue to determine if Defendants' offer to allow conditional inspections of their facility is even necessary because compliance with the terms of a Consent Decree could be determined via documentation.

Again, to simply give FDA the remedy it seeks because it may prevail on a motion for summary judgment would operate as a prejudice to Defendants.

Thus, and for the reasons stated above, Defendants' motion to bifurcate the issues of liability and remedy are well taken and their instant motion should be granted.

Dated this 16th day of August, 2012

Respectfully submitted,

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[5] FDA's allegations on pages 5, 6 and 9 of its motion for summary judgment that Defendants have allegedly "refused to cooperate with FDA," have allegedly "defied this Court's authority" and allegedly "will not voluntarily comply with the law or this Court's authority" are examples of the several untrue statements in FDA's motion that Defendants' will deny and will clarify for the Court's benefit to the expense of FDA's credibility.

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CERTIFICATE OF SERVICE

I hereby certify that on August 16th, 2012, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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DATED this 16th day of August, 2012, at Franklin County, Ohio

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