FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

COUNTY OF SANTA CLARA,
Plaintiff-Appellant,

v.

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORPORATION; BRISTOL-MYERS SQUIBB COMPANY; PFIZER, INC.; SCHERING-PLOUGH CORPORATION TAP PHARMACEUTICAL PRODUCTS, INC.; ZENECCA INC.; ZLB BEHRING LLC; SMITHKLINE BEECHAM CORPORATION; SMITHKLINE BEECHAM CORPORATION, dba GlaxoSmithKline; WYETH, INC.; WYETH PHARMACEUTICALS, INC.,
Defendants-Appellees.

No. 06-16471
D.C. No.
CV-05-03740-WHA
OPINION

Appeal from the United States District Court
for the Northern District of California
William H. Alsup, District Judge, Presiding

Argued and Submitted
March 11, 2008—San Francisco, California

Filed August 27, 2008

Before: Stephen Reinhardt, Melvin Brunetti and
Raymond C. Fisher, Circuit Judges.

Opinion by Judge Fisher

COUNSEL

Patrick J. Coughlin, Sanford Svetcov (argued), Jeffrey W. Lawrence, Jacqueline E. Mottek, Aelish M. Baig and Jennie

Lee Anderson, Coughlin Stoia Geller Rudman & Robbins LLP, San Francisco, California; Ann Miller Ravel and Cheryl A. Stevens, Santa Clara County Counsel's Office, San Jose, California; Steve W. Berman and Douglas C. McDermott, Hagens Berman Sobol Shapiro LLP, Seattle, Washington, for plaintiff-appellant County of Santa Clara.

Robert S. Litt (argued), Jeffrey L. Handwerker and Sharon Douglass Mayo, Arnold & Porter LLP, Washington, D.C., for defendants-appellees Astra USA, Inc., AstraZeneca Pharmaceuticals, LP and Zeneca Inc.; Alicia J. Donahue and Sara Romano, Shook, Hardy & Bacon LLP, San Francisco, California, for defendants-appellees Aventis Pharmaceuticals, Inc. and ZLB Behring LLC; Timothy T. Scott, Geoffrey M. Ezgar and Paul Yanosy, Sidley Austin LLP, San Francisco, California, for defendant-appellee Bayer Corporation; Paul J. Riehle and Matthew A. Fischer, Sedgwick Detert Moran & Arnold LLP, San Francisco, California, for defendant-appellee Bristol-Myers Squibb Company; Federick G. Herold, Valerie M. Wagner and Philip Barilovits, Dechert LLP, Palo Alto, California, for defendant-appellee SmithKline Beecham Corporation; Molly M. Lane and Tera Heinz, Morgan, Lewis & Bockius LLP, San Francisco, California, for defendant-appellee Pfizer Inc.; Kirke M. Hasson and Colin T. Kemp, Pillsbury Winthrop Shaw Pittman LLP, San Francisco, California, for defendant-appellee Schering-Plough Corporation; Peter N. Larson, Jones Day, San Francisco, California, for defendant-appellee TAP Pharmaceutical Products, Inc.; Fletcher Alford, Gordon & Rees, LLP, San Francisco, California, for defendants-appellees Wyeth, Inc. and Wyeth Pharmaceuticals Inc.

OPINION

FISHER, Circuit Judge:

Certain federally funded medical clinics — so-called "Section 340B covered entities" — are able to purchase prescrip-

tion drugs at a discount from drug manufacturers under a standardized agreement between the federal government and the drug companies. During 2003, for example, these covered entities spent $3.4 billion on outpatient prescription drugs. They claim in this lawsuit that they have been overcharged for those drugs in violation of pharmaceutical pricing agreements between the Secretary of Health and Human Services ("Secretary") and the drug manufacturer defendants-appellees ("Manufacturers"). Applying the federal common law of contracts, we hold that the covered entities are intended direct beneficiaries of these agreements and thus have the right to enforce the agreements' discount provisions against the Manufacturers and sue them for reimbursement of excess payments. We have jurisdiction under 28 U.S.C. § 1291, and reverse the district court's dismissal of the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

BACKGROUND[1]

In part to "enable . . . certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients," *see* H.R. Rep. No. 102-384(II), at 7 (1992), Congress enacted Section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943, 4967. That provision, entitled "Limitations on Prices of Drugs Purchased by Covered Entities," requires the Secretary of Health and Human Services to:

> 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

[1]Because this is an appeal from an order granting a motion to dismiss, we accept all facts alleged as true and construe them in the light most favorable to the plaintiff. *See Karam v. City of Burbank*, 352 F.3d 1188, 1192 (9th Cir. 2003).

> an amount equal to the average manufacturer price for the drug under [§ 1396r-8(k)(1)] in the preceding calendar quarter, reduced by [a] rebate percentage described in [§ 256b(a)(2)].

42 U.S.C. § 256b(a)(1).[2] This drug discounting program is commonly known as the "Section 340B program," tracing back to its original location within the Public Health Service Act.[3] The program is managed by the Health Resources and Services Administration ("HRSA"), a subdivision of the Department of Health and Human Services ("DHHS"). *See* Statement of Organizations, Functions, and Delegations of Authority, 58 Fed. Reg. 19,137-02 (Apr. 12, 1993). In accordance with statute, the Secretary entered into a standard Pharmaceutical Pricing Agreement ("PPA") with each of the Manufacturers.

One of the Manufacturers' principal obligations under the PPA is "to charge covered entities a price . . . that does not exceed . . . the [average manufacturer price] for the covered outpatient 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).[4] The PPA defines "average manufacturer price," "covered entity," "manufacturer" and "rebate percentage" to "have the meanings specified in [§§ 256b and 1396r-8], as interpreted and applied herein." *See* PPA §§ I(a)-(o). Also known as the "ceiling price," the maximum price that covered entities may

[2]Hereinafter, all citations are to Title 42 of the United States Code unless otherwise noted.

[3]Section 602 of the Veterans Health Care Act of 1992 added a new Section 340B to Part D of Title III of the Public Health Service Act. *See* 106 Stat. at 4967. The Public Health Service Act is itself codified at Chapter 6A of Title 42 of the United States Code. *See* National Institutes of Health Revitalization Act of 1993 § 2008(i)(1)-(2), Pub. L. No. 103-43, 107 Stat. 122, 212-13.

[4]The PPA establishes different discounts for other classes of drugs that are not relevant here. *See* PPA §§ II(b)-(c).

be charged under the PPA is calculated using proprietary sales and pricing information the Manufacturers disclose only to the Secretary.

The genesis of the present appeal is a putative class action filed in California state court by the county of Santa Clara and a number of county-operated medical facilities ("Santa Clara"), which are covered entities within the meaning of § 256b(a)(4) and PPA § I(e). Relying chiefly on reports published by DHHS's Office of the Inspector General ("OIG"), Santa Clara alleged that the Manufacturers have systematically overcharged its medical facilities, and all similarly situated covered entities, for covered drugs. OIG's March 2003 report estimated that overcharges during the one-year period ending September 1999 totaled $6.1 million. Its June 2004 report, which was withdrawn in October 2004 because of "problems with the underlying data," concluded that covered entities overpaid $41.1 million in the month of September 2002. In October 2005, OIG confirmed that its June 2004 calculation was erroneous because the Centers for Medicare and Medicaid Services had provided it with comparison "ceiling prices from the wrong timeframe." OIG did not retreat, however, from its other, more general findings that HRSA was not adequately overseeing the Section 340B program and that "HRSA lacks the oversight mechanisms and authority to ensure that [covered] entities pay at or below the . . . ceiling price." The October 2005 report also "introduce[d] new concerns" that "systemic problems with the accuracy and reliability" of the government's pricing data could interfere with HRSA's ability to monitor the Section 340B program. Finally, a 2006 OIG report estimated that covered entities overpaid $3.9 million in June 2005 alone.

Santa Clara initially brought claims under the California False Claims Act and California Unfair Competition Law in state court. After the Manufacturers removed the action to federal district court, Santa Clara amended its complaint for the first time. The district court granted the Manufacturers'

motion to dismiss, but with leave to amend. Santa Clara's second amended complaint, now including claims for breach of the PPA, breach of the implied covenant of good faith and fair dealing, negligence and quantum meruit, fared no better than the first. The district court granted the Manufacturers' second motion to dismiss and denied as futile Santa Clara's subsequent motion for leave to file a third amended complaint. Santa Clara appeals only the district court's rejection of its PPA breach of contract claim on a third party beneficiary theory.

STANDARD OF REVIEW

"We review de novo the district court's dismissal of a complaint for failure to state a claim under Rule 12(b)(6)." *Vasquez v. Los Angeles County*, 487 F.3d 1246, 1249 (9th Cir. 2007). The interpretation of a contract is a mixed question of law and fact that we review de novo. *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210 (9th Cir. 1999).

DISCUSSION

We agree with Santa Clara that covered entities are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract. We also conclude that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, even though the statute itself does not create a federal private cause of action. Finally, we reject the Manufacturers' argument that primary jurisdiction is appropriate.

I.

[1] Federal law controls the interpretation of the PPA, which is a "contract[ ] entered into pursuant to federal law and to which the government is a party," *Smith v. Cent. Ariz. Water Conservation Dist.*, 418 F.3d 1028, 1034 (9th Cir.

2005), and which expressly provides that it "shall be construed in accordance with Federal common law," *see* PPA § VII(g).[5] "For guidance, we may look to general principles for interpreting contracts." *Kennewick Irrigation Dist. v. United States*, 880 F.2d 1018, 1032 (9th Cir. 1989). Among these principles, we interpret every part of a written contract with reference to the whole and give terms their ordinary meaning unless a contrary intent appears. *See Klamath*, 204 F.3d at 1210. When possible, we ascertain the intent of the parties from the contract itself. *See id.*

[2] Under the federal common law of contracts, "[b]efore a third party can recover under a contract, it must show that

[5]"[F]ederal jurisdiction cannot be created by contract," of course, and we have an independent obligation to scrutinize our jurisdiction. *ARCO Envtl. Remediation, L.L.C. v. Dep't of Health & Envtl. Quality of Mont.*, 213 F.3d 1108, 1117 n.11 (9th Cir. 2000) (internal quotation marks omitted). Here, regardless of whether federal or state law creates the cause of action underlying Santa Clara's contract claim — a question we will not reach out to resolve because the complaint is ambiguous, neither party has briefed the issue and the precedent is famously obscure, *see, e.g.*, *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677 (2006); *Boyle v. United Tech. Corp.*, 487 U.S. 500, 506-07 & n.3 (1988); *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union*, 457 U.S. 15, 20-23 (1982); *Miree v. DeKalb County*, 433 U.S. 25, 29-31 & n.3 (1977) — it "necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities," and so was properly heard by the district court in the exercise of its 28 U.S.C. § 1331 federal question jurisdiction. *See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). Santa Clara seeks enforcement of an obligation created by a nationwide federal contract whose terms are mandated by federal statute and which must be interpreted according to federal law. Its claim plainly "implicate[s] the government's . . . interests" in the uniform administration of the Section 340B program and the parties' compliance with federal law. *See Smith*, 418 F.3d at 1034; *Almond v. Capital Prop., Inc.*, 212 F.3d 20, 22-24 (1st Cir. 2000); *Price v. Pierce*, 823 F.2d 1114, 1119-21 (7th Cir. 1987); *Eatmon v. Bristol Steel & Iron Works, Inc.*, 769 F.2d 1503, 1516-17 (11th Cir. 1985); *see also Flick v. Liberty Mut. Fire Ins. Co.*, 205 F.3d 386, 390 (9th Cir. 2000).

the contract was made for its direct benefit — that it is an *intended beneficiary* of the contract." *Id.* (emphasis added). "A promisor owes a duty of performance to any intended beneficiary of the promise, and 'the intended beneficiary may enforce the duty' " by suing as a third party beneficiary of the contract, whereas an "incidental beneficiary acquires 'no right against the promisor.' " *Id.* at 1211 n.2 (quoting Restatement (Second) of Contracts §§ 304, 315 (1979)). To qualify as an intended beneficiary, the third party "must show that the contract reflects the express or implied intention of the parties to the contract to benefit the third party." *Id.* at 1211 (citing *Montana v. United States*, 124 F.3d 1269, 1273 (Fed. Cir. 1997)). Although intended beneficiaries "need not be specifically or individually identified in the contract," they still must "fall within a class clearly intended by the parties to benefit from the contract." *Id.*

[3] Demonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task. *See Smith*, 418 F.3d at 1035; *Kremen v. Cohen*, 337 F.3d 1024, 1029 (9th Cir. 2003) (explaining that a "more stringent test applies"). We have explained that "[p]arties that benefit from a government contract are generally assumed to be incidental beneficiaries," rather than intended ones, and so "may not enforce the contract *absent a clear intent to the contrary*." *See Orff v. United States*, 358 F.3d 1137, 1145 (9th Cir. 2004), *aff'd on other grounds*, 545 U.S. 596 (2005) (quoting *Klamath*, 204 F.3d at 1211). This "clear intent" hurdle is not satisfied by a contract's recitation of interested constituencies, *Klamath*, 204 F.3d at 1212, "[v]ague, hortatory pronouncements," *id.*, "statement[s] of purpose," *Smith*, 418 F.3d at 1037, "explicit reference to a third party," *Orff*, 358 F.3d at 1145, or even a showing that the contract "operates to the [third parties'] benefit and was entered into with [them] 'in mind,' " *id.* at 1147. Rather, we examine the "precise language of the contract for a 'clear intent' to rebut the presumption that the [third parties] are merely incidental beneficiaries." *Id.* at 1147 n.5.

[4] Having done this analysis, we are persuaded that covered entities are intended beneficiaries of the PPA and, accordingly, that Santa Clara has stated a breach of contract claim on a third party beneficiary theory. At the outset, we reject the suggestion that the availability of a third party contract claim is conditioned on the contract's inclusion of a provision expressly granting the third party the *right to sue*. Any intended beneficiary has the right to enforce the obligor's duty of performance; the right to sue inheres in one's status as an intended beneficiary. *See Klamath*, 204 F.2d at 1211 n.2; *see also Far W. Fed. Bank, S.B. v. Office of Thrift Supervision Director*, 119 F.3d 1358, 1363 (9th Cir. 1997) ("[A] third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain an appropriate remedy for breach."); Restatement (Second) of Contracts § 304 (1981). To require additionally of intended beneficiaries that the contract by its terms provide for third party enforcement would read the distinction between incidental and intended beneficiaries out of the federal common law of contracts. *See United States v. City of Los Angeles*, 288 F.3d 391, 403-04 (9th Cir. 2002) ("[W]e allowed intended third-party beneficiaries to sue . . . and did not allow incidental third-party beneficiaries to sue."); Restatement (Second) of Contracts § 302 (1981). In disavowing any absolute requirement that the contract expressly provide for third party enforcement, we reaffirm *Klamath*'s "clear intent" principle with respect to intended beneficiary status. We simply clarify that *if* the plaintiff is an *intended* beneficiary — with *Klamath* and progeny setting forth the requisite showing — then the third party contract claim may go forward.[6] Only when the plaintiff

[6]The Manufacturers suggest that *US Ecology, Inc. v. United States*, 245 F.3d 1352 (Fed. Cir. 2001), is to the contrary. Not so. The Federal Circuit declined to allow third party beneficiary enforcement of the contract because there was no "evidence of an intent by the federal government to benefit" the plaintiffs. *Id.* at 1357; *see also id.* at 1356 ("It is undisputed that the evidence contains no statement by the federal government that it intended for the alleged contract to benefit any third party."). *US Ecology*

would qualify solely as an *incidental* beneficiary of the government contract is it necessary to have an express, specific statement of the promisor's contractual liability to that third party (such as by an express right-to-sue clause). *See Smith*, 418 F.3d at 1038; *Montana*, 124 F.3d at 1273 & n.6; Restatement (Second) of Contracts § 313(2) & cmt. a (1981).

[5] We hold that the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement. *See Kremen*, 337 F.3d at 1029. In determining this central question of the parties' intent, we look at the contract's "text and purpose," *Smith*, 418 F.3d at 1034, "[e]xamin[ing] . . . the contract as a whole," *Klamath*, 204 F.3d at 1212. We also weigh the "circumstances of the transaction," *Far West*, 119 F.3d at 1364, which, when a contract is mandated by a federal statute, includes the "governing statute and its purpose," *Sec'y of State for Def. v. Trimble Navigation Ltd.*, 484 F.3d 700, 706 (4th Cir. 2007) (internal quotation marks omitted); *see also Rendleman v. Bowen*, 860 F.2d 1537, 1541-42 (9th Cir. 1988).

[6] 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. *See* PPA § II(a) (emphasis added). *Smith*, *Kremen*, *Orff* and *Klamath* — all of which rejected plaintiffs' claims to be intended beneficaries — are distinguishable on this ground alone.[7] There is a stark contrast

---

reaffirmed the principle stated in the text. "In order to create rights in a third party, 'the contract must reflect[ ] the express or implied intention of the parties to benefit the third party.' " *Id.* at 1356 (quoting *Montana*, 124 F.3d at 1273) (alteration in original). "*One* way" — but by no means the exclusive one — of ascertaining whether the parties had such an intent is to ask whether the contract expressly "confer[s] a right" to performance on third parties. *See id.* (emphasis added).

[7]*Cf. Smith*, 418 F.3d at 1036-37 (agreement simply "specifie[d] that the government's obligation . . . is subject to . . . federal law," confirmed

between "recitation of constituencies," "explanatory recitals" of purpose and references to individuals that the contracting parties had "in mind" — all insufficient to "prove [the plaintiffs'] intended beneficiary status" — and the terms at issue here. *See Smith*, 418 F.3d at 1037; *Orff*, 358 F.3d at 1147; *Klamath*, 204 F.3d at 1212. Section II(a) of the PPA sets forth an unambiguous, concrete limitation on how much the Manufacturers may charge the covered entities.[8] Other provisions of the PPA explain how to calculate the ceiling price, *see* PPA §§ I(a), (b), (*l*), identify who is eligible to receive the discounted price, *see* PPA §§ I(e), III(a), and require the parties to maintain records relevant to those matters, *see* §§ PPA II(c)-(f), III(b)-(c). 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. We are therefore persuaded that the PPA, on its face, was clearly intended to benefit the covered entities directly.

[7] Consideration of § 256b, the "governing statute" specifying the PPA's terms, and its purposes reinforces this interpretation. *See Trimble Navigation*, 484 F.3d at 706. (The PPA

water district's "agree[ment] to abide by the terms of . . . subcontracts" and otherwise amounted to "hortatory statement[s] of purpose"); *Kremen*, 337 F.3d at 1029 (agreement only articulated defendant's responsibility to effectively, efficiently and timely to manage Internet domain name registration system); *Orff*, 358 F.3d at 1145-46 (agreement "ma[de] reference" to the plaintiffs only in context of setting forth "conditions precedent" that they had to satisfy); *Klamath*, 204 F.3d at 1211-12 (agreement "grant[ed] discretion to the United States . . . to enforce the Contract by taking control of the Dam" and "preserve[d] the United States' ultimate control over the Dam").

[8]Although the PPA does not state in so many words that it was entered into "for the benefit" of the covered entities, *see Far West*, 119 F.3d at 1364 n.2, we have never conditioned our analysis of intended beneficiary status on formalistic recitals. *Cf. United States v. FMC Corp.*, 531 F.3d 813, 822 (9th Cir. 2008) ("[A] contract can use whatever terms the parties wish to express their agreement.").

itself provides that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." *See* PPA § VII(g).) Section II(a) of the PPA closely tracks Section 602 of the Veterans Health Care Act of 1992, which was enacted to "require a manufacturer to extend the same price reduction to a covered entity for a drug or biological as is provided under the Medicaid outpatient drug rebate program." *Joint Explanatory Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211. Its purpose was "to *enable . . . certain Federally-funded clinics [i.e., covered entities] to obtain lower prices* on the drugs that they provide to their patients" by prohibiting "Medicaid matching funds [from being] available for State spending on [a manufacturer's covered drugs] unless the manufacturer enters into, and *complies with*, an agreement . . . under which these protected purchasers [e.g., covered entities] would pay the same amount for a covered outpatient drug that Medicaid pays." H.R. Rep. No. 102-384(II), at 7-8 (1992) (emphasis added). "In giving these 'covered entities' access to price reductions the Committee intends to *enable these entities* to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *Id.* at 12 (emphasis added). Thus, although we agree with the Manufacturers that § 256b's general purpose is to "conserve federal resources so as to reach as many eligible patients as possible," the legislative history makes plain that Congress intended to accomplish this objective by enabling covered entities (and other "protected" purchasers, a revealing choice of words) to obtain discounted prices on covered drugs through the PPAs.[9]

Relying on *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985), the Manufacturers contend that the PPA's

[9]Protected purchasers also include the Department of Veterans Affairs, the Department of Defense, the Public Health Service and the Indian Health Service. *See* Veterans Health Care Act of 1992 § 603(a), Pub. L. No. 102-585, 106 Stat. 4943, 4972 (codified at 38 U.S.C. § 8126(b)); H.R. Rep. No. 102-384(II), at 7-8.

provision of an "elective" or "informal" dispute resolution process means the parties intended to preclude third party enforcement of the contract by the covered entities. Sections IV(a), (b) and (d) of the PPA allow manufacturers to refer certain disputes they have with covered entities to the Secretary to conduct an investigation. If the Secretary then finds that the covered entity is in violation, he may impose monetary liability or remove the entity from the list of eligible entities.[10] Conversely, if the Secretary believes a manufacturer has overcharged covered entities, he may initiate an "informal dispute resolution process," which could result in the covered entities being reimbursed and the manufacturer's PPA being terminated. *See* PPA § IV(c). The Manufacturers also cite DHHS's regulations, which, apart from the PPA, establish a "voluntary process for the resolution of certain disputes between manufacturers and covered entities concerning compliance with the provisions" of § 256b. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406-01, 65,411-13 (Dec. 12, 1996). This process is also voluntary: "Covered entities or manufacturers are not required to enter this informal process for resolution of disputes . . . ." *Id.* at 65,411.

D'Amato does not support the Manufacturers' argument. There, the plaintiffs attempted to bring suit as third party beneficiaries of affirmative action provisions whose inclusion in procurement contracts was required by Section 503 of the Rehabilitation Act of 1973. As a threshold matter, the contracts themselves suggested that the plaintiffs were not

[10]The informal dispute resolution remedies against the covered entities run through the Secretary, who has the power to "establish a mechanism to ensure that covered entities comply" with the Section 340B program's requirements and sanction them for noncompliance. *See* § 256b(a)(5)(A)(ii), (D). We construe these PPA provisions as simply restating the covered entities' statutory obligations, because as a matter of federal common law, even a third party beneficiary "cannot be bound to a contract it did not sign." *See Comer v. Micor, Inc.*, 436 F.3d 1098, 1102 (9th Cir. 2006).

intended beneficiaries; they were "not directed at the handicapped in any way but instead focus[ed] exclusively on the government-contractor relationship." *D'Amato*, 760 F.2d at 1479. The court found *further* support for its conclusion that the disabled were not intended beneficiaries in Section 503 and its implementing regulations, which established an administrative remedy for any "handicapped individual [who] believe[d] any contractor has failed . . . to comply" with the affirmative action provisions and emphasized the resolution of disputes "by informal means, including conciliation[ ] and persuasion." *See id.* at 1477 n.1, 1481-82 (citing 29 U.S.C. § 793(b) and 41 C.F.R. § 60-741.28(a) (1984)).

We perceive four material differences between the contract and statute in *D'Amato* and those here. First, as discussed above, the PPA sets forth the contracting parties' clear intent to directly benefit the covered entities. *Cf. id.* at 1479-80. Second, § 256b says nothing about the covered entities' remedies, whether judicial or administrative. *Cf. id.* at 1481 ("The statutory grant of *one* remedy . . . without mention of any other . . . implies that Congress intended to bar *other* remedies.") (emphasis added). Third, allowing covered entities to bring suit as third party beneficiaries would not conflict with the PPA's informal dispute resolution process, given that the entities themselves are unable to initiate that process.[11] Last, the voluntary administrative dispute resolution procedure created by DHHS's regulations expressly leaves open resort to "other remedies which may be available under applicable principles of law." *See* 61 Fed. Reg. at 65,412; *see also id.* at 65,411 ("[Covered] entities are only encouraged to participate in the

[11]*Cf. FMC Corp.*, 531 F.3d at 823 (declining to recognize intended beneficiary status because that would "grant a broader range of dispute-resolving rights to [third parties] than to the [contracting] parties," who were required to exhaust the contract's "prescribed dispute resolution mechanisms" before bringing suit). By contrast, the PPA provides that its informal dispute resolution process will not "preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law." *See* PPA § IV(e).

process before seeking other remedies."). In sum, neither the PPA nor § 256b establishes an exclusive "elaborate administrative procedure," *D'Amato*, 760 F.2d at 1482, that — were such a procedure to exist — would signal the parties' intent to deny covered entities the right to enforce the PPA through litigation as intended beneficiaries.

The Manufacturers' remaining arguments against the covered entities' intended beneficiary status are no more convincing. First, they contend it is "illogical" that the United States and the Manufacturers would have intended to expose themselves to suit by the large number of covered entities, about 13,000 reported as of this writing.[12] The breadth and indefiniteness of a class of beneficiaries is entitled to some weight in negating the inference of intended beneficiary status. *See Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987) (commenting that parties would not likely have intended that "almost every lower-income person in the United States" could enforce the contract). But numbers alone are not determinative. For example, in *Hook v. State of Ariz., Dep't of Corr.*, 972 F.2d 1012, 1014-15 (9th Cir. 1992), we recognized all inmates of the Arizona prison system as intended beneficiaries of a consent decree regulating mail policies. Similarly in this case, covered entities constitute a narrow, well-defined class, not at all akin to members of the public at large. *See* § 256b(a)(4) (defining "covered entity"); PPA § III(a) (making available list of eligible covered entities), § IV(b) (procedure for challenging eligibility of covered entities).

We are also unmoved by the Manufacturers' protest that they "surely would not have agreed to subject themselves to a large number of lawsuits that could undermine the confidentiality" of pricing data through discovery, given the PPA's inclusion of a confidentiality provision.[13] The confidentiality

[12]*See* Department of Health and Human Services, Office of Pharmacy Affairs, *Growth of 340B Covered Entity Sites From 01/1998 to Present*, http://opanet.hrsa.gov/opa/Report/StatisticalReport.aspx.

[13]This argument is problematic for another, more pragmatic reason, which is that the PPA was not a conventionally negotiated contract. Pre-

provision itself, however, contemplates that such information could well be subject to disclosure for purposes of enforcing the PPA's discount pricing requirements beyond any actions the Secretary might initiate. Section V(a) specifies that information disclosed to the Secretary by the Manufacturers, "*except as otherwise required by law*, will not be disclosed *by the Secretary or his designee* in a form which reveals the Manufacturer, except as necessary to carry out the provisions of [§ 256b] and to permit review by the [OIG]." (Emphasis added.) As the italicized phrases highlight, 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. To the extent a drug company would rightly be concerned about sensitive pricing information, district courts routinely enter protective orders to prevent the undue disclosure of commercially sensitive information. *See* Fed. R. Civ. P. 26(c); *Phillips ex rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206, 1210-12 (9th Cir. 2002). Thus we are unwilling to read the PPA's confidentiality proviso as negating third party covered entities' right to enforce the discount pricing requirements themselves.

---

sumably, the Manufacturers would have preferred not to give covered entities any discount at all, but they faced an overwhelmingly powerful incentive to accept the PPA. Eligibility for a number of substantial federal healthcare programs is conditioned on having an effective § 256b agreement with the Secretary. *See* § 1396r-8(a)(1), (a)(5)(A); *see generally Joint Explanatory Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211 (explaining that § 256b makes the "use of federal matching funds for payment for a covered outpatient drug [by State Medicaid programs] . . . contingent on . . . a manufacturer's entering into [ ] an agreement . . . under which the manufacturer agrees to provide rebates or discounts to" covered entities).

II.

Although we conclude that covered entities are intended beneficiaries of the PPA, and so would ordinarily be entitled to bring suit to enforce it, the Manufacturers urge that this is not the usual intended beneficiary case and that permitting third party enforcement of the PPA would conflict with Congress' intent in creating the Section 340B program.[14] In this vein, they point to Santa Clara's concession before the district court that there is no private federal cause of action under § 256b.[15] *See generally Alexander v. Sandoval*, 532 U.S. 275 (2001). Because Congress did not provide a *statutory* remedy, the Manufacturers argue, it necessarily did not intend to allow covered entities to make an "end-run" around the statutory scheme by pursuing *contractual* remedies under the federal common law.

[8] The starting point of this argument is the truism that federal common law, of which the federal common law of contracts forms a part, "is 'subject to the paramount authority of Congress.' " *City of Milwaukee v. Illinois & Michigan*, 451 U.S. 304, 313 (1981) (quoting *New Jersey v. New York*, 283 U.S. 336, 348 (1931)). We presume that Congress legislates with the expectation that the principles of the federal common law "will apply except 'when a statutory purpose to the contrary is evident.' " *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)). However, when Congress "speak[s] directly" to a question addressed by the federal common law, it may displace it even without

[14]Although this argument was raised for the first time in the Manufacturers' reply to Santa Clara's opposition to its motion to dismiss and the district court did not address it, we will pass on the merits here. The issue is one of law and has been fully briefed by both parties. *See Pocatello Educ. Ass'n v. Heideman*, 504 F.3d 1053, 1060 n.5 (9th Cir. 2007); *Bibeau v. Pac. Northwest Research Foundation Inc.*, 188 F.3d 1105, 1111 n.5 (9th Cir. 1999).

[15]Santa Clara has not pursued this matter on appeal, so we assume without deciding that § 256b does not create a private cause of action.

"affirmatively proscrib[ing]" its use. *United States v. Texas*, 507 U.S. 529, 534 (1993); *see also Gardiner v. Sea-Land Service, Inc.*, 786 F.2d 943, 947 (9th Cir. 1986). "In evaluating the displacement issue, courts must assess the scope of the legislation and whether the legislative scheme addresses the problem formerly governed by federal common law." *Gardiner*, 786 F.2d at 947.[16] The Manufacturers, relying almost exclusively on *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir. 2003), contend that § 256b does just that and, therefore, to allow covered entities to enforce the PPA as a matter of contract would be inconsistent with Congress' choice of remedies.

In *Grochowski*, the Second Circuit did not permit the plaintiffs to bring suit as third party beneficiaries of a contract between the contractor defendants and New York City's public housing authority. *See* 318 F.3d at 83. Under the Davis-Bacon Act, 40 U.S.C. § 3141, all construction contracts for federally funded projects must include the following provision: "[t]he Contractor shall pay to all laborers . . . not less than the wages prevailing in the locality of the Project, as predetermined by the Secretary of Labor of the United States." *Id.* (first alteration in original). Exercising his authority under 40 U.S.C. § 3145 to "prescribe reasonable regulations for contractors" subject to the Davis-Bacon Act, the Secretary of

[16]This is a different and less demanding inquiry than that used to evaluate whether a federal statute preempts a state-law cause of action, *see City of Milwaukee*, 451 U.S. at 316-17; *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), or whether a federal statute's comprehensive remedial scheme impliedly displaces a more general federal private cause of action such as 42 U.S.C. § 1983, *see Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 20-21 (1981); *Flores v. Arizona*, 516 F.3d 1140, 1174-75 (9th Cir. 2008). *See generally Resolution Trust Corp. v. Frates*, 52 F.3d 295, 296-97 (10th Cir. 1995) (explaining difference between preemption of state law and supersession of the federal common law). We conclude that § 256b does not abrogate the cause of action ordinarily provided by the federal common law of contracts; thus it does not preempt a state-law contract cause of action, if that indeed is how Santa Clara's claim should be characterized. *See supra* note 5.

Labor established an administrative remedial scheme. *See id.* at 85; *Chan v. City of New York*, 1 F.3d 96, 102 (2d Cir. 1993) (citing 29 C.F.R. §§ 1.8, 5.6(a)(3), 5.11). Given these administrative remedies, and the absence of an explicit private cause of action, *Grochowski* concluded that the "plaintiffs[']efforts to bring their claims as state common-law [contract] claims [were] clearly an impermissible 'end run' " around congressional intent as to the availability of remedies under the Davis-Bacon Act. 318 F.3d at 86.

[9] Assuming *Grochowski* was correctly decided, the case is clearly inapposite on its own terms.[17] Its analytical underpinning was the " 'elemental canon' of statutory construction that where a *statute expressly provides a remedy*, 'courts must be especially reluctant to provide *additional* remedies.' " *Id.* at 85 (quoting *Karahalios v. Nat'l Fed'n of Employees, Local 1263*, 489 U.S. 527, 533 (1989)) (emphasis added). Here, § 256b does not "expressly provide" any remedies to covered entities.[18] And unlike the Davis-Bacon Act, § 256b is silent about the agency's power to promulgate regulations against *manufacturers* with the force of law. *Cf.* § 256b(a)(5)(A)(ii) ("The Secretary shall establish a mechanism to ensure that *covered entities* comply . . . .") (emphasis added). Although the Secretary may terminate the PPA with a manufacturer for a violation of its provisions, this remedy is a matter of contract, not statute. *See* PPA § VI(c). Reflecting this paucity of statutory authority, DHHS's regulations

[17]Because the *Grochowski* plaintiffs' contract claims were based on state law, not federal law, it is puzzling that the majority did not frame its analysis in terms of whether Congress intended to preempt those claims. *See, e.g.*, *Grochowski*, 318 F.3d at 90-91 (Lynch, J. dissenting); *Cox v. NAP Constr. Co., Inc.*, 10 N.Y.3d 592, 603-07 (N.Y. 2008).

[18]Section 256b does provide a number of remedies *against* covered entities. *See, e.g.*, § 256b(a)(5)(C) ("A covered entity shall permit the Secretary and [manufacturers] . . . to audit . . . records of the entity that directly pertain to the entity's compliance" with the program.); (a)(5)(D) ("If the Secretary finds . . . that a covered entity is in violation . . . the covered entity shall be liable . . . .").

establish only an informal, nonexclusive dispute resolution process, in which neither covered entities nor manufacturers are required to participate. *See* 61 Fed. Reg. at 65,411. Nothing in the statute suggests that Congress intended that DHHS create a substitute, administrative remedial scheme for covered entities to invoke against manufacturers. Thus, there is nothing "additional" about the federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the PPA. *Cf. Golt v. United States*, 186 F.3d 1158, 1164 (9th Cir. 1999) (holding that Civil Service Reform Act, which expressly created exclusive administrative remedy, abrogated remedies under federal common law).

[10] Permitting covered entities to sue as intended beneficiaries of the PPA is therefore wholly compatible with the Section 340B program's objectives. *Cf. Trimble Navigation*, 484 F.3d at 707 ("[R]ecognition of third-party beneficiary status in a contract made under a statutory scheme must accord with that scheme . . . ."); Restatement (Second) of Contracts § 313(1) (1981) (limiting application of third party beneficiary doctrine when it "would contravene the policy of the law authorizing the contract or prescribing remedies for its breach"). As we have explained, the Section 340B program was created to give covered entities discounts so they could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Federal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide those discounts. *See Price*, 823 F.2d at 1121 (observing that it "seemed more sensible" to permit third parties to sue as intended beneficiaries than to "place the entire burden of enforcement" on the government).

III.

[11] Finally, we hold that the doctrine of primary jurisdiction does not require that Santa Clara's contract claim be

stayed or dismissed without prejudice pending its referral to the Secretary for agency resolution. The doctrine of primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). "[P]rimary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* (quoting *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002)). The doctrine does not require that all claims touching on an agency's expertise first be decided by the agency, however. *See id.* "The particular agency deferred to must be one that Congress has vested with the authority to regulate an industry or activity such that it would be inconsistent with the statutory scheme to deny the agency's power to resolve the issues in question." *United States v. Culliton*, 328 F.3d 1074, 1082 (9th Cir. 2003) (internal quotation marks omitted). To determine whether primary jurisdiction should be applied, we have "employed such factors as (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781.

[12] In our view, there is nothing "particularly complicated" about Santa Clara's contract claim on the merits.[19] Santa Clara alleges that the Manufacturers did not comply with their

[19]Although the issue of whether covered entities are entitled to sue as third party beneficiaries of the PPA is by no means straightforward, DHHS's regulatory authority does not extend to the federal common law of contracts, so we have no occasion to defer to the agency's expertise in deciding this appeal.

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.[20] 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).[21] 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.

[20]We do not decide whether the PPA's "reporting" limitation is consistent with § 256b(a)(1)'s requirements for pharmaceutical purchasing agreements.

[21]The relationship between states and manufacturers under the Medicaid State Rebate Agreement is roughly analogous to that between covered entities and manufacturers under the PPA. Neither party requested that the district court or we seek the views of the Secretary of Health and Human Services as amicus curiae.

CONCLUSION

As intended direct beneficiaries of the PPA, covered entities may enforce the Manufacturers' ceiling price obligations under the federal common law of contracts. Although the statute mandating the PPA does not create a federal private cause of action, allowing Santa Clara's contract claim to go forward is consistent with Congress' intent in enacting the legislative scheme. Because it lies within the conventional competence of the courts, that claim is not within the primary jurisdiction of DHHS.

REVERSED and REMANDED.