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United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

COUNTY OF SANTA CLARA, on behalf
of itself and all others similarly situated,

No. C 05-03740 WHA

Plaintiff,

**ORDER REGARDING CROSS
MOTIONS FOR PROTECTIVE
ORDER AND TO COMPEL;
ORDER VACATING HEARING**

v.

ASTRA USA, INC.; ASTRAZENECA
PHARMACEUTICALS LP; AVENTIS
PHARMACEUTICALS, INC.; BAYER
CORP.; BRISTOL-MYERS SQUIBB CO.;
PFIZER, INC.; SCHERING-PLOUGH
CORP.; SMITHKLINE BEECHAM
CORP.; TAP PHARMACEUTICAL
PRODUCTS, INC.; WYETH, INC.;
WYETH PHARMACEUTICALS, INC.;
ZENECA, INC.; ZLB BEHRING LLC; and
DOES 1 through 100, inclusive,

Defendants.

In this putative class action, the County of Santa Clara seeks to recover overcharges from drug manufacturers for charges that exceeded price ceilings imposed by Section 340B of the Public Health Service Act of 1992 and contractual agreements thereunder. A May 2009 order denied plaintiff’s motion for class certification without prejudice to renewal at a later date. The order also accepted in part and rejected in part defendants’ setoff argument. It explained that the manufacturers have a statutory claim to recover any discounts they had extended to ineligible covered entities, but this statutory remedy requires a finding by the Secretary. 42 U.S.C. 256b(5)(D) (“[i]f the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B) [including

1 diversion], the covered entity shall be liable to the manufacturer . . .”). The May 2009 order
2 therefore ruled that if any manufacturer obtains such a finding by the Secretary, the
3 manufacturer may assert that statutory claim as a setoff in this action. It also stated that
4 defendants would be afforded the ongoing benefit of discovery in this action due to the potential
5 relevance of the statutory claim herein. Following the May 2009 class-certification order,
6 defendants sought discovery pertaining to their setoff claim and defendant Bayer submitted the
7 requisite letter to the Secretary to initiate the dispute-resolution process.

8 The parties now dispute defendants’ right to seek discovery for their setoff claim.
9 Plaintiff has filed a motion for a protective order to prohibit defendants from conducting
10 discovery in this action for the administrative proceedings and setoff claims. Defendants have
11 filed a cross-motion to compel discovery and for related relief, including for an order modifying
12 the protective order in this action to permit them to present evidence to the Secretary.

13 Plaintiff contends that permitting discovery in this action for use in the separate
14 administrative proceeding is inappropriate. It first argues that discovery must be denied when it
15 is sought for use in a separate proceeding. *See Oppenheimer Fund v. Sanders*, 437 U.S. 340,
16 352 n.17 (1978). In contrast to *Oppenheimer Fund*, however, here discovery into plaintiff’s
17 compliance with the 340b requirements is proper due to its potential relevance for defendants’
18 setoff claim in this action, as the Court previously ruled.

19 Plaintiff also contends that the discovery defendants seek is inappropriate because the
20 administrative proceedings are governed by its own procedures that limit the scope of
21 discovery. Plaintiff argues that allowing discovery for the Section 256b(5)(D) claims in this
22 action would circumvent those procedures.

23 The administrative proceedings includes an audit stage and a dispute resolution process.
24 The manufacturer has the option to proceed directly to the dispute-resolution process without an
25 audit if it believes that it has sufficient evidence of a violation absent an audit. The regulatory
26 guidelines provide that:

27 A manufacturer shall conduct an audit only when it has
28 documentation which indicates that there is reasonable cause.
“Reasonable cause” means that a reasonable person could believe

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that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B)

61 Fed. Reg. at 65409. The manufacturer must submit an audit workplan to the to the agency. The agency reviews the plan for reasonable purpose and scope, and it also “will review the documentation submitted to determine if reasonable cause exists.” *Id.* at 65410. If it determines that reasonable cause exists, the agency will permit the manufacturer to proceed with the audit. The regulatory guidelines provide that “normally, audits shall be limited to an audit period of one year and shall be performed in the minimum time necessary with the minimum intrusion on the covered entity’s operations.” *Id.* at 65410.

Plaintiff argues these procedures were carefully tailored to minimize intrusion on the covered entity’s operations and should not be supplemented with discovery in this action. The regulations, plaintiff emphasizes, require manufacturers to demonstrate “reasonable cause” for seeking discovery via an audit and afford the agency authority to review and approve the audit workplan. The audit, however, is not a required step and does not purport to be an exclusive means of collecting evidence. The manufacturers are expressly given the option to skip the audit and proceed directly to the dispute-resolution process if they believe they have sufficient evidence of a violation. Plaintiff’s motion for a protective order barring all discovery into defendants’ setoff claim is denied.

Manufacturers initiate the dispute-resolution process by submitting a written request for review with the agency. As stated, defendant Bayer has submitted a letter to initiate the dispute-resolution process. It wishes to supplement its request for review with evidence attained in this action, and the other defendants seek discovery for a possible future Section 256b(5)(D) claim and setoff.

The regulatory guidelines explain that:

The party requesting the review may not rely only upon allegations but is required to set forth specific facts showing that there is a genuine and substantial issue of material fact in dispute that requires a review.

The request for review shall include a clear description of the dispute, shall identify all the issues in the dispute, and shall contain a full statement of the party’s position with respect to

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such issue(s) and the pertinent facts and reasons in support of the party's position.


Id. at 65412. Upon filing of a request for review, the agency appoints a committee to review the matter. The covered entity is given an opportunity for response. The committee then considers the matter if it finds that certain preliminary requirements have been met and submits its written findings.

As stated, this order rejects plaintiff's effort to bar all discovery relevant to defendants' setoff claims and reiterates defendants will be permitted discovery to for inclusion with their requests for review with the Secretary due to the relevance of the statutory claims as setoffs in this action. The protective order dated May 8, 2006, in this action is hereby **AMENDED** to permit defendants to submit evidence in support of their Section 256b(5)(D) claims to the Secretary. The protective order is unchanged in all other respects.

The parties also dispute the appropriate scope of the discovery. Discovery disputes in this matter have been referred to Magistrate Judge Chen. All other discovery disputes, including disputes regarding the relevance and timing of particular discovery requests, should be brought before Magistrate Judge Chen. The parties are reminded to do so promptly given the pending October 30 discovery cutoff in this matter. The hearing scheduled for August 20, 2009, is hereby **VACATED**.

IT IS SO ORDERED.

Dated: August 17, 2009.



WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE