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 WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[1] *See* PhRMA, "About PhRMA," *available at* http://www.phrma.org/about/about-phrma; PhRMA, "PhRMA Member Companies," *available at* http://www.phrma.org/about/member-companies. Pharmaceutical and biotechnology companies are the primary source of new drugs and biologics. These new medicines are estimated to account for 40 percent of the increase in human lifespan between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity* 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003).

Developing new medicines takes years of work and billions of dollars of investment in research and development. PhRMA members make these investments in reliance on a legal regime that protects any resulting intellectual property. A critical component of this legal regime is the right to market new drugs approved by the Food and Drug

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[1] Pursuant to this Court's Rule 37.6, *amicus curiae* affirms that no counsel for any party authored this brief in whole or in part, that no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than amicus or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. *Amicus curiae* notes that Respondent Novo Nordisk Inc. is a member of PhRMA. The parties have consented in writing to the filing of this brief.

Administration ("FDA") for a defined period without copycat marketing by generic drug companies. This legal protection provides an incentive for innovator companies to invest in research and development of new pharmaceutical products.

PhRMA's members have a strong interest in preserving the carefully crafted regime for FDA approval of drugs. They also have an interest in the predictability and stability of the laws that protect new drugs from premature copying, and in the legal framework designed to permit prompt and orderly resolution of patent disputes. This complex balance should be maintained, particularly in a case where congressional intent is clear.

BACKGROUND

1. Throughout the history of the United States, the federal government has recognized the importance of intellectual property rights as a means of encouraging innovation. The Constitution provides that Congress has power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. Art. I, § 8, cl. 8. Congress has exercised that power by enacting the Patent Act, 35 U.S.C. § 1 *et seq*., which has recently been amended by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

Patents are especially critical for the development of new pharmaceutical products. Pharmaceutical research is extremely expensive. Creating a new medicine takes, on average, over a billion dollars. *See PAREXEL Biopharmaceutical*

R&D Statistical Sourcebook 2011/2012, at 163 (Mark P. Mathieu ed., 2011); Joseph A. DiMasi and Henry G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," 28 *Managerial and Decision Economics* 469 (2007). The Congressional Budget Office has determined that "pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm." Congressional Budget Office, Pub. No. 2589, *Research and Development in the Pharmaceutical Industry* 9 (Oct. 2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf; *see also* Nam D. Pham, ndp consulting, *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports* 13 (April 2010) (pharmaceutical and medicine industry has average annual research and development expenditure per employee that is more than ten times larger than the average among industries studied). In 2010, PhRMA members invested an estimated $49.4 billion in discovering and developing new medicines. Industry-wide, research and development in 2010 was about $68 billion. *See* PhRMA, *2011 Profile: Pharmaceutical Industry*, at 11 (2011), *available at* http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf

In addition to being extraordinarily expensive, pharmaceutical research involves a high risk of failure. "The attrition rate from stage to stage is unusually high. It is estimated that as many as 10,000 compounds are synthesized for every ten that reach the stage of human testing. Of these ten

compounds, only one eventually reaches the market." Bert Spilker, *Guide to Drug Development: A Comprehensive Review and Assessment* 21 (2009); *see also PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2011/2012*, at 259 (citing failure rate of 81% to 89% for drugs from first-in-man studies to approval). Only a fraction of new drugs are expected to recoup their research and development costs. Henry Grabowski, John Vernon, & Joseph A. DiMasi, "Returns on Research and Development for 1990s New Drug Introductions," 20 *Pharmacoeconomics* supp. 3, 11, at 22-23 (2002).

2. Congress recognized the importance of patents to the field of pharmaceutical research in crafting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. The Hatch-Waxman Act sought to restore some of the patent term that is lost as a result of FDA's sometimes-lengthy drug approval process. At the same time, Congress sought to prevent patent terms from casting too long a shadow on the efforts of other companies to study and eventually replicate the patented product. The Hatch-Waxman Act "sought to eliminate this distortion from both ends of the patent period." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

The Hatch-Waxman Act enables generic "drugs to be marketed more cheaply and quickly" and at the same time maintains incentives for innovation by, among other things, "guard[ing] against infringement of patents relating to pioneer drugs." *Id.* at 676-77. The process Congress created seeks to ensure that disputes between drug pioneers

and generic companies are resolved as early as possible. For example, the Act deems certain filings with FDA to be acts of patent infringement, so that litigation regarding the parties' patent rights can be initiated and resolved promptly. *See id.* at 677-78.

Title I of the Hatch-Waxman Act established a series of steps that ultimately leads, in appropriate cases, to approval of a generic drug.

i. The innovating company files a New Drug Application ("NDA") with FDA. 21 U.S.C. § 355(b)(1). The NDA holder is required to

> file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

Id.

ii. A generic company wishing to market a generic version of an approved drug may file an Abbreviated New Drug Application ("ANDA"), 21 U.S.C. § 355(j)(1), relying on the fact that the Reference Listed Drug ("RLD"), *i.e.* the drug that the ANDA applicant seeks to copy, was found safe and effective by FDA, *id.* at § 355(j)(2)(A)(i).[2] An ANDA

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[2] A generic company may also submit a section 505(b)(2) application for drug approval under certain circumstances. *See* 21 U.S.C. § 355(b)(2).

must contain one of four certifications as to the patent information identified by the NDA holder stating, in substance, that:

(I) no patent information has been filed,

(II) the patent has expired,

(III) the patent will expire on some stated later date; or

(IV) the patent is invalid or would not be infringed by the generic drug seeking approval.

See 21 U.S.C. § 355(j)(2)(A)(vii).

iii. If a generic company submits a "paragraph IV" certification with its ANDA, it must provide notice to the patent holder and the NDA holder. 21 U.S.C. § 355(j)(2)(B). This notice includes a detailed statement of the factual and legal basis for the generic company's position that the patent is invalid or would not be infringed. 21 U.S.C. § 355(j)(2)(B)(iv).

iv. Pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), if a method-of-use patent is listed with respect to the RLD and the claimed method is not one for which an ANDA applicant is seeking approval, the ANDA applicant may submit a statement that the ANDA does not seek approval for the claimed method. This statement is referred to as a "section viii statement." If an ANDA applicant submits a section viii statement, it is required to carve out those portions of the RLD's labeling that encompass the claimed method. FDA has taken the position that, if a section viii statement is submitted with respect to an approved use claimed by a method-of-use patent, the ANDA applicant is not required to submit a

paragraph IV certification with respect to that patent. *See, e.g.,* FDA, *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed*, 68 Fed. Reg. 36676, 36682 (June 18, 2003) (final rule) [hereinafter "Orange Book Rule"].

v. Pursuant to 35 U.S.C. § 271(e)(2), it is an act of patent infringement to submit an ANDA application "for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain [FDA approval] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." An ANDA submitted with a paragraph IV certification thus provides a basis for a patent infringement lawsuit. This provision allows for early resolution of patent disputes before a generic drug goes to market. In certain circumstances, commencement of a patent infringement lawsuit pursuant to a paragraph IV certification imposes a 30-month stay on FDA's ability to approve the ANDA. *See* 21 U.S.C. § 355(j)(5).

FDA has issued a series of regulations, forms, and other guidance to implement the complex interaction between intellectual property rights, public health and safety, and market competition established by the Hatch-Waxman regime.

In particular, FDA publishes patent information after approval of an NDA in a compendium titled "Approved Drug Products With

Therapeutic Equivalence Evaluations," popularly known as the "Orange Book." *See* Orange Book Rule, 68 Fed. Reg. at 36676. In addition, FDA has established rules for types of patents that can be listed in the Orange Book. *See* 21 C.F.R. § 314.53 ("Orange Book listing rules").

3. In 2003, Congress amended the Hatch-Waxman regime by, in relevant part, adding a provision that provides a generic drug company in patent litigation with a pioneer company limited rights to assert a counterclaim challenging the Orange Book's listing of patents. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I), *added by* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("Hatch-Waxman Amendments"). The counterclaim statute provides:

> If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either–
>
> > (aa) the drug for which the application was approved; or
> >
> > (bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I).

FDA's Orange Book listing rules specify, among other things, that "[f]or patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved application." 21 C.F.R. § 314.53(b)(1). These rules also note that the following information is required:

> (P) Information on each method-of-use patent including the following:
>
> > (1) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;
> >
> > (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and
> >
> > (3) The description of the patented method of use as required for publication.

21 C.F.R. § 314.53(c)(2)(ii)(P).

The Orange Book listing rules further specify that a patent is submitted for listing in the Orange Book by submitting a form, FDA Form 3542. *See* 21 C.F.R. § 314.53(c)(1); FDA Form 3542, Patent Information Submitted Upon and After Approval of an NDA or Supplement, *available at* http://www.fda.gov/downloads/AboutFDA/Reports

ManualsForms/Forms/UCM048345.pdf [hereinafter "Form 3542"].

Form 3542 includes Question 4.2(b), which asks the applicant to "provide the information on the indication or method of use for the Orange Book 'Use Code' description." The form also provides the following directive for answering Question 4.2(b): "Submit the description of the approved indication or method of use that you propose FDA include as the 'Use Code' in the Orange Book, using no more than 240 total characters including spaces."

"Use codes" are neither required nor defined by the Hatch-Waxman Act; they are a creation of FDA. FDA instructs applicants that the "use code" may track *either* an approved indication *or* method of use. In its "Information and Instructions for Form 3542," FDA provides the following guidance on answering Question 4.2(b):

> The answer to this question will be what FDA uses to create a "use-code" for Orange Book publication. The use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist 505(b)(2) and ANDA applicants in determining whether a listed method of use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval. Use a maximum of 240 characters for each "use code."

Form 3542 at 4.

FDA takes the position that its role with respect to patents and Orange Book listings is "ministerial." *See, e.g.,* Orange Book Rule, 68 Fed. Reg. at 36683. It employs the use code system to decide whether to accept an ANDA with carved-out labeling and a section viii statement or to require the ANDA applicant to submit a paragraph IV certification. As noted by FDA, "[u]nless the ANDA applicant can show that it is carving out certain method-of-use labeling, a section viii statement is not a correct submission for the listed patent." *Id.* at 36682.

FDA has stated: "In determining whether an ANDA applicant can 'carve out' the method of use, rather than certify to the listed patent, [FDA] will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book." Orange Book Rule, 68 Fed. Reg. at 36682. Moreover, FDA has explained that "[u]se codes are intended to alert ANDA and 505(b)(2) 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." *Id.* at 36683.

SUMMARY OF ARGUMENT

The Hatch-Waxman counterclaim provision does not provide generic drug companies with a means of seeking judicial reformation of the use codes employed by pioneer companies in the Orange Book. Petitioners' argument to the contrary requires rewriting the statutory language, including the requirement that the patent not claim "an approved method of using the drug" and the limitation of relief

to an "order requiring the [NDA] holder to correct or delete the patent information."

1. The plain language of the counterclaim provision precludes Petitioners' interpretation. The provision can be invoked only "on the ground that the patent does not claim either . . . [1] the drug for which the application was approved; or [2] an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Petitioners rely on the second ground for invoking the counterclaim provision, but this ground is inapplicable because Respondents' patent claims "an approved method of using the drug." Moreover, the provision is limited to an order "requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c)." *Id.* "[P]atent information" includes only the patent number and expiration date. It does not include the use code, and thus revision of the use code is not a remedy available under the statute.

2. Because the plain language of the statute is clear, there is no need to consult the legislative history of the counterclaim provision. In any event, the legislative record shows that the provision was intended to provide a means of de-listing from the Orange Book patents that should not have been listed. The provision was a response to the Federal Circuit's ruling in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). There is no indication that Congress was concerned with overbroad use codes.

3. Petitioners have not established that they are unable to challenge an allegedly overbroad use code. Use codes are a creation of FDA. Accordingly,

Petitioners could have sought a remedy from FDA by, for example, using FDA's Citizen Petition process to ask FDA to engage in notice-and-comment rulemaking to adjust its guidance on use codes or to create a more robust process for interested parties to obtain revisions to use codes. Petitioners could also have requested that FDA change its required labeling for the drug at issue, thereby affecting the choices available to Respondents with respect to the use code. If Petitioners were not satisfied with the FDA's action, they could have brought a judicial challenge under the Administrative Procedure Act. At bottom, Petitioners' complaint is properly directed to FDA; any remedy must involve that agency, not judicial re-writing of use codes.

ARGUMENT

I. The Plain Language Of The Counterclaim Provision Precludes The District Court's Effort To Re-Write The Use Code For Prandin.

This case arises from Petitioner Caraco's effort to market a generic version of PRANDIN® (containing the active ingredient repaglinide) ("Prandin"), a diabetes drug for which Respondent Novo Nordisk Inc. obtained approval pursuant to the filing of an NDA. Respondent Novo Nordisk Inc. submitted U.S. Patent No. 6,677,358 ("the '358 patent), which is assigned to Novo Nordisk A/S, to FDA for publication (*i.e.*, listing) in the Orange Book. As the court of appeals explained, the listing originally included the use code "U-546–use of repaglinide in combination with metformin to lower blood glucose" for this patent. Pet. App. 8a. Respondents later changed the use code for Prandin

to "U-968–A method for improving glycemic control in adults with type 2 diabetes mellitus." *Id.* at 9a. Petitioners view this change, and FDA's subsequent actions based on this change, as improperly hindering their efforts to market a generic version of the drug. In litigation against Respondents, Petitioners invoked the counterclaim provision of the 2003 Amendments to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C)(ii)(I).

The district court agreed with Petitioners that the counterclaim provision provided a basis for injunctive relief, and ordered Respondents to revert to the original use code. Pet. App. 9a-10a. The Federal Circuit disagreed, finding this to be an improper use of the counterclaim provision. *Id.* at 2a-3a, 12a-17a. The Federal Circuit's decision is correct.

1. When Congress uses unambiguous statutory language, the courts' interpretive task is straightforward. As this Court has stated, "in interpreting a statute a court should always turn first to one, cardinal canon before all others. We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). "When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" *Id.* at 254 (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)).

By its terms, the counterclaim provision can be invoked only "on the ground that the patent does not claim either . . . [1] the drug for which the application was approved; or [2] an approved method

of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Petitioners rely only on the second ground. By its plain terms, however, the second basis for invoking the counterclaim provision is inapplicable, because Respondent Novo Nordisk A/S's patent claims "an approved method of using the drug."

Specifically, the patent at issue claims "[a] method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin." Claim 4, U.S. Patent No. 6,677,358; *see also* Pet. App. 8a. This method—use of repaglinide in combination with metformin—is one of the three FDA-approved uses for Prandin. Pet. App. 7a-8a. The other two approved uses are (a) repaglinide by itself and (b) repaglinide in combination with thiazolidinediones ("TZDs"). *Id.*; *see also* Prandin Approved Labeling (Clinical Trials and Dosage and Administration sections), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020741s038lbl.pdf.

Thus, there is no dispute that Respondents' patent claims "an approved method of using" Prandin. It follows from the plain language of the statute that the counterclaim provision, which addresses patents that have been listed in error, cannot be invoked by Petitioners.

This reading of the statutory language makes good sense and is consonant with FDA regulations. FDA's position is that "[f]or patents that claim a method of use, the applicant shall submit information *only* on those patents that claim indications or other conditions of use that are described in the pending or approved [new drug]

application." 21 C.F.R. § 314.53(b)(1) (emphasis added). Thus, if the patent claims an approved method of use, it should be listed in the Orange Book, so that generic companies are aware of the innovator company's patent and can decide whether and how to proceed and make appropriate certifications under the statute. The corollary to this is that, if a method-of-use patent does not claim an approved method of using a drug, it should not be listed in the Orange Book. The counterclaim provision thus serves a simple yet important purpose: ensuring that those patents that should be listed in the Orange Book are included, and that patents that should not be listed are not included.

In an effort to avoid this straightforward result, Petitioners present a strained interpretation of the statutory language, asserting that, because there are two other approved methods of using repaglinide (*i.e.*, Prandin by itself and Prandin in combination with TZDs), the patent "does not claim . . . an approved method of using the drug." In other words, Petitioners argue that even though Respondent's patent *does* claim an approved use of repaglinide (Prandin in combination with metformin), it somehow simultaneously *does not* claim an approved use, because there exist other approved uses not claimed by the patent. This makes no sense.

Aside from bending logic and normal English usage, Petitioners' interpretation leads to the remarkable conclusion that a patent must claim *all* potential methods for using the drug to be listed in the Orange Book. Under Petitioners' theory, a patent that claimed less than all approved uses

would "not claim . . . an approved method of using the drug," and a counter-claimant would be able to invoke the counterclaim provision. Because the "patent information" defined in the statute does not include the use code, *see infra* pp. 17-19, the only remedy available would be delisting of the patent. There is no reason to think that Congress intended such an unlikely result.

If Congress had meant to establish the regime Petitioners urge, "there were available such infinitely more clear and simple ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected." *Eli Lilly & Co.*, 496 U.S. at 667.

2. Even if the counterclaim provision could be invoked, its plain language precludes the injunctive relief Petitioners seek here. The statute provides that, in the case of a drug listed in error, the counterclaimant may "seek[] an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c)." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

The cross-referenced subsections expressly set forth what Congress meant by "patent information" subject to correction or deletion: "the patent number and the expiration date" of the relevant patent. *Id.* § 355(b)(1); *see also id.* § 355(c)(2) (same information for patents issued after filing of NDA). Subsection (c) addresses situations in which "*the patent information* described in subsection (b)" could not be filed at the same time as the NDA. *Id.* § 355(c)(2) (emphasis added). Language throughout the rest of subsections (b) and (c) reiterates that the patent number and expiration date are "the information"

submitted under these subsections. *See id.* § 355(b)(1), (c)(2).

Moreover, subsection (c) provides that "[u]pon the submission of *patent information* under this subsection, the Secretary shall publish it." *Id.* § 355(c)(2) (emphasis added). This language again makes clear that Congress required that the patent-holder submit the number and expiration date of its patent, and that FDA then publish this information in the Orange Book. *See also id.* § 355(b)(1) ("Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences").

In this case, no court has found that the "patent information," *id.* § 355(b)(1), (c)(2), (j)(5)(C)(ii)(I)—the patent number and expiration date—submitted by Respondents to FDA, and thereafter published by FDA in the Orange Book, is incorrect. Thus, there is no basis to invoke the remedy of "correct[ing] or delet[ing]" the patent information.

Petitioners and their *amici* attempt to inject ambiguity into the counterclaim provision by arguing that confining "patent information" to patent number and expiration date, as defined by the statute, *id.* § 355(b)(1), (c)(2), (j)(5)(C)(ii)(I), would render "correct[ion]" of patent information, *id.* § 355(j)(5)(C)(ii)(I)—as distinct from deletion of patent information—a nullity. Not so. The counterclaim allows for a patent that is listed in the Orange Book under the wrong number to be corrected. And it permits an erroneous expiration date, including one that overstates the duration of the patent, to be corrected. These corrections of

patent information are significant and work to the benefit of generic companies.

The counterclaim provision thus accomplishes important objectives. It prevents the listing in the Orange Book of patents that do not belong there, and it provides for the correction of important information concerning the patents that are listed there. These are material remedies that should not be minimized.

Nothing in the language of the Hatch-Waxman Act or the Hatch-Waxman Amendments supports the view that the "patent information" subject to correction under the counterclaim provision includes use codes. Subsections (b) and (c) do not require submission of use codes or refer to use codes at all. *See id.* § 355(b)(1), (c)(2). Indeed, the Hatch-Waxman Act and Hatch-Waxman Amendments nowhere discuss use codes, let alone define them. There is no textual indication that Congress was concerned with use codes or potential overreaching concerning such entries in the Orange Book. Use codes are thus outside the scope of the counterclaim's correction or deletion remedy.

3. As explained in Part III below, other avenues, apart from the counterclaim provision, were available to Petitioners if they wished to challenge FDA's use code regime. But even if that were not so, it would not justify departure from clear statutory language. As this Court stated recently,

> it is not our task to assess the consequences of each [interpretive] approach and adopt the one that produces the least mischief. Our charge is to give effect to the law Congress

> enacted. . . . If [a certain] effect was unintended, it is a problem for Congress, not one that federal courts can fix.

Lewis v. City of Chicago, 130 S. Ct. 2191, 2200 (2010); *see also Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 457 (2007) ("The 'loophole,' in our judgment, is properly left for Congress to consider, and to close if it finds such action warranted.").

II. The Legislative History Confirms That Congress Intended The Counterclaim Provision To Address Circumstances Not Present Here.

Because the plain language of the counterclaim provision precludes Petitioners' request for judicial re-writing of Prandin's use code, there is no occasion to consider the legislative history of the provision. *See Boyle v. United States*, 129 S. Ct. 2237, 2246 (2009) ("Because the statutory language is clear, there is no need to reach petitioner's remaining arguments based on statutory purpose, legislative history, or the rule of lenity."); *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994) ("[W]e do not resort to legislative history to cloud a statutory text that is clear."). But even if this Court were to consult the legislative history, it would not support the remedy Petitioners seek.

The legislative record makes clear that the counterclaim provision was intended to provide a means of de-listing from the Orange Book patents that should not have been listed. There are multiple references to the counterclaim provision as authorizing an ANDA applicant to "seek[] removal of a patent listed in the Orange Book," but no

suggestion that the provision had any greater reach. House Conf. Rep. 108-391, at 836 (Nov. 21, 2003), 108th Cong., 1st Sess.; House Debate on Conf. Rep. to accompany H.R. 1, 149 Cong. Rec. H12099 (daily ed. Nov. 20, 2003) (same).

In hearings before the Senate Judiciary Committee on the proposed counterclaim provision, the Chief Counsel of FDA stated that under the Senate bill, "[i]f a suit has been filed, the applicant may assert a counterclaim for an order to require deletion of patent information that the NDA-holder shouldn't have submitted for listing in the Orange Book." Senate Jud. Comm., *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearings on Sen. 1 and H.R. 1*, 108th Cong. 1st Sess., S. Hrg. 108-390 (Aug. 1, 2003) (statement of Daniel E. Troy).

This provision responded to the Federal Circuit's decision in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). In that case, the court of appeals ruled that a generic drug manufacturer does not have a private cause of action to seek de-listing of a patent from the Orange Book. *Id.* at 1325. The generic manufacturer's complaint was that the patent in question "did not claim [the drug] or an approved method of using [the drug]." *Id.* at 1331. This language is mirrored in the statutory counterclaim provision, as is the relief the generic company sought: de-listing from the Orange Book. Congress was well aware of *Mylan* when it enacted the 2003 amendments to the Hatch-Waxman Act. *See, e.g.*, Senate Daily Digest, Debate on Pub. L. No. 108-173, 148 Cong. Rec. S7636-39 (statement of Sen. Wallop) (daily ed. July 31, 2002) (Letter and

policy statement from New York Attorney General Spitzer commenting on S. 812, bill considered prior to eventual amendments, referring several times to the *Mylan* case). The government acknowledges that "*Mylan* was surely significant to Congress" in its consideration of the 2003 amendments. Amicus Br. of United States at 30; *see also* Amicus Br. of the Generic Pharmaceutical Ass'n at 25 ("it is generally agreed that Congress enacted the counterclaim provision in part to respond to the Federal Circuit's decision in *Mylan*").

Notably absent from the legislative record of the counterclaim provision is any congressional concern with use codes. Use codes were not mentioned in connection with the counterclaim provision—or, as far as we can tell, elsewhere in the legislative history of the 2003 amendments. It would be surprising if Congress had expressed a concern with allegedly misleading use codes, because until very shortly before the counterclaim provision was enacted, use codes were drafted *by FDA*. Orange Book Rule, 68 Fed. Reg. at 36683. Overbroad use codes were simply not a concern of Congress's in enacting the counterclaim provision.

In 2002, moreover, Congress considered requiring by statute the submission of additional information beyond the patent number and expiration date. This 2002 bill, which Congress did not ultimately enact, would have amended 21 U.S.C. § 355 by, in relevant part, stating that "[t]he patent information required to be filed" by NDA applicants would include

> (i) the patent number;
> (ii) the expiration date of the patent;

(iii) with respect to each claim of the patent—

(I) whether the patent claims the drug or claims a method of using the drug; and

(II) whether the claim covers—

(aa) a drug substance;

(bb) a drug formulation;

(cc) a drug composition; or

(dd) a method of use;

(iv) *if the patent claims a method of use, the approved use covered by the claim*;

(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

(vi) a declaration that the applicant, as of the date of the filing, has provided complete and accurate patent information for all patents described in subparagraph (A).

S. 812, 107th Cong., 2nd Sess., § 3(a)(1) (as sponsored by Sen. Kennedy, July 11, 2002) (emphasis added). But Congress did not enact this provision, and it did not re-define patent information to include "the approved use covered by the claim."

Because Congress declined to enact a definition of "patent information" encompassing a meaning now urged by Petitioners, there is all the more reason to adhere to the plain language of the statute and interpret that phrase as including only the patent number and expiration date. This Court has previously noted instances in which Congress "cut out the very language in the bill that would have authorized" the requested relief. *Doe v. Chao*, 540

U.S. 614, 622 (2004). As the Court explained, "[t]he deletion of [certain language] from the bill is fairly seen . . . as a deliberate elimination of" the covered concept. *Id.* at 623.

The broader statutory context confirms the plain meaning of the statutory language. The Hatch-Waxman Act as a whole was intended to strike a reasonable compromise between the interests of the pioneer drug companies and the generic manufacturers that market copies of the drugs developed by the pioneer companies. As noted in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001):

> These provisions of the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Thus, Title I of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." Title II, on the other side of the scale, was intended to benefit pioneer drug manufacturers by "restoring . . . some of the time lost on patent life while the product is awaiting pre-market approval."

Id. at 1326 (internal citations omitted).

The 2003 Amendments promote a balance among all members of the pharmaceutical industry. *See, e.g.*, Senate Daily Digest, Debate on S.1, Prescription Drug and Medicare Improvement Act of 2003, at S8190-91 (June 19, 2003) (statement of Sen. McCain); *id.* at S8191-92 (statement of Sen. Schumer). The 2003 statutory language was carefully crafted to achieve this purpose. Disregarding the plain language of the statute would upset the balance struck by Congress by substituting the policy preferences of certain industry participants for the procedures set forth by statute.

Federal law does not allow "knowingly supplying false use codes," "fraud," Amicus Br. of AARP and U.S. PIRG at 13, 16, or "misrepresenting the scope of [the] patent," Petitioners' Br. at 12. To cite only one example, companies submitting FDA Form 3542 (which calls for the use code) must certify that the information submitted is "accurate and complete," "verify under penalty of perjury that the foregoing is true and correct," and acknowledge a warning that "[a] willfully and knowingly false statement is a criminal offense under 18 U.S.C. [§] 1001." FDA Form 3542. This Court has recognized that

> FDA is empowered to investigate suspected fraud, and citizens may report wrongdoing and petition the agency to take action. In addition to the general criminal proscription on making false statements to the Federal Government, the FDA may respond to fraud by seeking injunctive relief, and civil penalties, . . . and pursuing criminal prosecutions. The FDA thus has

> at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration.

Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 349 (2001) (internal citations and footnotes omitted).

If this Court were to look beyond the plain language of the statute, it should consider that Congress enacted the 2003 counterclaim provision against the backdrop of this Court's 2001 ruling in *Buckman*. In that case, the Court held that private parties may not bring state law tort claims to redress allegedly fraudulent statements made by regulated companies to FDA. As this Court reasoned, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and . . . this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348. The same reasoning applies here, where the Hatch-Waxman regime reflects a careful and somewhat delicate balance of congressional objectives, and where (as described in more detail in the next Part) FDA is amply empowered to adjust its approach to use codes.

In its 2003 amendments to Hatch-Waxman, Congress did not respond to *Buckman* by creating a private right of action to challenge submissions to FDA. Hence, as the law stands, there is no presumption that a private party in Petitioners' position can police, via litigation between two private parties, Orange Book use code statements filed with FDA.

III. Petitioners Are Free To Pursue Other Remedies For Perceived Problems In The Use Code Regime.

Petitioners and their *amici* suggest that, apart from the counterclaim provision, generic manufacturers have no way to challenge use codes on the ground that they are overbroad. *See, e.g.*, Petitioners' Br. at 41-45, Amicus Br. of Mylan Pharmaceuticals Inc. at 16-18. Petitioners have not shown that this is so, and it appears that options for addressing the breadth of use codes are available.[3]

As explained above, use codes are a creature of FDA, not Congress. *See* p. 10, *supra*. FDA Form 3542 instructs pioneer companies to "[s]ubmit the description of the approved indication or method of use" that they propose for the use code. The form, by its terms, provides the option to choose a use code that tracks an approved indication *or* method of use. *See* Form 3542 Question 4.2(b).

FDA has clearly stated that use codes are not strictly limited to a statement of the method of use claimed in the patent. Indeed, in some cases that

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[3] After a bench trial, the district court found the patent-in-suit invalid as obvious and unenforceable due to inequitable conduct. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 775 F. Supp. 2d 985, 989 (E.D. Mich. 2011). The Federal Circuit has stayed the appeal pending the outcome in this Court. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, Nos. 2011-1223, 2011 U.S. App. LEXIS 15545 (Fed. Cir. July 27, 2011). If the Federal Circuit affirms on either ground, Petitioner Caraco will have no further need to challenge the Prandin use code narrative.

would be impossible, because of the 240-character limit on use codes:

> Use codes are intended to alert ANDA and 505(b)(2) 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. We understand that in some cases 240 characters may not fully describe the use as claimed in the patent.

Orange Book Rule, 68 Fed. Reg. at 36683, 36712.

In 2007, FDA changed its approach to the labeling requirements for oral diabetes treatments. As part of its new approach, FDA "required Novo to replace all separate indications with the following sentence: 'PRANDIN is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.'" Pet. App. 48a n.18 (Dyk, J., dissenting).

Respondents complied with FDA's directive by changing the indication on their Prandin label to conform to FDA's new prescribed language. *See* Respondents' Br. at 49. Respondents also filed papers to have FDA change Prandin's use code in the Orange Book to track the revised indication, *see* Pet. App. 8a-9a, which is one of the approaches contemplated by FDA Form 3542.

It appears that several avenues were available to Petitioners to challenge Prandin's use code.

1. Because FDA's actions are the ultimate source of Petitioners' complaint, FDA is the logical place to turn for potential relief. FDA has a long-

standing Citizen Petition process that allows any person to request virtually any action on the part of FDA, from "issu[ing], amend[ing], or revok[ing] a regulation" to "issu[ing], amend[ing], or revok[ing] an order" to "tak[ing] or refrain[ing] from taking any other form of administrative action." 21 C.F.R. § 10.30.

a. Petitioners could have filed a Citizen Petition asking FDA to engage in notice-and-comment rulemaking that would adjust the applicable regulations and forms (as well as the instructions to the forms) to clarify the policies applicable to situations in which a patent claims some but not all FDA-approved uses. In particular, Petitioners could have asked FDA to adjust its guidance to require the use code to track the method or methods of use claimed in the patent, eliminating the option of having the use code track the approved indication or approved method of use. Petitioners could request that the regulations, forms, and instructions be revised, for example, to require that the NDA applicant submit a use code that either directly quotes the claim language in the patent or paraphrases the claim language with specificity. Relatedly, Petitioners could ask FDA to eliminate from its guidance any statement that permits the use code to be framed in terms of *either* the indication *or* the method of use, and to eliminate the 240-character cap on use code narratives.

b. Petitioners could also have asked FDA to engage in notice-and-comment rulemaking that would create a more robust process for interested parties to obtain revisions to the use codes listed in the Orange Book, as appropriate. FDA allows any

person a limited right to dispute the accuracy or relevance of information submitted under the agency's Orange Book listing rules. *See* 21 C.F.R. § 314.53(f).[4] Caraco is free to pursue a Citizen Petition seeking a different rule, which could complement any revised limitations on use codes by providing a procedure for interested parties (i) to ensure that such limitations are observed and (ii) to request that FDA order any necessary revisions to non-compliant use codes.

c. While changes to the substantive rules and procedures governing use codes would likely be the best means of providing Petitioners with the relief they seek, the same result—having Respondents revert to the original use code for Prandin—could also be achieved if FDA were to withdraw its 2007 directive on the labeling requirements for oral diabetes treatments. If FDA were to change the required labeling so that it distinguished between

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[4] It appears that Caraco sent a letter to the Orange Book staff under this provision, seeking to have the original use code for Prandin reinstated. *See* Caraco Reply Comments, FDA Docket No. FDA-2008-P-0411 (June 16, 2009), at Ex. 2. After Respondents declined to change the use code, Caraco did not follow up with a Citizen Petition asking FDA to order a change to the use code. Nor did it ask FDA to engage in a rulemaking to alter its overall policy under Section 314.53(f) to provide a more robust opportunity for generic companies to seek mandatory changes to use codes.

FDA's public docket reflects that Caraco filed a Citizen Petition regarding repaglinide, but the petition related to Caraco's rights vis-à-vis other generic companies that might file ANDAs, and did not seek a change to Novo's use code. *See* Caraco Citizen Petition, FDA Docket No. FDA-2008-P-0411 (July 14, 2008).

use of repaglinide by itself and use of repaglinide in combination with other therapies, in place of the merged indication the agency currently requires, the result could be that Respondents would not employ the use code to which Petitioners object.

Petitioners have submitted no evidence that they petitioned FDA to provide any of these forms of relief.

2. If FDA did not provide Petitioners with the relief they seek, Petitioners could bring a judicial challenge under the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

Petitioners had several potential opportunities to seek APA review of FDA's actions, most pertinently when FDA, in the Federal Circuit's words, "disallowed Caraco's section viii statement" on the ground that Caraco's "proposed carve-out label overlapped with the use code U-968 for the '358 patent," Pet. App. 9a; Petitioners also could have filed an APA challenge to FDA's use code regulations or pursued an APA appeal of FDA's denial of any Citizen Petition that Petitioners could have filed. *See generally* 21 C.F.R. § 10.45(d).

The counterclaim provision is not an invitation for courts to enter the business of re-writing use codes. Indeed, we are unaware of any instance, other than the injunction issued by the district court in this case, in which a court has used the counterclaim statute as a basis for ordering revisions to a use code.

The fact that courts have not intervened in this fashion is telling. FDA, which created the use code system, has both the authority and the responsibility to define and regulate the content of use codes.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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