257 F.R.D. 207
(Cite as: 257 F.R.D. 207)

H

United States District Court,
N.D. 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.
May 5, 2009.

Background: County filed state court action alleging that pharmaceutical companies overcharged its public health care institutions for medications used for indigent medical care. After removal, county moved for class certification to sue on behalf of all California counties and public health care institutions.

Holding: The District Court, William Alsup, J., held that class certification was not warranted, given concern as to manageability of the action.

Motion denied.

West Headnotes

[1] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, Purchasers, Borrowers, and Debtors. Most Cited Cases

Class certification was not warranted in county's proposed class action seeking to recover overcharges from a dozen drug manufacturers for charges that exceeded price ceilings imposed by the Public Health Service Act and contractual agreements thereunder, given concern as to manageability of action related to vast number of drugs, public health care institutions, and prices involved. Public Health Service Act, § 340B, 42 U.S.C.A. § 256b; Fed.Rules Civ.Proc.Rule 23, 28 U.S.C.A.

[2] Federal Civil Procedure 170A 164

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)1 In General
170Ak164 k. Representation of Class; Typicality. Most Cited Cases

A named plaintiff's motion for class certification should be denied where there is a real danger that the representative will be preoccupied with defenses unique to it, to the detriment of the class. Fed.Rules Civ.Proc.Rule 23(a)(4), 28 U.S.C.A.

***207 ORDER REGARDING CLASS CERTIFICATION**

WILLIAM ALSUP, District Judge.

INTRODUCTION

In this proposed class action, the County of Santa Clara seeks to recover overcharges from a dozen drug manufacturers for charges that exceeded 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, plaintiff County now moves for class certification to sue on behalf of all California counties and Section 340B entities. For the reasons that follow, the motion will be denied without prejudice to renewal at a later date. ***208** Although a class will not be certified at present, plaintiff's claims against one defendant, Bayer Corporation, will be given priority for summary judgment and trial. Santa Clara will be allowed to litigate its claims on behalf of its own multiple Section 340B entities against Bayer while its claims against the remaining defendants will proceed at a slower pace. This procedure will allow the Court to learn, in this unprecedented genre of litigation, which issues and complications are real and

which are over-hyped and see how practical class treatment will be as to other defendants. If experience then suggests that class treatment is warranted, a renewed class motion may be brought as to defendants other than Bayer. Put differently, if it were necessary finally to rule on the proposed sprawling class, it would be deemed unmanageable and not superior on the present record. But we can proceed against one defendant, learn from that experience, and then revisit a possible class as against the remaining twelve defendants.

STATEMENT

Plaintiff County of Santa Clara owns and operates the Santa Clara Valley Health and Hospital System. Plaintiff alleges that approximately a dozen pharmaceutical manufacturers breached contractual duties owed to plaintiff as a third-party beneficiary of agreements between the manufacturers and the Secretary of the Department of Health and Human Services called Pharmaceutical Pricing Agreements ("PPAs").[FN1]

FN1. The complaint originally named thirteen defendant drug companies, but some have since merged with or have been acquired by other defendants.

The PPAs 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 certain federally funded hospitals and clinics. 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). Thus, the Secretary must to enter contractual agreements with drug manufacturers *inter alia* to set the Section 340B price ceiling.

Those contractual agreements are the PPAs, which are standardized agreements. Each defendant is bound by a PPA.[FN2] Section II(a) of the PPA states (emphasis added): [FN3]

FN2. Most defendants admitted in their answer that they entered into a PPA, although a few admitted only that their participation in Medicaid requires them to do so. None has argued that it has *not* entered into a PPA.

FN3. Defendants' request for judicial notice pursuant to Rule 201 is granted. The November 2008, order took judicial notice of the PPA. The PPA is appended to the Third Amended Complaint as Exhibit D and is referred to repeatedly by both sides. The OIG reports are government reports also referenced in the complaint and referred to by both sides. Similarly, the HHS regulatory guidelines are public government documents. The Ninth Circuit briefs are not relied upon.

> 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.*

Therefore, under Section 256b and the PPA, the ceiling price (per unit) for covered drugs is set according to the following formula:

Ceiling Price = Average Manufacturer Price ("AMP")-Unit Rebate Amount ("URA").[FN4]

FN4. 42 U.S.C. 256b(a)(1). The AMP and URA are defined terms. The **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 **URA** defines the percentage of the AMP rebated to covered entities. It is comprised of the same AMP as well as a "best price"-the URA (per unit) is the greater of: (1) a fixed percentage of the AMP, or (2) the AMP minus the **"best price,"** a term de-

> fined as (again simplifying slightly) the manufacturers' best price charged to wholesalers, with certain exclusions. 42 U.S.C. 1396r-8(c).

***209** Plaintiff's sole remaining claim is that each defendant breached the PPA (of which plaintiff is a third-party beneficiary) by overcharging for covered drugs. Plaintiff sued in state court 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.

On appeal, however, the Ninth Circuit ruled that plaintiff *was* a third-party beneficiary of the PPA and therefore may proceed with its contract claim. *County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094 (9th Cir.2008). Following remand, a case management conference was held and the parties were directed to proceed with discovery. Defendants thereafter moved for a protective order on the grounds that plaintiff was not entitled to discovery into the underlying data utilized by drug manufacturers to calculate the AMP and the URA (*i.e.*, the data used to calculate the components of the ceiling price), but only to the AMP and best prices actually reported to the Secretary. The motion was granted based on a directive in the appellate decision, but the protective order-which substantially defined the scope of plaintiff's third-party beneficiary rights-was certified for interlocutory appeal. That appeal remains pending. The Court has considered the possible outcomes on the appeal and concluded that the course charted below is most prudent under all circumstances.

Plaintiff filed a third amended complaint in December 2008 (Dkt. No. 284). The third amended complaint eliminated all claims except for the breach-of-contract claim and made certain modifications to the class allegations. Plaintiff now moves to certify the following class under Rules 23(a) and 23(b)(3) (Br. at 1):

> All 340B participants in the State of California, including California counties that fund participants in the 340B Drug Discount Program and the 340B participants funded by them under the Public Health Service Act of 1992, that were overcharged by the defendants for drugs and other pharmaceutical products used in the outpatient context.

Plaintiff represents that there are approximately 1,400 such 340B entities across California, including 58 counties. Plaintiff also requests that the County of Santa Clara be appointed class representative and that its counsel be appointed class counsel.

ANALYSIS

[1] In determining whether class certification is appropriate, "the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather, whether the requirements of Rule 23 are met." *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-178, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1974). Although we may not investigate the likelihood of prevailing on the merits, judges are at liberty to, and indeed must, consider evidence relating to the merits if such evidence also goes to the requirements of Rule 23. *Dukes v. Wal-Mart, Inc.*, 509 F.3d 1168, 1177 n. 2 (9th Cir.2007). Significantly, the party seeking class certification bears the burden of showing that each of the four requirements of Rule 23(a) and at least one of the requirements of Rule 23(b) are met. *Id.* at 1176; *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1019-22 (9th Cir.1998)

Pursuant to Rule 23(a), for a named plaintiff to obtain class certification, the court must find: (1) numerosity of the class; (2) that common questions of law or fact predominate; (3) that the named plaintiff's claims and defenses are typical; and (4) that the named plaintiff can adequately protect the interests of the class. In addition, in the instant case, plaintiff seeks to certify the class under Rule 23(b)(3). Certification under Rule 23(b)(3) requires that a district court find "that questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the ***210** fair and efficient adjudication of the controversy." This last requirement is the crux of the problem.

1. RULE 23(A)(1): NUMEROSITY.

Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." As stated, plaintiff indicates that there are approximately 1,400 covered 340B entities across California, including 58 counties, and that joinder of each would be impracticable. Defendant does not challenge nu-

merosity. This order therefore finds that the proposed class would satisfy the numerosity requirement.

2. RULES 23(A)(2) AND (B)(3): COMMONALITY AND PREDOMINANCE.

To qualify for certification under Rule 23(b)(3), a class must satisfy two requirements: common questions must "predominate over any questions affecting only individual members" and class resolution must be "superior to other available methods for the fair and efficient adjudication of the controversy." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997); Rule 23(b)(3). This Rule 23(b)(3) analysis presumes that the existence of common issues of fact or law has been established pursuant to Rule 23(a) (2). It "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation ... In contrast to Rule 23(a)(2), Rule 23(b)(3) focuses on the relationship between the common and individual issues. When common questions present a significant aspect of the case and they can be resolved for all members of the class in a single adjudication, there is clear justification for handling the dispute on a representative rather than on an individual basis." *Hanlon*, 150 F.3d at 1022 (quotations and citations omitted).

Plaintiff contends that "the predominant question is the same for each [class member]: whether defendants breached, and continue to breach, their contractual obligations under the PPA by charging Santa Clara and the Class more than the ceiling price for covered drugs" (Br. at 2-3). Plaintiff argues that "virtually all" elements of the class claims will require the same proof, including "the contractual 340B prices, and Santa Clara and the Class's payments based upon those prices." Plaintiff argues that because "the prices charged were uniform," the "only differences will be in the amount of damages" (Br. at 7).

* * *

The breadth of the proposed class and the vast factual permutations involved pose major concerns about case manageability. Significantly, *plaintiff does not allege any conspiracy among the dozen defendants.* Why so many separate cases were joined in a single proceeding has never been explained. But the joinder (or misjoinder) has multiplied the scope of permutation by at least a factor of twelve.

Plaintiff has joined a dozen different defendants in a similar suit on a similar theory but raises stand-alone allegations against each. Plaintiff nevertheless moves to certify a single class consisting of all California 340B entities allegedly overcharged by any of the dozen defendants. This is not a standard consumer or antitrust class action in which most of the legal and factual issues have been previously ventilated. This novel suit is uncharted territory. There is no prior experience to draw on. Certification at this stage would be a massive undertaking fraught with a long list of questions that will vary from defendant to defendant. It may turn out that such manageability concerns are unwarranted, but at this stage it also appears very possible, probable really, that certification would be wholly impractical.

Granted, some aspects of the lawsuit are common. Defendants were all bound by the same form of contract (the PPA), and each defendant thus owed the proposed class the same obligation: to charge a specified maximum price for covered drugs. That maximum price is calculated pursuant to a common statutory formula. Therefore, the maximum or "ceiling" price is common to the class-for each given drug in each time period, the 340B ceiling price was the same for each 340B entity. That is the easy part.

This case, however, is unlike a standard consumer or antitrust class action where a ***211** single, uniform breach is alleged and only the individual damages of each class member will differ. Plaintiff alleges not a single, uniform breach but rather overcharges on numerous drugs by a dozen different defendants, all acting independently. The complaint alleges overcharges just to plaintiff's own health entities on approximately 119 different drugs sold by the dozen defendants. Each drug had a distinct ceiling price for each period, and each proposed class member purchased a different mix of those drugs. The ceiling price is ultimately set for drug packages (*e.g.*, bottles of pills rather than individual pills) and thus requires calculation of a per-unit price based on dosage form and strength and then conversion to a package price based on the number of such units actually paid for, a process that could potentially inject further differentiation depending on how the drugs were sold. Plaintiff states that it wants to include additional (yet unidentified) drugs-the proposed class definition already would allow recovery for drugs that Santa Clara's 340B entities did *not* purchase but that other absent class members did purchase.

Plaintiff Santa Clara alone consists of various clinics and health centers that each constitute distinct members of the Section 340B program (and thus will each require separate overcharge calculations). Plaintiff proposes to expand its claim to approximately 1400 Section 340B entities, each of which purchased a different mix of drugs from the various defendants. The factual permutations involved are vast.

Furthermore, although the contracted "ceiling" price was uniform for each drug, in the sense that the same formula applied, the ceiling price surely varied by time period even for the very same drug. The record does not establish, moreover, that the actual prices *charged* were uniform. Plaintiff provides no evidence of a "uniform" price for the drugs nor of a uniform overcharge, and defendants, in contrast, point to evidence that covered entities "frequently" negotiated individual arrangements to purchase drugs at prices below the ceiling price (Stein Exh. 6 at 4). Under the contract, a breach occurred only if defendants "charged" a 340B entity an excessive price, not when defendants merely miscalculated the ceiling price. Any separately negotiated prices will thus add individual facts to the proposed class claim.

* * *

Defendants raise another challenge to predominance. This order rejects this challenge but in one way described below the issue could nonetheless add individualized complications. Defendants argue that inquiry into class members' compliance with the 340B program's statutory eligibility criteria will pose extensive individual issues. Defendants waver between two versions of the argument. *First*, they argue that each class member must *prove* its compliance with the statutory requirements as part of its third-party beneficiary claim. Under this view, each class member would have to prove that it did not engage in the disqualifying acts of diversion or double dipping (defined below). *Second*, defendants contend (presumably in the alternative) that they have a right of offset against plaintiff's overcharge claim, *i.e.*, a right to deduct from plaintiff's contract claim any discounts for which plaintiff was ineligible in the first place. Either way, defendants contend, highly individualized facts will predominate.

This order rejects defendants' broader contention: that class members must *prove* total compliance with the statutory criteria on a transaction-by-transaction basis to have a third-party beneficiary claim for overcharges. Under the statutory scheme, an entity's qualification for and participation in the 340B program is established via a separate regulatory process whereby the Secretary determines the "covered entities" eligible for the program and maintains a published list of such participating entities. Defendants are correct, however, that they would be entitled to apply ripened claims for covered entity non-compliance as a setoff against plaintiff's eventual recovery, but the statutory scheme requires them to perfect the claim with the Secretary in the first instance.

Specifically, the statute defines the "covered entities" that are entitled to receive the Section 340B discount. It states: "The term 'covered entity' means an entity that meets the requirements described in paragraph (5) ***212** and is one of the following [enumerated categories of publicly funded health organizations]." 42 U.S.C. 256b(a)(4). Subsection (5), in turn, sets forth various "requirements for covered entities." These include, among others, (A) a ban on "diversion," *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non-340B entities, and (B) a ban on "double dipping," *i.e.*, a requirement that covered entities refrain from billing Medicaid for drugs purchased at a discount under the Section 340B program. *Id.* at § 256b(a)(5)(A), (B).

Defendants' broader argument-that plaintiff must *prove* its own compliance as part of its contract claim-is contrary to the regulatory scheme. Defendants' obligations under the PPA are not contingent on a covered entity proving its own compliance (and thus its status as a third-party beneficiary). Instead, the list of "covered entities" participating in the 340B program is governed by the Secretary. The Office of Pharmacy Affairs in HHS's Health Resources and Services Administration maintains a list of 340B "covered entities" eligible for the discount. To participate in the 340B program and be entitled to receive the 340B discount, at least as an initial matter, an entity need only be deemed eligible by the agency and be included on OPA's list of "covered entities."

This conclusion is clear from the statute itself and regulatory guidelines thereunder. As stated, Section 256b(5) sets forth the covered-entity compliance cri-

teria here at issue. Section 256b(a)(9), in turn, states that "[t]he Secretary shall notify manufacturers ... of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5)." HHS regulations further clarify that the Secretary is responsible for determining which entities are eligible:

> Section 340B(a)(4) of the PHS Act lists the various categories of PHS programs eligible to receive section 340B outpatient drug discount pricing. For each category, there is a Federal program office which oversees the grant program. *The respective Federal program offices determine which individual facilities receive the grant funds specified by section 340B or are eligible under other criteria and compile a list of such entities.* The Federal program office then submits this list to the Office of Drug Pricing (ODP) for inclusion on the master list of eligible facilities ("covered entities").

60 Fed.Reg. 39762-01 (Aug. 3, 1995) (emphasis added). Significantly, the guidelines prohibit manufacturers from conditioning the 340B discount on a covered entity's proof or certification of its compliance with the statutory criteria:

> A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions. Covered entity assurances regarding the following activities may not be required: (1) eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; ... [and other matters]

59 Fed.Reg. 25110-01, at 25113-14 (May 13, 1994).[FN5]

> FN5. An entity can be removed from the 340B list by the Secretary alone. *See* 61 Fed.Reg. 65406-01, at 65412 (Dec. 12, 1996). Defendant's own expert confirmed as much (Lawrence Exh. A at 95-98, 120-25, 129-31).

In sum, the statute and regulations indicate that the Secretary determines which drug purchasers are "covered entities" eligible in the program and thus entitled to the discount, and manufacturers may not condition the 340B discount on further assurance that the covered entity is in compliance.

This statutory and regulatory background informs interpretation of the PPA. The PPA itself, moreover, confirms that defendants' contractual obligations are not contingent on each covered entity proving compliance. Under the PPA, the Secretary agreed "to make available a list of covered entities ... for access by participating Manufacturers, covered entities [and others]." In return, the manufactures agreed "to charge covered entities a price for each drug" not exceeding the ceiling price. The PPA does not pre-condition manufacturers' obligation to provide the 340B discount on covered entities' ***213** proof of compliance with the statutory criteria.

* * *

Manufacturers are not, however, without recourse where covered entities fail to conform with the statutory criteria. The Act affords manufacturers a claim to recover discounts that were extended to covered entities in breach of the statutory criteria, but it establishes the administrative process to perfect the claim. 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 diversion], the covered entity shall be liable to the manufacturer ..."). This order holds that once any manufacturer obtains such an order from the Secretary, then the manufacturer may assert that statutory claim either as an independent lawsuit or as a counterclaim or as a setoff.

Defendants must, however, have a perfected claim in order to assert a setoff. The only way to perfect one is via the administrative process. The burden is on them to initiate the administrative process to tee up the statutory claim. This case has been pending since 2005 and there is no indication that any manufacturer has done so. If defendants are able to establish their claim in a timely fashion, the Court will consider amendment to allow them to assert it as a counterclaim or setoff in due course, assuming due diligence. The Court will also allow defendants discovery to obtain (from plaintiffs) and to supply the necessary information to the Secretary.[FN6]

> FN6. In fact, amendment arguably would not be necessary. Defendants pled setoff as a *defense* to plaintiff's third-party beneficiary contract claim but not as a counterclaim. Courts have indicated a willingness to over-

> look such mistaken designations in pleadings. *See* *Reiter v. Cooper*, 507 U.S. 258, 263, 113 S.Ct. 1213, 122 L.Ed.2d 604 (1993) ("it makes no difference that petitioners may have mistakenly designated their counterclaims as defenses, since Federal Rule of Civil Procedure 8(c) provides that 'the court on terms, if justice so requires, shall treat the pleading as if there had been a proper designation.' ") *See also* 5 C. Wright & A. Miller, Federal Practice and Procedure § 1275, ¶ 459-460 (2d ed. 1990) ("Inasmuch as it is not clear whether set-offs and recoupments should be viewed as defenses or counterclaims, the court, by invoking the misdesignation provision in Rule 8(c), should treat matter of this type as if it had been properly designated by defendant, and should not penalize improper labeling").

Because defendants have not pursued any administrative remedies, this whole argument is theoretical at present. This is not a cause for denying certification but we must be aware that the possibility of setoffs as an individual issue poses some downstream risk.

* * *

Finally, it is important to note that the sums at stake are likely large enough for the 340B entities to justify launching their own stand-alone suits. Each entity would be able to protect its own interests. Put differently, the 340B entities are not consumers with small claims that need a collective action to vindicate their rights. They are sophisticated and, more to the point, they have sufficiently large stakes involved to justify their own litigation catered to their own circumstances. *See* Rule 23, Notes, 1966 Amendment ("[t]he court is to consider the interests of individual members of the class in controlling their own litigations and carrying them on as they see fit ... On the other hand ... the amounts at stake for individuals may be so small that separate suits would be impracticable"). This is hardly a case where the amounts at stake for the proposed class members are so small that separate suits would be impracticable.

Plaintiff contends, for example, that *its* various 340B health facilities were charged approximately $30 million or more per year for covered drugs (although plaintiff does not allege what percentage was improperly charged). Similarly, a 2006 OIG report sampled seventy hospitals and found that overcharges (among the entire sample) for a *single month* totaled approximately $3.9 million. The bulk of the class is likely to have ample incentive to sue independently.

This circumstance does not bar class certification, of course, but it should be considered in deciding whether a class action is "superior to other available methods for the fair and efficient adjudication of the controversy." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 615, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997); Rule 23(b)(3).

***214 3. RULE 23(A)(3): TYPICALITY.**

Rule 23(a)(3) requires that "the claims or defenses of the representative parties be typical of the claims or defenses of the class." The test "is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir.1992). Defendants do not challenge class certification on the basis of no typicality. This order finds that Santa Clara's claims are typical of the proposed class.

4. RULE 23(A)(4): ADEQUACY.

[2] Rule 23(a)(4) permits certification of a class action only if "the representative parties will fairly and adequately protect the interests of the class." "This factor requires: (1) that the proposed representative Plaintiffs do not have conflicts of interest with the proposed class, and (2) that Plaintiffs are represented by qualified and competent counsel." *Dukes*, 509 F.3d at 1185. A named plaintiff's motion for class certification should be denied where there is a real danger that the representative will be preoccupied with defenses unique to it, to the detriment of the class. *See, e.g.*, *Hanon*, 976 F.2d at 508.

Defendants contend that Santa Clara is not an adequate class representative because it will be the target of unique defenses. In particular, defendants point to Santa Clara's alleged problems with Section 340B's eligibility criteria, including problems with "diversion" and violation of the so-called "double dipping" rule. Defendants contend that evidence already uncovered in discovery establishes that Santa Clara engaged in double dipping and/or diversion, and

that such conduct (unique to it) would thus constitute a major focus of the case. The facts underlying defendants' adequacy challenge are largely the same as those underlying its commonality and predominance challenges-including alleged double dipping and diversion. As explained, such compliance issues are not a defense but may be asserted by way of setoff if defendants separately establish a claim. Litigation of the claim against defendant Bayer will help the Court evaluate Santa Clara's adequacy as a class representative.

CONCLUSION

For all of the above-stated reasons, plaintiff's motion to certify a sprawling class against a dozen major companies is denied without prejudice to renewing the motion in due course as to defendants other than Bayer Corporation. Plaintiff's claim against Bayer Corporation will effectively be severed in order to give it priority for summary judgment and trial. Plaintiff's claims against defendants other than Bayer Corporation will proceed at a slower pace. Discovery should proceed, however, as to all defendants.

Given the novelty of this litigation, this approach-taking the Bayer case to trial-will flush out the germane issues embedded in these twelve cases and allow the Court better to determine if the case against the eleven is manageable on a class basis given that the case involves numerous issues as well as vast numbers of drugs, 340B entities, and prices, and many permutations thereof. Manageability is a severe concern, albeit potentially a surmountable one as the Court gathers experience and details about the issues. Allowing the case against Bayer to proceed on a priority basis will allow the Court to better grasp the true preponderance of common versus individual issues and to assess possible management techniques for a larger class. In the end, the experience may illuminate the way to certify a class against the remaining defendants (even if Bayer escapes a class outcome in the present case).

Finally, plaintiff has filed a motion in limine to exclude the testimony of defendants' expert, Kenneth Lowrie. Mr. Lowrie provided an expert opinion regarding the functioning of the 340B program, including the compliance criteria and covered entity eligibility for the program. Plaintiff argues that these matters are irrelevant to this case. For the above-stated reasons, however, these matters ***215** are germane to the case. Plaintiff's motion in limine is **DENIED.**[FN7]

FN7. Plaintiff has also filed a motion to seal four exhibits to the Stein declaration in support of defendants' opposition brief that were designated confidential under the confidentiality agreement. The exhibits include internal notes and a memorandum pertaining to Santa Clara's internal practices relating to drug purchasing. Because this is not a dispositive motion, plaintiff must only show good cause to seal. The motion is granted.

IT IS SO ORDERED.

N.D.Cal.,2009.
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