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,

Plaintiff,

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.
_____/

No. C 05-03740 WHA

ORDER GRANTING MOTION FOR PROTECTIVE ORDER AND CERTIFYING INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. 1292(b)

INTRODUCTION

In this proposed class action, the County of Santa Clara alleges that, through its public health service, it paid several drug manufacturers prices for drugs greater than price ceilings imposed by Section 340B of the Public Health Service Act of 1992 and contractual agreements thereunder. After an appeal and remand reinstating a contract claim as third-party beneficiary, defendants moved for a protective order limiting the subjects into which plaintiff may seek discovery, the motion based upon an express limitation in the appellate order. The motion requires resolution of important questions regarding the meaning of the pertinent contractual

agreements and the permissive scope of this lawsuit going forward. For the reasons that follow, defendants' motion for a protective order is **GRANTED**. The order, however, is certified under 28 U.S.C. 1292(b) for immediate appeal for confirmation of this Court's interpretation of the following passage from the Ninth Circuit's recent order in this case:

> The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; *they cannot claim that the reported figure was itself somehow erroneous*.

County of Santa Clara v. Astra USA, Inc., 540 F.3d 1094, 1109 (9th Cir. 2008) (emphasis added). The essence of the problem is that plaintiff now wishes to go behind "the reported figure" and investigate whether the figure should have been reported lower. This order hews to the plain meaning of the Ninth Circuit ruling but this question will be certified.

STATEMENT

Plaintiff, the County of Santa Clara, a public entity which owns and operates the Santa Clara Valley Health and Hospital System, alleges that defendants, several pharmaceutical manufacturers, breached contractual duties owed to plaintiff as a third-party beneficiary of agreements between defendants and the Secretary of the Department of Health and Human Services ("HHS") called Pharmaceutical Pricing Agreements ("PPAs"). The agreements implement 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 qualified hospitals and clinics. That section, entitled "Limitation on prices of drugs purchased by covered entities," stated at all relevant times:

> The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . 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.A. § 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

Id. at 256b(a)(1) (bracketed text in original). The Secretary administered the program through the Health Resources and Services Administration ("HSRA"), an agency within HHS; more specifically, by HSRA's Office of Pharmacy Affairs.

Acting pursuant to Section 340B, the Secretary entered into Pharmaceutical Pricing Agreements with drug manufacturers, including defendants. Section II(a) of the PPA stated (Def. Req. Notice Exh. D at 5; emphasis added):[1]

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) for single source and innovator multiple source drugs, 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 section 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

In this lawsuit, plaintiff contends that defendants violated their obligations under the PPA to plaintiff, a third-party beneficiary of the agreements, by charging plaintiff a price exceeding the price ceiling defined in Section 340B and the PPA.

Section 340B and the PPA set the price limitation by reference to the *average manufacturer's price* ("AMP"), a term both the PPA and Section 340B defined by incorporating statutory definitions prescribed for a Medicaid drug rebate program. The Medicaid program was (and still is) administered by the Center for Medicaid Services ("CMS"), an agency within HHS. Although manufacturers rather than the agency calculated the AMP, the agency was permitted (but not required) to audit the manufacturers' reported AMP data. *Id*. at § 1396r-8(b)(3)(B)–(C). The agency also provided manufacturers with guidance regarding how to calculate the AMP (Br. at 5–6; Def. Req. Not. F–K). Pursuant to intra-agency agreements, after being reported to CMS, the AMP and best-price data were provided to HSRA for use in the Section 340B program.

[1] Pursuant to FRE 201, defendants' request that the Court take judicial notice of the HSRA's model PPA is granted (Def, Req. Notice Exh. D). The PPA is publicly available on HSRA's website. The parties make several additional requests for judicial notice. Plaintiff asks that the Court take judicial notice of three reports by HHS's Office of Inspector General (Pl. Req. Notice Exh. A–C). Pursuant to FRE 201, the Court takes judicial notice of the three reports. Defendants also request judicial notice of several documents (Def. Req. Notice Exh. A–P). The Court takes judicial notice of the PPA, the 2006 Office of the Inspector General report, and the agencies' guidance regarding the calculation of the AMP (Def. Req. Notice Exh. D, E–K). Defendants' remaining requests are moot as those documents are not pertinent to the issues decided in this motion.

Plaintiff's contract claim alleges that defendants charged plaintiff a price greater than the price ceiling agreed upon in the PPA (and required by Section 340B). Plaintiff filed this lawsuit following a series of reports by HHS's Office of Inspector General ("OIG") raising concerns about overcharges. OIG issued a report in March 2003 that concluded that five manufacturers had overcharged various 340B-covered entities during a one-year period ending September 30, 1999. OIG issued another report in June 2004 that examined the prices paid by 340B entities in a sample month, September 2002, and again found overcharges. OIG, however, withdrew the June 2004 report, explaining that it had identified problems with the report's underlying data. The agency issued additional reports on Section 340B drug prices in 2005 and 2006.

Plaintiff filed in the Superior Court of Alameda County in August 2005, and the case was removed to federal court. After a first motion to dismiss was granted, defendants moved to dismiss all claims in the second amended complaint for failure to state a claim. The motion also asserted various defenses, including primary jurisdiction. A May 2006 order granted the motion (without reaching the primary jurisdiction argument).

On appeal, the Ninth Circuit ruled that plaintiff *was* a third-party beneficiary of the Pharmaceutical Pricing Agreement and therefore may proceed with its contract claim. The decision also addressed defendants' alternate claim for dismissal based on primary jurisdiction. It ruled that the doctrine of primary jurisdiction did *not* require that the claim be stayed or dismissed without prejudice pending its referral to the Secretary for agency resolution. Its stated reason for rejecting primary jurisdiction is now the critical premise for this protective order motion:

> In our view, there is nothing "particularly complicated" about Santa Clara's contract claim on the merits. Santa Clara alleges that the Manufacturers did not comply with their obligation under the PPA to charge covered entities a price that "does not exceed ... the [average manufacturer price] for the [covered drug] reported ... to the Secretary in accordance with the Manufacturer's responsibilities under [§ 1396r-8(b)(3)] ... reduced by the rebate percentage." *See* PPA § II(a) (emphasis added). Contrary to the Manufacturers' suggestion, resolution of this claim presents no "far-reaching question that 'requires expertise or uniformity in administration.'" *Cf. Brown*, 277 F.3d at 1172. *The PPA is drafted, for instance, so that covered entities are*

> *entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported figure was itself somehow erroneous*. Moreover, when a covered entity sues a manufacturer for failing to comply with its ceiling price obligations under the PPA, but "'does not seek to impose any additional or contrary obligations[,][it] is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit.'" *See generally Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314, 329 (D.Mass. 2005) (quoting amicus brief of the United States filed in suit brought by states to enforce Medicaid State Rebate Agreement). We do not understand Santa Clara's complaint as taking issue with the agency's established guidance for calculating prices under § 1396r-8, so we conclude that its contract claim does not implicate DHHS's primary jurisdiction.

County of Santa Clara v. Astra USA, Inc., 540 F.3d 1094, 1109 (9th Cir. 2008) (emphasis added).

On remand, a case management conference was held in September 2008, at which the parties were instructed to proceed with discovery. As permitted at the conference, defendants subsequently brought the instant motion for a protective order to prevent discovery into the data and manner by which the "reported figures" were derived, *i.e.*, "the calculation of the Medicaid-derived components of 340B ceiling prices," the AMP and best-price data (Br. at 2).

Relying predominantly on the italicized sentence in the above-quoted primary jurisdiction holding, defendants argue that the only way the contract claim survived the primary jurisdiction defense was by the above limitation — namely, by limiting the contract claim to whether defendants honored the *reported* figure in its sales to the county — not whether errors occurred in the manufacturers' reporting of the data underlying that calculation. Evidently, this case is worth little unless plaintiff is allowed to go behind the reported numbers, for it appears from counsel's discussion at the hearing that there was substantial compliance, though not perfect compliance, with the reported numbers.

The Section 340B ceiling price (per unit) is calculated by the following simple formula:

$$\underline{\text{AMP} - \text{Unit Rebate Amount}} = \text{Ceiling Price}$$

42 U.S.C. 256b(a)(1)–(2). The average manufacturer's price ("AMP") is (simplifying slightly) just the average price paid to the manufacturers by wholesalers in the United States. 42 U.S.C. 1396r-8(b)(3)(A), (k)(1). The unit rebate amount ("URA") is, in some

circumstances, just a fixed percentage of the AMP, and in others is the AMP minus the "best price," term defined as (again simplifying slightly) the manufacturers' best price charged to wholesalers, with certain exclusions. 42 U.S.C. 1396r-8(c). Both the AMP and the "best price" are calculated or collected *by the manufacturers* and are then simply *reported to* the Secretary. *Id*. at § 1396r-8(b)(3)(A). Once that data are reported, the calculation of the Section 340B ceiling price is a fairly simple, mechanical, arithmetic calculation.

The question presented by the motion is whether the manufacturers' contractual obligation to plaintiff, a third-party beneficiary of the agreement, is simply to charge a price no greater than the AMP minus URA calculated from the data *actually reported* to the Secretary (whether or not they were *accurately* reported), or rather is to charge a price no greater than the AMP minus URA calculated with AMP and best price figures that should have been reported. Defendants argue that plaintiff may not, through discovery, "look behind" the *reported* AMP or best price figures, to determine whether those figures were accurately reported according to the dictates of Section 340B, the agreement, and the Secretary's policy guidance. Rather, defendants argue, plaintiff is entitled only to the *actually reported* AMP and best price figures, to determine whether the ceiling prices were properly derived taking those as given.

The parties' positions on this question arise from differing interpretations of the contract — the PPA. Section II(a) of the PPA states (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 drugs, 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 . . . to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

Defendants rely predominantly on the sentence in the appellate order quoted above but repeated here for convenience:

> The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

County of Santa Clara, 540 F.3d at 1109.

As stated, this is an important part of plaintiff's case. At the hearing, defendants indicated that, if the reported figures are taken as given, instances of overcharges will be isolated and *de minimus*. If true, plaintiff's only avenue for recovery on their claim for overcharges is to go behind the reported numbers to show that those reported numbers were too high.[2]

For the reasons stated below, the undersigned would be inclined to permit the contested discovery but cannot in good faith do so given the language from the Ninth Circuit opinion that plaintiffs "cannot claim that the reported figure was itself somehow erroneous." The Ninth Circuit clearly stated that plaintiff cannot look behind the reported figures to demonstrate that those reported figures were incorrect. The quoted passage is a "show stopper."

ANALYSIS

Were we writing on a clean slate, a plausible argument would favor allowing the discovery in question. The PPA obligates defendants as follows (Def. Req. Notice 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 drugs, 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 section 1927(b)(3)* of the Social Security Act[, 42 U.S.C. 1396r-8(b)(3)], reduced by the rebate percentage.

The PPA does not merely instruct manufacturers to charge a ceiling price calculated from the AMP "reported"; it instructs manufacturers to use the AMP "reported . . . to the Secretary *in accordance with the Manufacturer's responsibilities under* [42 U.S.C. 1396r-8(b)(3)]." As stated, Section 1396r-8(b)(3), in turn, requires manufacturers to report the AMP *as defined* in

[2] Defendants indicate that, even under their interpretation, some minimal issues would remain. For example, there has been some indication of isolated problems in the conversion from per-unit (*i.e.*, per-pill) to full-product or container ceiling prices. Also, on occasion, the above-described formula can produce a negative ceiling price, and in such cases the Section 340B regime dictates a price of one cent. There have been indications of isolated problems applying that rule.

Section 1396r-8(k)(1). If manufacturers reported wrongly calculated AMPs, therefore, plaintiff has an argument that the manufacturers failed to live up to their obligation under the PPA.

The parties dispute the meaning of the phrase "*in accordance with* the Manufacturer's responsibilities under [the Act]." That language must be interpreted in context. *County of Santa Clara*, 540 F.3d at 1102 (courts must weigh the circumstances of the transaction, including here, the governing statute and its purpose). Section II of the PPA states that the obligations therein arise "[p]ursuant to requirements under section 340B of the Act." Section 340B, in turn, states:

> [t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . *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.A. § 1396 et seq.] . . . reduced by the rebate percentage described in paragraph (2).

42 U.S.C. 256b(a)(1) (emphasis added). Section 340B prescribes not merely a ceiling price calculated from "reported" figures, but instead that manufacturers enter agreements under which the prices paid for drugs "do[] not exceed" the statutorily defined price ceiling. It is unlikely, therefore, that the disputed "in accordance with" language merely "directs a reader to the particular manufacturer [AMP] reports at issue," as defendants have argued. Rather, the PPA implements Section 340B's substantive pricing obligation. The Ninth Circuit interpreted the PPA in this manner:

> In acceding to the PPA, the Manufacturers undertook a specific responsibility to the covered entities: "Pursuant to [§ 256b], the Manufacturer agrees . . . . to charge covered entities a price for each unit of the drug that does not exceed" the ceiling price of that drug . . . . *Section II(a) of the PPA sets forth an unambiguous, concrete limitation on how much the Manufacturers may charge* the covered entities . . . . Upon a fair reading of the PPA, we are unable to discern any substantial purpose of the PPA other than to grant eligible covered entities a discount on covered drugs.

Id. at 1102–03 (emphasis added).

Plaintiff's complaint specifically averred that "[t]he data necessary to identify the overpayments for §340B drugs is under the exclusive control of defendants, including, but not limited to, *the data underlying the AMP*, the best price and the §340B ceiling price calculations.

Indeed, the OIG confirmed that participating entities cannot verify that they receive the §340B ceiling price due to confidentiality provisions in the authorizing statute" (Compl. ¶ 45; emphasis added). The Ninth Circuit's decision arguably contemplated the discovery of such otherwise-confidential pricing information:

> the confidentiality provision anticipates that disclosures could be required other than to or by the Secretary. A district court's discovery order compelling the production of documents would be a disclosure 'required by law'; and it would be the manufacturer, not the Secretary, disclosing the information.

County of Santa Clara, 540 F.3d at 1105–06. The appellate decision ruled that plaintiff's contract claim can proceed; it did not state, at least not in so many words, that such discovery would be limited to the AMP data which the manufacturers had already reported to the agency. Similarly, the Ninth Circuit decision quoted a District of Massachusetts decision with approval. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 329 (D.Mass. 2005). That decision — which addressed the Medicaid program rather than the Section 340B program — contemplated an inquiry into the accuracy of the reported figures such as the "best price" data. *Ibid.*[3]

Defendants argue that allowing plaintiff the contested discovery would be akin to allowing the "tail to wag the dog" because, if permitted to question the accuracy of the reported figures, the claim could have ramifications not only for the Section 340B program but also for the much larger Medicaid rebate program from which Section 340B draws the AMP and best price data (Br. at 13, 16–17; Reply at 3). The undersigned finds this argument unpersuasive. If defendants have *not* committed significant reporting errors, there should be no widespread impact on the Medicaid rebate program, and if defendants *have* systematically misreported data to the Medicaid program, defendants fail to explain why it would be undesirable (for anyone other than defendants) for such conduct to come to light. In fact, under defendants' interpretation of the PPA, even if reporting problems were to be discovered in the ongoing

[3] The Ninth Circuit emphasized the similarities between the rights of third-party beneficiaries under the two programs: "[t]he relationship between states and manufacturers under the Medicaid State Rebate Agreement is roughly analogous to that between covered entities and manufacturers under the PPA." *County of Santa Clara*, 540 F.3d at 1109 n.21.

litigation concerning the Medicaid program, *see Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314 (D.Mass. 2005), covered entities under the *Section 340B* program such as plaintiff would have no recourse because defendants' duties under the PPA and Section 340B would be limited to charging ceiling prices calculated from the figures that had *actually been reported* under the Medicaid program, even if those reported figures were inaccurate.

For these reasons, given the contract ruling by the appellate court, the undersigned would be somewhat inclined to interpret the PPA as creating a duty to charge ceiling prices calculated with *accurately reported* AMP and best price figures, not merely a ceiling price calculated from *as-reported* figures.

The slate, however, is not clean. The undersigned is unable to overlook the following clear-cut statement of the Ninth Circuit's decision, a statement that seems to have been central to its primary jurisdiction holding:

> [t]he PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

That is precisely what plaintiff seeks to do — plaintiff claims that the *reported figures* were somehow erroneous and seeks discovery to go behind the reported figures. The Court has considered the possibility that, because the italicized passage referred to the "average manufacturer price," the appellate court intended its limitation to apply only to that "reported figure" and did not intend any limitation as to the "best price." Since, however, the "best price" is also an allied "reported figure," there is no reasoned way to draw such a limitation. The rationale of the appellate court, as reflected in the italicized passage, appears to be a limitation on both reported figures.

Defendants' motion for a protective order is therefore granted, and the question is certified for immediate appeal under Section 1292(b).

CONCLUSION

For all of the above-stated reasons, defendant's motion for a protective order is **GRANTED**. This order is certified for immediate appeal under 28 U.S.C. 1292(b). The undersigned finds that the above-described question involves "a controlling question of law as to which there is substantial ground for difference of opinion" and that "an immediate appeal from the order may materially advance the ultimate termination of the litigation." Discovery will meanwhile proceed on all other issues.

IT IS SO ORDERED.

Dated: November 25, 2008

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE