No. 10-844

IN THE

Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD. AND SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Petitioners,

v.

NOVO NORDISK A/S AND NOVO NORDISK INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENTS

JOSH A. KREVITT
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, N.Y. 10166
(212) 351-4000

MARK A. PERRY
Counsel of Record
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
mperry@gibsondunn.com

WAYNE BARSKY
GIBSON, DUNN & CRUTCHER LLP
2029 Century Park East
Los Angeles, CA 90067
(310) 552-8500

MICHAEL A. SITZMAN
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street
San Francisco, CA 94105
(415) 393-8200

Counsel for Respondents

RULE 29.6 STATEMENT

The disclosures in the brief in opposition remain accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

SUPPLEMENTAL BRIEF FOR RESPONDENTS

Contrary to the recommendation of the Acting Solicitor General, the petition should be denied.

I. THE FEDERAL CIRCUIT CORRECTLY CONSTRUED THE HATCH-WAXMAN COUNTERCLAIM

If a patent listed in the Orange Book "does not claim … an approved method of using the drug," the patentee may be ordered "to correct or delete the patent information submitted … under subsection (b) or (c) of this section." 21 U.S.C. § 355(j)(5)(C)(ii). The court of appeals construed this language to mean that the counterclaim is available only if the listed patent does not claim *any* approved method of use, and to allow correction only of *statutory* patent information (*i.e.*, the patent number and expiration date). Pet. App. 11a-17a.

The government assigns three errors to the court of appeals' statutory construction. *See* U.S. Br. 11-17. It is trebly wrong.

1. To invoke the counterclaim, petitioners had to show that the '358 patent "does *not* claim … an approved method of using [repaglinide]," yet they conceded below that the patent "*does* claim an approved method of use." C.A. Stay Opp. 13. In the face of that concession, the government's contention that petitioners "properly invoked the counterclaim" (U.S. Br. 12-13) is remarkable.

The government inverts the statutory language, arguing that a challenger can show that the patent "does not claim … an approved method" by "identify[ing] an approved method of using the drug … that the relevant patent does not claim." U.S. Br. 12.

This inversion, however, requires substituting a definite article for the indefinite article that Congress actually used, as the government admits. *See id.* at 13 ("the '358 patent does not claim *the use* of repaglinide as monotherapy, which is 'an approved method'") (emphasis added). But courts have no license to rewrite statutes in this fashion.

The words actually enacted by Congress mean that the counterclaim is available only if the listed patent does not claim *any* approved method of using the drug, as the court of appeals recognized. Pet. App. 12a ("When an indefinite article is preceded and qualified by a negative, standard grammar generally provides that [it] means 'any'"). That is because the construction "not … an" equates to "none." American Heritage Dictionary of the English Language 1 (4th ed. 2006) ("not a drop to drink"); *see Barnhart* v. *Thomas*, 540 U.S. 20, 26 (2003) (adopting grammatically sensible construction).

The government *concedes* that the majority's construction is a "textually plausible interpretation[]." U.S. Br. 13. That concession alone justifies denial of the petition: In the acknowledged absence of any circuit conflict, a "textually plausible" decision in a pure statutory construction case hardly "so far depart[s]" from the accepted course of judicial proceedings as to warrant an exercise of this Court's supervisory authority. S. Ct. R. 10(a).

The government, however, maintains that the alternative construction offered by Judge Dyk, dissenting below, is also "plausible." U.S. Br. 13. But it isn't: Just like the government's inversionary reading, Judge Dyk's proposal would require substituting the definite article for the indefinite. Pet. App. 42a ("'an' refers to a particular method of using the drug, that is, *the particular approved method* listed by the

NDA holder") (emphasis added). Indeed, Judge Dyk *admitted* that his alternative would necessitate inserting a word into the statute: "[T]he statute must be construed to read …. 'an [associated] approved method of using the drug.'" *Id.* at 42a-43a (bracketed word added by Judge Dyk). Adding a term to a statute "from which it is conspicuously absent more closely resembles invent[ing] a statute rather than interpret[ing] one." *Hardt* v. *Reliance Standard Life Ins. Co.*, 130 S. Ct. 2149, 2156 (2010) (internal quotation marks omitted).

Moreover, the government makes no effort to demonstrate that Judge Dyk's reading is *more* plausible than the majority's construction. Instead, the government argues that it is "more *flexible*" and, therefore, "superior." U.S. Br. 13 (emphasis added). This Court, however, has never adopted a canon of construction favoring "flexibility" (whatever that might mean); rather, when faced with competing alternatives, the Court chooses the one that best fits the statutory text, structure, and purpose. *Bhd. of Locomotive Eng'rs* v. *Atchison, Topeka & Santa Fe R.R.*, 516 U.S. 152, 162 (1996); *cf.* U.S. Br. in *Apotex, Inc.* v. *Sebelius*, No. 10-453 (Dec. 2010) ("The court of appeals was wrong to rely on its perception of the [Hatch-Waxman] statute's 'incentive structure' to displace the statutory text"). As the government implicitly concedes, when measured against *those* metrics the majority's construction is far superior.

2. The counterclaim authorizes the correction only of "the patent information submitted … under [21 U.S.C. §] 355(b) or (c)." The government concedes that "the only patent information that Sections 355(b) and (c) *require* to be submitted is the patent number and expiration date." U.S. Br. 14; *see Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294,

1296-97 (11th Cir. 2003). The majority's conclusion that the counterclaim is limited to that information (Pet. App. 14a-17a) surely is not the kind of out-of-step decision that merits this Court's intervention.

The government maintains, however, that "*everything* FDA requires NDA holders to submit in the course of seeking and maintaining approval of an NDA" is patent information "submitted … under" Sections 355(b) or (c). U.S. Br. 14-15 (emphasis added). But the wide variety of data about patented drugs and methods collected by FDA (*see* C.A. App. A918-921), including use code narratives, are "submitted under" FDA's regulation (21 C.F.R. § 314.53)—which may be changed after notice and comment at any time—*not* Section 355(b) or (c). The government's simplistic observation that these data constitute "'information' … about a 'patent'" (U.S. Br. 13) ignores the statutory context, which makes the counterclaim applicable only to *specific* "patent information"—that is, information "submitted under" (and thus specified in) Section 355(b) or (c). *Cf. FCC* v. *AT&T, Inc.*, 131 S. Ct. 1177, 1183-84 (2011) ("two words together may assume a more particular meaning than those words in isolation").

The government tries to elide the "submitted under" clause with *Ardestani* v. *INS*, 502 U.S. 129 (1991)—the only judicial decision cited in its entire brief. U.S. Br. 14. *Ardestani*, however, recognized that "[t]he word 'under' has many dictionary definitions and must draw its meaning from its context." 502 U.S. at 135. The statute here refers to "the patent information *submitted* … under" Section 355(b) or (c). The statute in *Ardestani* did not include the word "submitted," and adoption of the *Ardestani* formulation here (as the government suggests) would impermissibly read this word out of the statute. *See*

Astoria Fed. Sav. & Loan Ass'n v. *Solimino*, 501 U.S. 104, 112 (1991).

It is telling that the government does not agree with petitioners that FDA's information-gathering regulation was promulgated under Section 355(b) or (c), such that data submitted under the regulation are indirectly submitted under those statutory subdivisions. *See* Pet. 35. Indeed, the government expressly disavows petitioners' erroneous argument that the decision below "invalidates" any FDA regulation. U.S. Br. 15 n.2. That is because FDA's regulation is *not* an interpretation of "patent information" in Section 355(b) or (c), but rather was adopted pursuant to its general rulemaking authority. *See* BIO 27-28. The Justice Department is not shy about making administrative deference arguments where appropriate; that none appears in the instant brief is a concession that there is no deference issue in this case.

3. The government complains that the decision below "hinders the effectuation of Congress's purpose in enacting the counterclaim provision." U.S. Br. 15. Of course, "vague notions of a statute's 'basic purpose' are … inadequate to overcome the words of its text regarding the *specific* issue under consideration." *Mertens* v. *Hewitt Assocs.*, 508 U.S. 248, 261 (1993). In any event, the government badly misrepresents the purpose of the counterclaim.

The counterclaim was a congressional response to *Mylan Pharms., Inc.* v. *Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), which held that a generic competitor could not assert, in an infringement action, that a patent was improperly listed in the Orange Book because it did not claim *any* approved drug or method of use. Pet. App. 13a. As construed by the majority, the counterclaim is available to any entity that finds

itself in the same position as Mylan was in *Mylan*. The congressional "purpose" is fully "effectuated."

Without mentioning *Mylan*, the government asserts that "Congress enacted the counterclaim provision … to combat *precisely* [the] sort of manipulation" alleged by petitioners here—*i.e.*, a patentee's submission of "an overbroad description of its method-of-use patent to FDA." U.S. Br. 11 (emphasis added). This proposition has no basis in history (or reality), since—unlike in *Mylan*—"the '358 patent was appropriately listed in the Orange Book." U.S. Br. 19. Congress never contemplated such a case when it enacted the counterclaim; the decision below cannot frustrate a nonexistent congressional "purpose."

Contrary to the government's implication (U.S. Br. 16), Senator Schumer's references to "enforc[ing] the patent listing requirements" simply refer to the *Mylan* situation in which a patent was improperly listed. *Nothing* in the legislative history so much as adverts to use code narratives, much less suggests that the counterclaim was intended to reach them. And in any event, this Court interprets statutes using the language actually enacted by Congress and signed by the President, not by isolated statements from individual legislators. *See*, *e.g.*, *Barnhart* v. *Sigmon Coal Co.*, 534 U.S. 438, 457 & n.15 (2002).

The government complains that "[t]he practical effect of the court of appeals' decision … is to preclude judicial enforcement of FDA's directive that NDA holders accurately describe their method-of-use patents." U.S. Br. 16. FDA, however, has ample authority to enforce its own "directives" and, absent express congressional authorization, the accuracy of FDA submissions may not be challenged in private litigation. 21 U.S.C. § 337(a); *see Buckman Co.* v.

Plaintiffs' Legal Comm., 531 U.S. 341, 348-51 (2001). FDA has established an administrative review mechanism to allow generic competitors to challenge use code narratives and other patent listing issues. 21 C.F.R. § 314.53(f). Petitioners availed themselves of that procedure, but were unsuccessful. *See* BIO 31-32. To the extent petitioners disagree with FDA's administration of that (or any other) aspect of the Orange Book regime, their avenue for judicial review was not the counterclaim, but an Administrative Procedure Act challenge. *See Andrx Pharms., Inc.* v. *Biovail Corp.*, 276 F.3d 1368, 1378-79 (Fed. Cir. 2002). Yet petitioners never filed an APA suit.

Finally, the government argues that "[t]he Federal Circuit's decision prevents the courts from performing their traditional function of resolving disputes about the scope of patent rights." U.S. Br. 17. But the use code narrative—limited by FDA to 240 characters—does not define patent rights; rather, it provides *notice* that a particular drug or method implicates a patent. 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) ("Use codes are intended to alert ANDA … applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling."). The "scope of patent rights" is defined and conferred *by the patent itself*; the federal courts, when properly invested with jurisdiction, remain fully available to adjudicate those rights. Pet. App. 14a. And Novo did identify the specific patent claim in the appropriate location on the FDA form (C.A. App. A672) ("[Box] 4.2 Patent Claim Number(s) *(as listed in the patent)*[:] Claim 4")—a fact to which neither petitioners nor the government responds.

The government apparently thinks it would be a *good idea* to allow generic competitors to more broad-

ly challenge use code narratives. *See* Pet. App. 21a (Clevenger, J., concurring). Regardless of the correctness of that contention as a matter of policy, it is plainly insufficient as a matter of law. The decision whether or not to extend the counterclaim beyond its terms is for Congress, not this Court. *Microsoft Corp.* v. *AT&T Corp.*, 550 U.S. 437, 457 (2007).

II. THIS IS AN INAPPROPRIATE VEHICLE IN WHICH TO REVIEW THE SCOPE OF THE HATCH-WAXMAN COUNTERCLAIM

The government does not dispute that this is the first appellate decision to construe the Hatch-Waxman counterclaim since it was enacted in 2003. And despite implying that "billions of dollars" could be at stake (U.S. Br. 19), the government cannot identify even *one* listed patent that could give rise to a lawsuit like this one. *See* BIO 12-13. FDA receives only a very few section viii carve-out applications each year, and the government identifies none that FDA denied because of an allegedly overbroad use code. For all that we (or the government) know, this case truly is unique. *See* U.S. Br. in *SMC Corp.* v. *Norgren, Inc.*, No. 09-412 (Dec. 2009) ("This case would be a poor vehicle to address the question presented, … because the court of appeals' decision is unique to the facts of this particular case").

Moreover, the government admits that the use code issue could "be of no continuing importance" depending on how the Federal Circuit resolves the pending appeal on the merits. U.S. Br. 21. The government traditionally takes the position that "[t]he interlocutory posture of [a] case makes it unsuitable for review." U.S. Br. in *PLIVA, Inc.* v. *Mensing*, Nos. 09-993, 09-1039 (Nov. 2010). The government offers

no reason that this interlocutory petition should be treated differently.

Nor does the government explain its indifference to the jurisdictional impediment that would likely preclude this Court from ever reaching the counterclaim itself. As the government is forced to acknowledge, petitioners do not have a "Paragraph IV" certification with respect to the patent claim at issue. *See* U.S. Br. 7 n.1. A Paragraph IV certification is a jurisdictional predicate to *both* an infringement suit *and* the Hatch-Waxman counterclaim. Although the government maintains that "nothing in the Hatch-Waxman Amendments states that the counterclaim becomes unavailable simply because post-filing events render the initial infringement suit non-justiciable" (U.S. Br. 22), petitioners have not had a Paragraph IV certification since April 2008, *before* the counterclaim was filed. Moreover, Congress included a separate clause—not mentioned by the government—which expressly precludes similar challenges "in any civil action or proceeding other than a counterclaim [to a Paragraph IV infringement action]." 21 U.S.C. § 355(j)(5)(C)(ii)(II). If the dispute is "non-justiciable," which the government allows is a possibility, then it is non-justiciable *in toto*. The counterclaim can't be carved off.

In any event, the government does not deny that the Court would have to *decide* the jurisdictional issue—which has not yet been reviewed by the Federal Circuit—before reaching the merits of the use code dispute. *Steel Co.* v. *Citizens for a Better Env't*, 523 U.S. 83, 88-89 (1998). But this Court would undoubtedly benefit from that court's views before considering the intricacies of Hatch-Waxman jurisdiction, which is at the outer limits of Article III. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678

(1990); *see also* U.S. Br. in *DBC* v. *PTO*, No. 08-1284 (June 2009) ("those questions were not addressed by the court of appeals, which is reason enough for this Court to decline to decide them in the first instance").

Finally, the government suggests, without elaboration, that it might not always be appropriate to base a use code narrative on the approved drug indication. U.S. Br. 20. The pertinent portion of FDA's regulation (not cited by the government), however, makes clear that the patentee may include "a description of each approved method of use *or indication*" (21 C.F.R. § 314.53(c)(2)(ii)(P)(1)), and FDA's form similarly instructs patentees to include "the description of the *approved indication* or method of use that you propose FDA include as the 'Use Code' in the Orange Book" (Pet. App. 213a) (emphases added). A great many use code narratives—including many written by FDA itself, which performed this function for years—are based on approved indications. *See*, *e.g.*, U-412 ("Treatment of type 2 diabetes"); U-978 ("Method of treating hyponatremia"); U-982 ("A method of treating osteoporosis") (C.A. App. A881; A912). These use codes, like Novo's, fully comply with all current FDA guidance, as well as Hatch-Waxman's legislative history, which similarly focused on indications. *See* H.R. Rep. No. 98-857, pt. 1, at 21 (1984).

The counterclaim, even if available, does not authorize a court to order an NDA holder to change an accurate use code narrative. *See* BIO 30-31. As Judge Clevenger pointed out, "Novo did nothing that was illegal or forbidden" and "there is nothing illegal, or even incorrect, about Novo's current use code." Pet. App. 19a, 21a. The government doesn't disagree with this assessment, arguing instead that "[t]he

Court can decide [whether the counterclaim is available] without determining whether respondents' own use code was deficient." U.S. Br. 20. But where the decision below "would be subject to affirmance on alternative grounds[,]" the government generally takes the position that "[f]urther review is especially unwarranted." U.S. Br. in *Golan* v. *Holder*, No. 10-545 (Jan. 2011). So, too, here.

In light of all the vehicular problems, it is ironic that the government should assert that "the Court can be confident of reaching the question presented." U.S. Br. 19. And it is doubly ironic when the government asserts that certiorari is warranted because "a judicial order directing respondents to 'correct' their use code would have tangible benefits for petitioners" (*ibid.*): In fact, petitioners' plants and goods have been seized by federal agents for failure to comply with safe manufacturing policies, and petitioners do not currently have FDA approval to manufacture *any* pharmaceuticals. Caraco Form 10-Q for Quarter Ended June 30, 2010, at 17.

Ignoring the usual certiorari considerations—unique circumstances, interlocutory posture, jurisdictional impediment not yet addressed by a court of appeals, alternative grounds for affirmance, and the correctness of the decision below—the government urges review to encourage "generic competition." U.S. Br. 11. While that might be politically expedient, there is no reason in substantive law or appellate procedure to rush the use code issue to early resolution, as the Acting Solicitor General proposes.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

MARK A. PERRY
Counsel of Record
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
mperry@gibsondunn.com

JOSH A. KREVITT
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, N.Y. 10166
(212) 351-4000

WAYNE BARSKY
GIBSON, DUNN & CRUTCHER LLP
2029 Century Park East
Los Angeles, CA 90067
(310) 552-8500

MICHAEL A. SITZMAN
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street
San Francisco, CA 94105
(415) 393-8200

June 3, 2011