IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE COUNTY OF SANTA CLARA
and THE COUNTY OF SANTA CRUZ,

Plaintiffs,

v.

ASTRA USA, INC., et. al.,

Defendants.
_____/

No. C 05-03740 WHA

ORDER REGARDING DISCOVERY AND DENYING DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

INTRODUCTION

In this action, two California counties allege that defendant pharmaceutical firms overcharged them by charging prices for drugs greater than the ceiling price imposed by Section 340B of the Public Health Service Act of 1992 and contractual agreements thereunder. After multiple trips to the court of appeals, the immediate issue concerns discovery, namely the extent to which plaintiffs may discover data behind the numbers reported to the federal agency so as to try to prove overcharges. All defendants now move for partial judgment on the pleadings, or in the alternative, a protective order. Defendant Bristol-Myers Squibb moves individually for a stay on primary jurisdiction grounds, or in the alternative, for a protective order. Defendants AstraZeneca and Bayer move for a protective order, or in the alternative, for a stay of discovery. Plaintiffs filed a cross-motion to compel discovery. For the following reasons, defendants' motion for partial judgment on the pleadings is **DENIED**. The stay motions are

DENIED. Discovery will proceed as to all defendants, except as to Bristol-Myers Squibb. As to it, discovery will proceed more slowly. Complete compliance with *all* of plaintiffs' requests, however, will not be required at this time. Instead, discovery will proceed in stages. This order lists the discovery to be produced in the first stage.

STATEMENT

Plaintiff County of Santa Clara owns and operates the Santa Clara Valley Health and Hospital System. Plaintiff County of Santa Cruz owns and operates the Santa Cruz County Health Agency. Plaintiffs allege that defendant pharmaceutical manufacturers breached contractual duties owed to plaintiffs as third-party beneficiaries of the agreements between the manufacturers and the Secretary of the Department of Health and Human Services called the Pharmaceutical Pricing Agreements ("PPAs").

The PPAs carry out statutory obligations that arise under Section 340B of the Public Health Service Act of 1992. 42 U.S.C. 256b. Congress passed Section 340B to provide discounts on outpatient drugs to certain federally-funded hospitals and clinics — so-called "covered entities." The Act mandates that the Secretary:

> enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396r-8(k)(1)] . . . reduced by the rebate percentage described in paragraph (2).

42 U.S.C. 256b(a)(1). Under this agreement, the manufacturers may not charge any 340B entities over the so-called "ceiling price" created by the statute.

Acting pursuant to Section 340B, the Secretary entered into PPAs with drug manufacturers, including defendants. Section II(a) of the PPA stated (Compl. Exh. D at 5) (emphasis added):

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) for single source and innovator multiple source drug, to charge covered entities a price for each unit of the drug *that does not exceed an amount equal to the AMP for the covered outpatient drug reported* (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) *to the Secretary in accordance with the Manufacturer's responsibilities*

> *under action 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

In this civil action, plaintiffs contend that defendants violated their obligations under the PPA by charging a price exceeding the ceiling price defined in Section 340B and the PPA.

The *amicus* brief filed in the most recent appeal on behalf of the Secretary explained the interplay between two programs of the Department of Health and Human Services ("HHS") (Br. 7). The first is the Medicaid Rebate Program, which is administered by the Centers for Medicare Services ("CMS"). The second is the 340B Program, which is administered by the Health Resources and Services Administration ("HRSA").

The 340B Program, governed by 42 U.S.C. 256b, is the basis for plaintiffs' complaint. Under it, so-called "ceiling prices" are calculated using average manufacturer price ("AMP") and best price ("BP"). The AMPs and BPs are originally calculated in accordance with the requirements of a separate and preexisting HHS program: the Medicaid Rebate Program.

Under the Medicaid Rebate Program, pharmaceutical manufacturers are required to sign a Medicaid Rebate Agreement with HHS in order for a state to receive federal payment for coverage of outpatient drugs (Br. 2). The agreement requires that the manufacturers pay drug rebates to the states. In order to determine the amount of rebates for a given drug, the number of "units" of the drug paid for by the state is multiplied by the drug's "Unit Rebate Amount" ("URA"). The URA is calculated in several different ways. For a "generic drug," the URA is 11% of the AMP. For a "single-source" drug, the URA is the *greater* of two calculations: (1) AMP – BP = URA; or (2) 15.1% of the AMP (*id*. at 3).

According to the Social Security Act, average manufacturer price is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. 1396r-8(k)(1)(A). The best price is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" and lists several exclusions. 42 U.S.C. 1396r-8(c)(1)(c). Under the Medicaid Rebate Program, manufacturers must make calculations of AMP and BP every quarter and are required to report the calculated numbers to CMS within thirty days after

the end of each quarter (Br. 4). Using these figures, CMS calculates the URA for each drug. The URA amount is sent to each state to enable them to calculate their quarterly rebate amount.

Although separate from the Medicaid Rebate program, the 340B program incorporates the AMP and URA values (and thus, BP values) in the formula for determining the ceiling prices. As stated, the PPAs required under Section 340B ensure that manufacturers may not charge any "covered entity" a price that exceeds the ceiling price. The simplified formula for the 340B ceiling price is: Ceiling Price = AMP – URA. *Once the ceiling price for a certain drug is determined, it is the ceiling for all of the 340B covered entities.*

Although the 340B program is enforced by the HRSA, it does so with "significant help" from CMS (Br. 9). This is "because ceiling prices depend on the AMP and Best Price calculations that manufacturers report to CMS under the Medicaid Rebate Program" (*ibid*.). Pursuant to inter-agency agreements, after being reported to CMS, the AMP and BP data is provided to HRSA for use in the Section 340B program.

Plaintiffs allege that each defendant breached the PPA by overcharging for covered drugs. Plaintiffs sued in state court in August 2005, and the case was removed to federal court. Defendants moved to dismiss all claims in the second amended complaint for failure to state a claim. The motion was granted in May 2006.

On appeal, however, the court of appeals ruled that plaintiffs *were* third-party beneficiaries of the PPA and therefore may proceed with their contract claim. *County of Santa Clara v. Astra USA , Inc*., 540 F.3d 1094 (9th Cir. 2008) ("*Santa Clara I*"). On remand, a case management conference was held. The parties were directed to proceed with discovery. Defendants thereafter moved for a protective order, stating that plaintiffs were not entitled to discovery into the underlying data utilized by drug manufacturers to calculate the AMP and URA (*i.e*., the data used to calculate the components of the ceiling price), but only to the AMPs and BPs actually reported. The motion was granted based on a sentence in the appellate decision, but the protective order was certified for interlocutory appeal to make sure the sentence was really intended by the circuit judges. Last December, the Ninth Circuit modified its earlier order to eliminate the offending sentence and vacated the protective order. *County of Santa Clara v. Astra*

USA, Inc., 588 F.3d 1237 (9th Cir. 2009) ("*Santa Clara II*"). On the latest remand, discovery was reopened to allow plaintiffs to take discovery regarding the information underlying defendant manufacturers' determination of AMP and BP.

To head off the very discovery that seemed indicated by the remand, defendants now move for partial judgment on the pleadings, or in the alternative, for a protective order. Defendants Bristol-Myers Squibb, Bayer, and AstraZeneca also move individually for protective orders and/or request a stay of discovery. Plaintiffs move to compel defendants' production of documents and information responsive to plaintiffs' discovery requests.

ANALYSIS

1. MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS.

Under Rule 12(c), "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." A motion for judgment on the pleadings is evaluated according to virtually the same legal standard as a motion to dismiss under Rule 12(b). *Brennan v. Concord EFS, Inc.*, 369 F. Supp. 2d 1127, 1130–31 (N.D. Cal. 2005). "Judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner and Co.*, 896 F.3d 1542, 1550 (9th Cir. 1990). Moreover, "[a]ll allegations of fact by the party opposing the motion are accepted as true, and are construed in the light most favorable to that party." *General Conference Corp. of Seventh-Day Adventists v. Seventh-Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989).

All defendants move for partial judgment on the pleadings on the ground that "plaintiffs have failed to state a claim regarding miscalculations of average manufacturer price and best price" and assert that plaintiffs must "at least be ordered to amend their pleadings" (Br. 1).

All defendants first argue that plaintiffs have not pled facts sufficient to allege a plausible claim for relief as to AMP and BP under *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Twombly v. Bell Atlantic Corp.*, 550 U.S. 544 (2007). Under the *Iqbal-Twombly* standard for a Rule 12(b)(6) motion to dismiss, a complaint needs to be plausible, meaning that "the plaintiff

[must] plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949. All defendants argue that because plaintiffs fail to allege the *nature* of the miscalculations of AMP and BP as to each defendant, that the complaint fails to meet the pleading standard.

The Ninth Circuit, however, has found that plaintiffs' contract claim can proceed, and therefore meets the pleading standard to survive a motion to dismiss. Plaintiffs have already demonstrated that in order to determine the actual nature of the miscalculations, they must have access to the information used in the original calculations of the AMPs and BPs. The court of appeals acknowledged that "[a]t this stage, the nature of the breaches Santa Clara will seek to prove is unclear . . .". *Santa Clara II*, 588 F.3d at 1252. The revised opinion recognized that the complaint was lacking a full description of the alleged breach. Regardless of this potential shortcoming, the claim for breach of contract was determined to have survived the Rule 12(b)(6) standard. Accordingly, the mere fact that plaintiffs have not alleged the specific nature of the breach does not preclude them from meeting the pleading standard under Rule 12(c).

All defendants also argue that discovery should be barred because it would violate the confidentiality provisions of the Social Security Act. The court of appeals was "unmoved" by defendants' original argument to bar disclosures under the PPA confidentiality provision. *Santa Clara II*, 588 F.3d at 1248. The wording of the PPA confidentiality provision and the relevant portion of the Social Security Act are materially similar. The Act states:

> information disclosed by manufacturers . . . under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section . . . is confidential and shall not be disclosed by *the Secretary* . . . in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler . . .

42 U.S.C. 1396r-8(b)(3)(D) (emphasis added). The PPA similarly stated: "[i]nformation disclosed by the Manufacturer in connection with the Agreement, except as otherwise provided by law, will not be disclosed by *the Secretary* . . . in a form which reveals the Manufacturer . . ." (Compl. Exh. D at 8) (emphasis added). The Ninth Circuit determined that "the confidentiality provision [of the PPA] anticipates that disclosures could be required other than to or by the

Secretary." Just as with the PPA, "it would be the manufacturer, not the Secretary, disclosing the information" and the disclosures would therefore not be barred by the confidentiality obligations of the Act. *Santa Clara II*, 588 F.3d at 1249. Just as the Ninth Circuit was unwilling to accept defendants' confidentiality argument with regard to the PPA, this order declines to find the almost-identical Social Security Act provision prohibitive of plaintiffs' ability to pursue their claim for breach of contract.

Lastly, defendants argue that discovery should be deferred until the Ninth Circuit rules on the pending petition for panel rehearing and rehearing *en banc*. Defendants' petition was denied on February 12, 2010 (Dkt. 586). It is therefore unnecessary for this order to address defendants' argument for deferral on these grounds.

For all of the above-stated reasons, defendants' joint motion for partial judgment on the pleadings is **DENIED**. Defendants' joint request that plaintiffs be required to amend their pleadings is also **DENIED**.

2. MOTIONS TO STAY.

Defendants AstraZeneca, Bayer, and BMS have requested a stay of discovery. These defendants argue that the discovery sought by plaintiffs implicates the primary jurisdiction of the HHS. Additionally, BMS makes an individual argument for their motion to stay, asserting that after their individual cooperative review, HHS reserved jurisdiction over "additional adjustments or revisions" (Br. 17).

The Ninth Circuit specifically rejected primary jurisdiction as a show stopper to this case. The court of appeals, however, did "leave open the possibility that the district court may decide after further factual development that referral to the Secretary is appropriate." *Santa Clara II*, 588 F.3d at 1252. After further discovery and factual development it may be proper to refer this case to the HHS. At this time, however, before discovery as to the AMP and BP calculations has been allowed, the "factual development" contemplated by the Ninth Circuit has not been established. The government's *amicus* brief filed on appeal also agrees that primary jurisdiction is not necessary at this point (Br. 14). Accordingly, the individual defendants' motions to stay are **DENIED**.

3. DISCOVERY.

A. Motions for Protective Order.

Along with the joint motion for partial judgment on the pleadings, all defendants also presented argument for a protective order to prevent discovery regarding the underlying information used to calculate AMP and BP.

Under Rule 26(c), "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." All defendants have two arguments in support of a protective order. The first is that case management would be served if plaintiffs were required to further articulate their claim and assert the nature of the AMP and BP miscalculations that led to the alleged breach. The argument continues that without such a limitation, plaintiffs' requests will amount to "fishing expedition" and will require the production of such a mass of information as to be unduly burdensome. The appellate court's most recent statement flat-out called for "further factual development" and the only practical way to do so is via discovery. *Santa Clara II*, 588 F.3d at 1252. This order will not require plaintiffs to amend their pleadings to further articulate their claim. The undersigned, however, will consider the possible burden on defendants when determining appropriate limitations on discovery.

Defendants Bayer, and AstraZeneca filed individual motions for protective orders. They argue that since they complied with the terms of the Corporate Integrity Agreement ("CIA") and were overseen by the HHS through this agreement, the discovery is irrelevant because plaintiffs may not second-guess HHS' approval and oversight of the AMP and BP calculations. Under the terms of the CIA, defendants were audited on a yearly basis by a independent review organization ("IRO"). Defendants AstraZeneca and Bayer contend "Plaintiffs requested discovery would merely repeat the intensive oversight and analysis that HHS has already undertaken through the CIAs, allowing Plaintiffs to substitute their biases for the judgment and expertise of HHS" (Br. 4). These defendants argue that allowing discovery would be allowing plaintiffs to second-guess the HHS, which "Plaintiffs have no right to do" (*ibid.*). Until we know the facts and know the extent to which HHS knew everything it should have known, it is

premature to say that we will wind up second-guessing anybody in this case. Accordingly, this order will not enter a protective order on those grounds and the motion by AstraZeneca and Bayer is **DENIED**.

Defendants Bristol-Myers Squibb ("BMS") also filed an individual motion for protective order. BMS asserts an individual argument that plaintiffs' requests are especially burdensome in its case because of the cooperative review with HHS that was conducted to revise hundreds of BMS' AMPs and BPs (Br. 3). BMS contends that plaintiffs' document requests would call for thousands of communications, many of them privileged, that were produced in connection with the review. BMS' request for a protective order is **GRANTED,** subject to the provisos below.

B. Plaintiffs' Cross-Motion to Compel.

Plaintiffs have filed a cross-motion to compel. Plaintiffs' motion is based on the same arguments set forth in the opposition to defendants' motions for a protective order. These arguments have been discussed above, and need not be addressed again. As to the motion to compel, this order reaches the same result discussed above. The undersigned will allow for discovery to proceed, however, complete production of documents responsive to all plaintiffs' requests will not be required at this time. In their motion, plaintiffs suggest several methods of limiting discovery including (Br. 5):

> (a) where there are a large number of drugs at issue, plaintiffs have offered to limit the discovery to only the top 25% of the drugs sold to Santa Clara and Santa Cruz for those manufacturers who sold over 100 drugs to 340B entities; and (b) plaintiffs have offered to limit the textual documents to be searched by agreeing to a sequencing of the production and by further agreeing to a list of custodians and search terms in advance of the search for textual documents.

This order will adopt some variations on these limitations.

C. First Stage of Discovery.

In order to facilitate further factual development while continuing to monitor the potential burden on defendants in complying with the entire list of requested discovery, this order will allow for further discovery in stages. Defendants must produce information and documents from the start of the limitations period (August 16, 2001) to the date of the filing of the third amended

complaint (December 23, 2008). In this first stage of discovery, defendants must produce the following:

1. All information responsive to plaintiffs' interrogatories numbers 1 through 4, regarding information underlying defendant manufacturers' determinations of AMP and BP. Request number 5 is rejected as overbroad and unduly burdensome.

2. All quarterly and monthly or other periodic reports of AMP and BP filed with CMS, if not already produced.

3. All work papers prepared or used by defendants or their agents or consultants in preparation of AMP or BP.

4. All communications and audits with or by CMS or IROs concerning the accuracy of AMPs and BPs in said reports.

5. All summaries and/or descriptions of guidelines or standard procedures or methods to be used by the defendants to prepare the quarterly reports to CMS.

6. Documents sufficient to identify the National Drug Codes for covered drugs with respect to which defendants were responsible for reporting AMPs and BPs to CMS.

7. Documents including organization charts, sufficient to show defendants' management structure and hierarchy and the positions and individuals responsible for or involved in determining AMP, BP and URA.

8. All materials explaining how the computer tracking systems worked to flag and determine the AMP and BP.

9. All invoices and other data necessary to verify the accuracy (or not) of the AMP and BP for the top three drugs sold by each defendant to each plaintiff for three quarterly reports to be selected by plaintiffs (said selection to be made in writing by **MARCH 31, 2010 AT NOON.**)

10. All communications and audits with or by CMS or IROs concerning the accuracy of AMPs and BPs in said reports.

11. All emails and memos that refer to "AMP" or "BP" sent or received by those assigned to help prepare or to review the reports to CMS (as well as, for emails, any other emails in the same chain).

All of the foregoing must be produced by **APRIL 30, 2010 AT NOON.** If subpoenas to third parties are needed, plaintiffs must serve them promptly. On or before **JUNE 18, 2010**, each defendant must make available one deponent who must be knowledgeable about the way in which the defendant calculated the AMP, BP, and URA for a one-day deposition. The deposition shall address the location and existence of further documents relevant thereto.

Each defendant may have until **MARCH 31, 2010, AT NOON** to meet and confer with plaintiffs to refine or streamline the foregoing. If they reach an agreement in writing and signed by both sides then the substitutes shall apply. If not, the foregoing shall apply. In no event shall the deadlines be changed.

If any responsive material is withheld as privileged, then it must be described in a privilege log served by **APRIL 30, 2010, AT NOON.** The privilege logs must be sufficiently detailed and informative to justify the privilege. No generalized claims of privilege or work-product protection shall be permitted. With respect to each communication for which a claim of privilege or work product is made, the asserting party must at the time of its assertion identify: (a) all persons making and receiving the privileged or protected communication; (b) the steps taken to ensure the confidentiality of the communication including affirmation that no unauthorized persons have received the communication; (c) the date of the communication; and (d) the subject-matter of the communication. Failure to furnish this information at the time of the assertion will be deemed a waiver of the privilege or protection.

Based on the foregoing Stage One discovery, both sides shall then file proposals for Stage Two discovery. Each side may have up to 40 pages. All defendants must share the 40 pages. The purpose of the submissions shall be to frame the Stage Two discovery. The same memoranda shall describe any further discovery or proceeding appropriate under Rule 23. These memoranda

must be filed simultaneously by **JUNE 28, 2010, AT NOON**, and a hearing therein shall be held on **JULY 8, 2010, AT 11:00 A.M.**

As to BMS, the foregoing does *not* apply due to the extensive agency review already done. Counsel must meet and confer and agree on a substantially narrowed universe of materials to be produced, failing which no BMS materials need be produced without a further order. As to AstraZeneca and Bayer, their motions for special relief are **DENIED**. They must produce the same discovery as all other defendants (except BMS).

* * *

Finally, this must be said. Although the undersigned judge was originally unconvinced that these plaintiffs were ever intended to have third-party beneficiary rights under these federal contracts, defense counsel were unable to sustain that view on appeal. The appellate court also rejected the defense's primary jurisdiction argument. There have now been two trips to the court of appeals. Defendants have lost twice. The hour has come for the defendants to accept the verdict on appeal and to assist this Court in making the remand work and to litigate this case to a just, speedy, and inexpensive determination. Neither side should ask for extensions or reconsideration, but should roll up their sleeves and do the work needed.

CONCLUSION

The parties shall comply with all deadlines regarding the discovery stages listed above.

IT IS SO ORDERED.

Dated: March 19, 2010.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE