

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 RESPONDENTS

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QUESTION PRESENTED

Under the Hatch-Waxman Act's counterclaim provision, if (1) the generic challenger maintains a "Paragraph IV" certification as to the patent claim-in-suit and (2) the generic challenger both (a) proves that the patent "does not claim ... an approved method of using the drug" and (b) challenges "the patent information submitted ... under" particular statutory provisions, then (3) the generic challenger may seek a judicial order requiring the patentee to "correct or delete" the specified information. 21 U.S.C. § 355(j)(5)(C)(ii).

In this case, (1) the generic challenger withdrew its Paragraph IV certification before initiating the counterclaim; (2) the generic challenger (a) concedes that the patent *does* claim an approved method of using the drug and (b) challenges the "use code narrative," which is not statutory "patent information"; and (3) the generic challenger seeks "correct[ion]" of a single entry on a notification form that complies with all applicable statutory and regulatory requirements and guidance.

The question presented is whether the Federal Circuit correctly concluded that the counterclaim is not available in these circumstances.

RULE 29.6 STATEMENT

The corporate disclosure statement included in the brief in opposition remains accurate.

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BRIEF FOR RESPONDENTS

Respondents Novo Nordisk A/S and Novo Nordisk Inc. respectfully submit that the judgment of the court of appeals should be affirmed or, alternatively, vacated and remanded with instructions to dismiss for lack of jurisdiction.

JURISDICTION

Petitioners invoke the jurisdiction of this Court under 28 U.S.C. § 1254(1). As explained in Argument Part I, *infra*, the federal courts lack subject-matter jurisdiction over this dispute.

STATUTORY PROVISIONS INVOLVED

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, amended various provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), including 21 U.S.C. § 355 (Pet. App. 104a-195a), and the Patent Act, including 35 U.S.C. § 271(e)(2)(A) (Opp. App. 108a-109a). The counterclaim provision at issue here (Pet. App. 145a-146a), added as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, states:

(ii) Counterclaim to infringement action

(I) In general

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 [generic] 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) of this section 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.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

21 U.S.C. § 355(j)(5)(C)(ii).

STATEMENT

The district court ordered respondents Novo Nordisk A/S and Novo Nordisk Inc. (collectively Novo) to alter the “use code narrative” published by the Food and Drug Administration in connection with Novo’s patented method of diabetes drug therapy. Pet. App. 65a-66a. The Federal Circuit reversed, concluding that petitioners Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. (collectively Caraco) do “not have a statutory basis to assert a counterclaim requesting such injunctive relief.” *Id.* at 2a-3a.

The decision below turned on two narrow issues of statutory construction. *First*, Caraco could not establish the counterclaim’s predicate that the “patent does not claim ... an approved method of using the drug” (21 U.S.C. § 355(j)(5)(C)(ii)) because Novo’s patent *does* claim an approved method of using the drug at issue. Pet. App. 11a-14a. *Second*, the counterclaim provision does not authorize court-ordered

changes to Novo’s use code narrative because the only “patent information submitted ... under subsection (b) or (c)” of 21 U.S.C. § 355—and thus the only information that can be “correct[ed] or delete[d]” pursuant to the counterclaim—is the patent number and expiration date. Pet. App. 14a-17a.

1. The Hatch-Waxman Act, originally enacted in 1984, governs many aspects of the intense competition among makers of branded and generic drugs. *See generally Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355-57 (Fed. Cir. 2008). In particular, Section 505 of the FDCA, as amended by Hatch-Waxman, regulates the process by which drug makers can secure FDA approval of new drugs, as well as the avenues of judicial relief available to patent holders and their generic competitors. *See* 21 U.S.C. § 355.

a. Section 505(a) prohibits the sale of a new drug “unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.” 21 U.S.C. § 355(a). Subsection (b) requires a pioneer company seeking to manufacture a new drug to file a New Drug Application (NDA), together with a variety of information on safety and effectiveness. *Id.* § 355(b)(1)(A)-(G). And subsection (c), in turn, addresses amendments to and approval of NDAs, and authorizes certain lawsuits by the NDA holder to enforce its rights. *Id.* § 355(c)(1)-(3).

Section 505(b) requires NDA filers to provide FDA with specified “patent information”: “The applicant shall file with the application the *patent number* and the *expiration date* of any patent which claims the drug ... or which claims a method of using such drug.” 21 U.S.C. § 355(b)(1)(G) (emphases added).

Section 505(c) states that “[i]f the patent information described in subsection (b) of this section could not be filed with the submission of an application,” the holder of an approved application “shall file with the Secretary the *patent number* and the *expiration date* of any patent which claims the drug ... or which claims a method of using such drug.” *Id.* § 355(c)(2) (emphases added).

FDA publishes a list of patents claiming approved drug products or methods, along with the statutory “patent information” and certain additional information required by regulation, in its “Approved Drug Products with Therapeutic Equivalence Evaluations”—commonly known as the “Orange Book.” *See Janssen*, 540 F.3d at 1355; *see also* J.A. 500-95 (excerpts).

b. Section 505(j) allows generic competitors to market copies of approved drugs by filing an Abbreviated New Drug Application (ANDA). 21 U.S.C. § 355(j). The ANDA process “substantially shorten[s] the time and effort needed to obtain marketing approval” of a generic copy by allowing the applicant to rely on the research of the pioneer pharmaceutical company, thus “avoid[ing] the costly and time-consuming [safety and efficacy] studies required for a pioneer drug.” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

Although the ANDA mechanism makes it easier for generic companies to go to market, it does not eliminate patent protections for pioneer companies. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). Rather, generic companies seeking approval to copy patented drugs must certify that (I) no patent covering the listed drug has been listed in the Orange Book; (II) the patent has ex-

pired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). The last of these options is commonly known as a Paragraph IV certification.

The filing of a Paragraph IV certification by an ANDA applicant is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A); *see also Eli Lilly*, 496 U.S. at 678. If the pioneer company initiates a timely suit, FDA may not approve the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). As an incentive for generic companies to risk an infringement suit, the first company to submit a Paragraph IV certification for a particular drug receives a 180-day period of marketing exclusivity. *Id.* § 355(j)(5)(B)(iv).

If an ANDA applicant wants to market a listed drug only for uses that are not covered by any method-of-use patent, it can ask FDA to “carve out” of the proposed product label—which generally must be identical to the branded label (21 U.S.C. § 355(j)(2)(A)(v))—any patented uses by filing what is known as a section viii statement. *Id.* § 355(j)(2)(A)(viii). The generic thereby represents that the “patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent.” *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). “ANDA applicants [must] use *either* a paragraph IV certification *or* a section viii statement—they may not use both.” *Ibid.*

2. The Hatch-Waxman Act carefully balances the competing interests of branded and generic drug companies. *See, e.g., Abbott Labs. v. Young*, 920 F.2d

984, 985 (D.C. Cir. 1990). In 2003, Congress enacted the only significant adjustments to that balance since the statute's initial enactment, including the counterclaim at issue here.

The impetus for the counterclaim was a 2001 decision that there was no statutory authorization for a generic competitor to seek delisting of a patent from the Orange Book on the ground that it “did not claim ... an approved method of using” the drug. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1331 (Fed. Cir. 2001). The congressional response to *Mylan* proceeded in several steps.

a. Senators Schumer and McCain introduced S. 812, the “Greater Access to Affordable Pharmaceuticals Act of 2002,” which (as amended on July 11, 2002) sought to add a new provision governing the “Filing of Patent Information with the Food and Drug Administration.” S. 812, 107th Cong. § 103 (2002). S. 812 would have required NDA holders to file an expanded list of “patent information” with FDA, including:

- (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;

[and]

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

Id. § 103(a)(2)(C). S. 812 also would have authorized ANDA applicants to bring a freestanding civil action for correction or deletion of this expanded list of statutorily required “patent information”:

A person that has filed an [ANDA] for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

(I) to correct patent information filed under subparagraph (A); or

(II) to delete the patent information in its entirety for the reason that—

(aa) the patent does not claim the drug for which the application was approved; or

(bb) the patent does not claim an approved method of using the drug.

Id. § 103(a)(2)(E).

The redefinition of “patent information” and accompanying civil action in S. 812 met a firestorm of opposition from Republican legislators. Senator Hatch, for example, criticized the proposed civil action as an “unwelcome foothold for trial lawyers to reach into the FDC Act” that would “create a parallel course of litigation to the well-established Paragraph IV patent contests.” 148 Cong. Rec. S6991 (July 18, 2002). He also noted “concern[s] about the policy and potential effects” of “significantly expand[ing] the type of patent information that must be filed, including requiring very precise claim by claim certifications of what each particular patent covers.” *Id.* at S6990; *see also, e.g.*, 148 Cong. Rec. S7633 (July 31,

2002) (Sen. Gregg); *id.* at S7644 (Sen. Grassley); 148 Cong. Rec. S7345 (July 25, 2002) (Sen. Hatch); 148 Cong. Rec. S6995 (July 18, 2002) (Sen. Frist).

President Bush likewise opposed S. 812, warning that the proposed civil action “would unnecessarily encourage litigation around the initial approval of new drugs and would complicate the process of filing and protecting patents on new drugs.” *Statement of Administration Policy: S. 812—Greater Access to Affordable Pharmaceuticals Act* (July 18, 2002). FDA communicated the Administration’s concerns to Congress and argued that the proposed civil action created an undesirable alternative by allowing ANDA holders “to file suit in lieu of certifying under par. IV.” 148 Cong. Rec. S6823 (July 16, 2002) (Sen. Gregg) (quoting FDA memo).

On July 31, 2002, S. 812 passed the Senate on a 66-33 vote. 148 Cong. Rec. S7634 (July 31, 2002). Senator McCain, the bill’s Republican co-sponsor, noted that “[t]he cause of action for generic manufacturers to ‘delist’ patents ... was added to S. 812 late in the process, and it is controversial.” *Id.* at S7644-7645. Although he suggested that the provision might warrant further consideration in conference (*see ibid.*), the House of Representatives—in which the Republicans held a majority—declined to take action on S. 812 or three virtually identical bills. *See* H.R. 5311, 107th Cong. § 3(a)(2)(E) (2002); H.R. 5272, 107th Cong. § 2(a)(2)(E) (2002); H.R. 5350, 107th Cong. § 10 (2002).¹

¹ Proponents of the civil action also tried—but failed—to move similar bills through Congress the following year. *See*

b. On July 30, 2002, one day before the Senate passed S. 812, the Federal Trade Commission issued a study examining drug competition under the Hatch-Waxman Act. *See* Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration* (July 2002), available at <http://www.ftc.gov/opa/2002/07/genericdrugstudy.shtm>. The FTC's recommendations diverged from S. 812 in two critical respects. *First*, rather than changing the *statutory* "patent information" that NDA holders must file, the FTC recommended that FDA "clarify its listing requirements" by regulation or guidance. *Id.* at v; *see also id.* at A-39. *Second*, instead of a stand-alone private right of action, the FTC recommended that Congress allow "a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation already initiated by the brand-name company in response to a [generic's] paragraph IV notice." *Id.* at v.

FDA responded on October 24, 2002 by issuing a proposed rule to require NDA applicants and holders to provide substantial additional information about patented drugs and methods not mandated by Section 505(b) or (c). *See* 67 Fed. Reg. 65,448 (Oct. 24, 2002). As relevant here, the proposed rule made clear that method-of-use patents could be submitted for listing in the Orange Book and, "[f]or each method of use claim identified," required the NDA applicant or holder to answer:

[Footnote continued from previous page]

S. 7, 108th Cong. § 201(a)(2)(E) (2003); S. 54, 108th Cong. § 3(a)(2)(E) (2003); H.R. 2640, 108th Cong. § 10(a)(2)(E) (2003).

Is the claim one that claims ... an approved method of use of the approved drug product?

———— Yes ———— No

If ... “yes,” please identify the use with reference to the approved labeling for the drug product and identify the relevant patent claim number(s).

Id. at 65,454. If the answer is “no,” the proposed rule continued, “[t]he patent may not be listed in the Orange Book as a patent that claims a method of use.” *Ibid.*

FDA issued its final rule on June 18, 2003. *See* 68 Fed. Reg. 36,676, 36,677 (June 18, 2003) (codified at 21 C.F.R. pt. 314). It requires the NDA holder to inform FDA “[w]hether the patent claims one or more approved methods of using the approved drug product.” 21 C.F.R. § 314.53(c)(2)(ii)(P)(1). If so, then the NDA holder must also provide additional information, including a proposed “use code narrative”—a “description of each approved method of use or indication [*i.e.*, the disease or condition to be treated].” *Ibid.*

FDA implemented this rule in Form 3542. *See* Pet. App. 211a-214a; *see also* 68 Fed. Reg. at 36,711-12 (draft form). Using the “yes” or “no” format, Form 3542 requires NDA holders to declare, under penalty of perjury, whether or not the patent “claim[s] an approved method of use of the approved drug product.” Pet. App. 212a. If the answer is “no,” then the patent cannot be listed in the Orange Book. *See id.* at 213a. If the answer is “yes,” then Form 3542 requires the submission of a “description of the approved indication or method of use” for a drug. *Ibid.*

Here is an excerpt from the form itself:

4.1 Does the patent claim one or more approved methods of using the approved drug product?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.2 Patent Claim Number(s) (as listed in the patent)	Does (Do) the patent claim(s) referenced in 4.2 claim an approved method of use of the approved drug product?		
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify the use with specific reference to the approved labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.)		
4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (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.)		
FDA will not list the patent in the Orange Book as claiming the method of use if: <ul style="list-style-type: none"> • the answer to question 4.1 or 4.2 is "No," or • if the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full. 			

Id. at 212a-213a.

The use code narrative cannot exceed 240 characters because of "limitations [in FDA's] database system." 68 Fed. Reg. at 36,683. As FDA explained:

Traditionally, we [FDA] have created the use code description for the Orange Book from the information submitted by the NDA applicant or holder. ... [W]e have determined that it is more efficient and accurate to ask the NDA holder to give us the exact use code description to be published in the Orange Book. *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.*

Ibid. (emphasis added).

c. After S. 812 failed, compromise legislation was drafted to address Republican objections and introduced by Senator Gregg as S. 1225 in June 2003. *See* 149 Cong. Rec. S8188 (June 19, 2003). Reflecting a

“carefully crafted bipartisan compromise” (*id.* at S8190), S. 1225 was significantly narrower than S. 812 and the other stalled bills. As Senator Schumer—a strong proponent of S. 812—acknowledged, the “modifications” in S. 1225 were necessary to “address the concerns that kept the bill’s critics from supporting [S. 812] last year.” *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: *Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 1 (2003).

Rather than create a broad, independent cause of action to correct or delete an expanded list of statutorily required “patent information,” S. 1225 allowed only a counterclaim, in a Paragraph IV suit for infringement, limited to correcting or deleting the patent number and expiration date. S. 1225, 108th Cong. § 2(a)(2)(C)(iii)(II)(aa) (2003). As the Conference Report explained, the counterclaim permits a generic “in a paragraph IV patent suit” to seek “removal of the patent” from the Orange Book. H.R. Rep. No. 108-391, at 836 (2003).

As enacted, the counterclaim echoes the language of *Mylan* in requiring the generic applicant to prove that the patent “does not claim ... the drug ... or ... an approved method of using the drug.” 21 U.S.C. § 355(j)(5)(C)(ii)(I). If the generic applicant can carry this burden—that is, if it can prove that the patent was not properly listed in the Orange Book—it may “see[k] an order requiring the [patentee] to correct or delete the patent information submitted ... under subsection (b) or (c) of this section.” *Ibid.*

3. Novo sells the diabetes drug repaglinide under the brand name PRANDIN[®]. Repaglinide is ap-

proved for treating diabetes when used alone (monotherapy) or in combination with other specified drugs, including metformin. J.A. 46. In 2004, Novo was issued U.S. Patent No. 6,677,358, Claim 4 of which claims a method for using repaglinide in combination with metformin to treat type 2 diabetes. *Id.* at 65-96. Only claim 4 is at issue in this litigation (*id.* at 367 ¶ 99); it, along with the rest of the '358 patent, will expire in 2018. *Id.* at 49. Novo submitted to FDA the statutory “patent information” along with a proposed use code narrative (*id.* at 98-99), which was published in the Orange Book as “U-546—Use of repaglinide in combination with metformin to lower blood glucose.” *Id.* at 54-55. Novo’s original Form 3542 stated in relevant part:

4.1 Does the patent claim one or more approved methods of using the approved drug product? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
4.2 Patent Claim Number (as listed in the patent)	Does the patent claim referenced in 4.2 claim an approved method of use of the approved drug product? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify the use with specific reference to the approved labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) Use of Prandin tablets in combination with metformin to lower blood glucose in patients whose hyperglycemia cannot be controlled by exercise, diet and either repaglinide or metformin alone.
4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (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 of repaglinide in combination with metformin to lower blood glucose.
FDA will not list the patent in the Orange Book as claiming the method of use if:	
<ul style="list-style-type: none"> the answer to question 4.1 or 4.2 is "No," or if the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full. 	

Id. at 98-99.

In 2005, Caraco filed an ANDA for generic repaglinide that included (at that time) a Paragraph IV certification that claim 4 of the '358 patent was invalid or would not be infringed by the sale of generic repaglinide. J.A. 116. Novo sued for infringement, and Caraco eventually stipulated that its ANDA for repaglinide would infringe the '358 patent if it “include[d] a label that discusses the combination of

metformin and repaglinide.” *Id.* at 177; *see also* Pet. 19 n.10.

In April 2008, Caraco amended its ANDA and, with respect to Claim 4, replaced its Paragraph IV certification with a section viii statement declaring that “Caraco ... does not seek approval for the use of Repaglinide in combination with Metformin to lower blood glucose.” J.A. 175. Caraco sought to “carve out” all information relating to the repaglinide-metformin combination therapy from its otherwise infringing label. *Id.* at 250-55. In December 2008, FDA indicated that it would permit this carve-out. *Id.* at 257. Novo moved for reconsideration on the ground, *inter alia*, that the carved-out label would render generic repaglinide less safe and effective. *Id.* at 303-08; *see also id.* at 315-20.

During the same time period, Novo revised the PRANDIN[®] label pursuant to an FDA directive “requesting changes to the professional labeling of all oral anti-diabetic drugs.” J.A. 163. FDA *required* Novo to “[r]eplace all the separate indications (e.g., monotherapy, combination therapy, and initial or second-line therapy) 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.’” *Id.* at 164.

In May 2009, after providing notice to FDA and in consultation with its regulatory counsel (J.A. 404, 407-09), Novo submitted an amended FDA Form 3542 “to amend the use code relating to [the ’358 patent] to correspond with the change in labeling required by FDA in [its directive].” *Id.* at 483; *see also*

id. at 408. The amended Form 3542 states:

4.1 Does the patent claim one or more approved methods of using the approved drug product?		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
4.2 Patent Claim Number(s) (as listed in the patent) Claim 4	Does (Do) the patent claim(s) referenced in 4.2 claim an approved method of use of the approved drug product?		<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify the use with specific reference to the approved labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) INDICATIONS AND USAGE: An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; CLINICAL PHARMACOLOGY (Combination Trials) and DOSAGE & ADMINISTRATION sections of the approved label.			
4.2b If the answer to 4.2 is "Yes," also provide the information on the indication or method of use for the Orange Book "Use Code" description.	Use: (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.) A method for improving glycemic control in adults with type 2 diabetes mellitus.			
FDA will not list the patent in the Orange Book as claiming the method of use if: <ul style="list-style-type: none"> the answer to question 4.1 or 4.2 is "No," or if the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full. 				

Id. at 485-86.

Caraco challenged the amended use code, invoking FDA's administrative review process under 21 C.F.R. § 314.53(f). *See* J.A. 331-39. FDA instituted the review procedures mandated by its regulation. *Id.* at 340-41, 374-75. Following that review, FDA accepted the revised use code and published it in the Orange Book: "U-968—A method for improving glycemic control in adults with type 2 diabetes mellitus." *Id.* at 592. Caraco did not seek judicial review of this FDA decision under the Administrative Procedure Act.

FDA then determined that Novo's request for reconsideration was "moot" in light of the new use code, as the "factual predicate" on which FDA's permissive decision had rested no longer applied. J.A. 369-73. FDA declined to allow Caraco to carve repaglinide-metformin combination therapy out of its label (*id.* at 377, 723), "because that would leave [Caraco's] labeling without any approved indication, rendering its drug not safe and effective." U.S. Br. 12. Instead, FDA directed Caraco to "submit an updated patent certification addressing the [358] patent and its associated use code," and to amend its

ANDA to “[a]dd back” information about the combination therapy into the labeling. J.A. 377-78; *see also* 21 C.F.R. § 314.53(f) (ANDA must “contain an appropriate certification for each listed patent”). Caraco neither complied with FDA’s ruling by making a Paragraph IV certification nor challenged it under the APA, electing instead to maintain its section viii statement as to Claim 4. J.A. 342-68.

4. In a counterclaim filed on June 11, 2009—more than a year *after* its conversion to section viii—Caraco requested, “[u]nder 21 U.S.C. § 355(j)(5)(C)(ii),” an order “requiring [Novo] to correct the use code information submitted by [Novo].” J.A. 366 ¶ 97. Novo opposed on the ground that both the cause of action asserted and the relief sought were not authorized by that counterclaim provision, and because there is nothing to “correct” about the revised use code, which—as established by the unopposed declaration of Novo’s FDA expert (*id.* at 414-33)—complies with all applicable regulations and directly tracks the FDA-mandated indication.²

a. Without any reference to the statutory text, the district court rejected Novo’s position that the counterclaim was unauthorized (Pet. App. 95a-96a) and ordered Novo to “submi[t] to FDA an amended Form FDA 3542 that reinstates its former U-546 listing for Prandin and describes claim 4 of the ’358 patent in section 4.2b as covering ‘the use of rep-

² Novo also argued that FDA was a necessary party because Caraco’s challenge was (and still is) a collateral attack on FDA’s administration of the Orange Book. *See* D.E. 373, at 10-11. To this day, FDA has not participated in these proceedings as a party or an *amicus*.

aglinide in combination with metformin to lower blood glucose.” *Id.* at 65a-66a.

b. The Federal Circuit vacated the injunction. Pet. App. 1a-52a.

“[D]etect[ing] no ambiguity in the statutory language,” the court held that “the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug.” Pet. App. 12a. Because Caraco conceded that the listed patent “does claim an approved method of use” (J.A. 688-89), the counterclaim was not available to Caraco.

The court also held that “the terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative.” Pet. App. 14a-15a. That is because the counterclaim provision authorizes an order compelling the patentee “to correct or delete the patent information submitted ... under subsection (b) or (c)” (21 U.S.C. § 355(j)(5)(C)(ii)(I)), and “the Act defined the term ‘patent information’ as ‘the patent number and the expiration date.’” Pet. App. 15a (citing *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294, 1296-97 (11th Cir. 2003)).

Judge Clevenger, who “agree[d] with Judge Rader’s analysis of the relevant statutory provisions in this case and therefore join[ed] [his] opinion,” wrote separately to emphasize that “Novo did nothing that was illegal or forbidden” and that “there is nothing illegal, or even incorrect, about Novo’s current use code.” Pet. App. 19a, 21a.

Judge Dyk dissented, arguing that “[a]n error in an Orange Book use code” should be “subject to correction” under the counterclaim provision. Pet. App.

43a; *see also id.* at 53a-64a (Gajarsa, J., dissenting from denial of rehearing) (similar).

5. Following the Federal Circuit's decision, proceedings on the remaining issues resumed in the district court.

Novo renewed its motion to dismiss for lack of subject-matter jurisdiction, arguing that Caraco's conversion from a Paragraph IV certification to a section viii statement defeated the jurisdictional basis for suit. The district court, however, denied that motion. Opp. App. 1a-10a.

On January 19, 2011, after a bench trial, the district court found Claim 4 invalid and unenforceable. Opp. App. 11a-106a. Novo's appeal from that judgment has been stayed pending the Court's decision in this case. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, No. 2011-1223 (Fed. Cir. July 27, 2011).

SUMMARY OF ARGUMENT

Caraco cannot even invoke, much less secure relief under, the Hatch-Waxman Act's counterclaim provision.

I. Caraco's conversion from a Paragraph IV certification to a section viii statement precludes the federal courts from entertaining the counterclaim.

A Paragraph IV certification is an act of patent infringement that vests the federal courts with jurisdiction (35 U.S.C. § 271(e)(2)(A)), and Congress limited the counterclaim to Paragraph IV suits. *See* 21 U.S.C. § 355(j)(5)(C)(ii). Caraco, however, withdrew its Paragraph IV certification with respect to the claim-in-suit in April 2008—more than a year *before* filing the counterclaim. Since then, it has proceeded under a section viii statement, which represents that there is no dispute regarding patent infringement. Caraco's conversion to section viii divested the feder-

al courts of jurisdiction over this lawsuit, including the subsequently filed counterclaim.

II. The Federal Circuit correctly construed the counterclaim, which requires the generic applicant to prove that “the patent does not claim ... an approved method of using the drug” and limits the remedy to “correct[ing] or delet[ing] the patent information submitted ... under subsection (b) or (c).” 21 U.S.C. § 355(j)(5)(C)(ii).

A. A patent either claims an approved use or it does not; the options are dichotomous. If the patent claims an approved use, then it may be listed in the Orange Book and the counterclaim is not available. Caraco’s only response is to contend that “it can simultaneously be true that the patent *both* (1) ‘claims an approved method of use’ *and* ‘does not claim an approved method of use’” (Caraco Br. 29-30), which is every bit as nonsensical as it sounds. FDA requires a “yes” or “no” answer to the question whether the patent claims an approved method; “both,” as Caraco would have it, is not an option.

The statutory phrase “not ... an approved use” is equivalent to “no approved use”—the counterclaimant has the burden of proving that the listed patent does not claim *any* approved uses. This construction accords with both common sense and standard grammar. Caraco tries to avoid this conclusion by inverting the language of the statute—“the generic can point to ‘an approved method’ that the patent ‘does not claim’” (Caraco Br. 29 (emphasis omitted))—so that the counterclaim would apply if the patent does not claim the singular use for which the generic applicant seeks carve-out approval. *Id.* at 27; *see also* U.S. Br. 15. But other provisions refer specifically to “a method of use patent which does not claim a use *for which the applicant is seeking approval.*” 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis add-

ed). Congress’s decision not to draft the counterclaim similarly must be given effect.

A patent is properly listed in the Orange Book if it claims “a method of using such drug.” 21 U.S.C. § 355(b)(1). Caraco concedes that this means *any* approved use, and affording the various provisions of the Hatch-Waxman Act a “complementary” reading (*Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673 (1990)) requires interpreting the counterclaim’s reference to “an approved use” in the same way.

The history and purpose of the counterclaim further confirm that it is available only if the patent does not claim any approved use. As Caraco acknowledges, the construction afforded the counterclaim by the court below fully addresses the problem that Congress set out to address. Additional adjustments to this complex regime are for Congress, not this Court, to implement. *See Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 457 (2007). At bottom, the counterclaim is a delisting provision; if a patent is properly listed in the Orange Book, as Novo’s patent concededly is, then the counterclaim is not available.

B. The counterclaim extends only to the “patent information submitted ... under subsection (b) or (c)” of Section 505; the referenced subsections, in turn, require submission (and publication) only of “the patent number and the expiration date.” 21 U.S.C. § 355(b)(1), (c)(2). Contrary to Caraco’s assertion, “patent information” does not include the use code narrative.

Caraco argues that “patent information” *also* includes anything else that FDA might by regulation require an innovative manufacturer to provide. That contention cannot be reconciled with the statutory text, which does not even hint that the “patent information submitted ... under” Section 505(b) and (c)

includes *non-statutory* submissions, or with the structure of the statute, which repeatedly uses “submitted under” to mean *statutory* patent information. Moreover, many other provisions expressly incorporate regulatory requirements; Congress’s decision not to do so in the counterclaim must be respected.

The drafting history of the counterclaim conclusively refutes Caraco’s argument. A predecessor bill would have expanded the statutorily required “patent information” to include a number of additional things, including “the approved use covered by the claim,” and would have been broad enough to authorize a judicial action to “correct” this newly required information—the very relief Caraco seeks here. That bill, however, did not pass into law. Instead, pursuant to a much narrower legislative compromise, the counterclaim was limited to challenging the patent number and expiration date. Caraco is now asking this Court to adopt, by judicial fiat, that which Congress was unwilling or unable to enact.

III. Injunctive relief is not warranted because “there is nothing illegal, or even incorrect, about Novo’s current use code.” Pet. App. 21a (Clevenger, J., concurring).

Caraco’s principal complaint is that Novo’s use code narrative does not accurately describe the “scope” of Novo’s patent. But a patent’s scope is defined by its claims, and is subject to the detailed requirements of the Patent Act; the Hatch-Waxman Act does not require these intricacies to be boiled down to a 240-character entry on an FDA form. Rather, FDA itself recognizes that the use code narrative serves solely a notice function and is “not meant to substitute for the [ANDA] applicant’s review of the patent and the approved labeling.” 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

FDA has expressly authorized use code narratives based on “a description of each approved method of use *or indication*.” 21 C.F.R. § 314.53(c)(2)(ii)(P)(1) (emphasis added). Novo has elected to base its use code narrative—for this patent, as for other listed patents in its portfolio—on the approved indication for the drug. This is consistent with FDA’s guidance and, indeed, with use code narratives drafted by FDA itself. After all, FDA regulates *drugs*, including their labels (which must recite approved indications), not *patents*.

Caraco’s objection to Novo’s current use code narrative is really a collateral attack on FDA’s longstanding decision to allow indication-based use codes. But that is not what the counterclaim is for. Rather, the appropriate avenue of judicial relief would have been a suit against FDA, in the appropriate forum, under the Administrative Procedure Act. Caraco elected not to pursue that course; as a result, all of its arguments that judicial review via the counterclaim is “necessary” ring hollow.

ARGUMENT

To prevail before this Court, Caraco must clear a series of obstacles, any one of which is sufficient to bar its counterclaim.

Caraco must establish the jurisdictional prerequisite to the counterclaim—a viable Paragraph IV dispute—even though it withdrew its Paragraph IV certification before filing the counterclaim. Caraco must satisfy the predicate for invoking the counterclaim—that the patent does not claim an approved method of using the drug at issue—even though it concedes that the patent does claim an approved method of using repaglinide. Caraco must fit itself within the counterclaim’s remedial scope—which authorizes correction or deletion only of the patent number and expiration date—even though the use

code narrative is neither. And Caraco must demonstrate the need for judicial intervention—that is, that Novo’s current use code narrative requires “correct[ion]”—even though that use code complies with all applicable rules.

Caraco cannot overcome any of these hurdles, much less *all* of them.

I. CARACO CANNOT PURSUE THE COUNTERCLAIM SINCE IT SWITCHED TO SECTION VIII

The Hatch-Waxman Act provides for jurisdiction in ANDA cases only if the generic applicant maintains a Paragraph IV certification with respect to the patent claim(s) at issue. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *see also* 35 U.S.C. § 271(e)(2)(A). The counterclaim, likewise, is available *only* in Paragraph IV litigation. *See* 21 U.S.C. § 355(j)(5)(C)(ii). Yet Caraco does not now have—and did not have at the time the counterclaim was filed—a Paragraph IV certification as to the sole patent claim at issue. Rather, Caraco amended its ANDA in April 2008 to assert only a section viii statement, thus depriving the federal courts of jurisdiction and destroying the statutory prerequisite for invoking the counterclaim.

An ANDA applicant may maintain either a Paragraph IV certification or a section viii statement as to a given patent claim, but not both. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). A Paragraph IV certification is appropriate when an innovator’s patent “claims a use” of the drug for which the ANDA filer seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). The ANDA applicant acknowledges the applicability of the patent, while certifying that it “is invalid or will not be infringed”

by the manufacture, use, or sale of the generic drug. *Id.* § 355(j)(2)(A)(vii)(IV). By contrast, a section viii statement asserts that the innovator’s patent “does not claim a use” for which the ANDA filer seeks approval. *Id.* § 355(j)(2)(A)(viii). Paragraph IV certifications and section viii statements are thus mutually exclusive: “[E]ither the applicant is seeking approval for the use claimed in the patent, or it is not.” *Purepac*, 354 F.3d at 880 (internal quotation marks omitted).

The choice between these two alternatives has significant consequences for federal jurisdiction. A Paragraph IV certification indicates the applicant’s intent to sell a potentially infringing product and constitutes an “artificial act of infringement,” thus “enabl[ing] the judicial adjudication” of claims for infringement and patent invalidity. *Eli Lilly*, 496 U.S. at 678; *see also* 35 U.S.C. § 271(e)(2)(A). In contrast, a section viii statement represents that there is no controversy between the parties regarding patent infringement. *Purepac*, 354 F.3d at 880; *see also* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 Food & Drug L.J. 417, 424 (2011) (section viii statement “does not constitute an act of infringement like a Paragraph IV certification”).

The Hatch-Waxman counterclaim does not provide any freestanding basis for federal jurisdiction; it may be invoked only if the patent holder “brings a patent infringement action against the applicant.” 21 U.S.C. § 355(j)(5)(C)(ii). The only such action that may be brought *before* FDA approves an ANDA is where a Paragraph IV certification has been made. 35 U.S.C. § 271(e)(2)(A). The jurisdictional basis for

the counterclaim is therefore coterminous with a Paragraph IV certification.

Congress expressly provided that the counterclaim provision “does not authorize the assertion” of the counterclaim “in any civil action or proceeding” *other than* a Paragraph IV lawsuit. 21 U.S.C. § 355(j)(5)(C)(ii)(II). In contrast to the original bill (S. 812), which would have permitted stand-alone challenges, the enacted provision reflects the legislative compromise to tie the counterclaim to Paragraph IV litigation. *See* H.R. Rep. No. 108-391, at 836 (2003) (Conf. Rep.) (counterclaim applies in “paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book”).

Although Caraco originally filed a Paragraph IV certification with respect to Claim 4 of the '358 patent, initially creating jurisdiction for this lawsuit, it subsequently (in April 2008) amended its ANDA by withdrawing the Paragraph IV certification and replacing it with a section viii statement. J.A. 175. This amendment divested the federal courts of jurisdiction over any challenges involving Claim 4 of the '358 patent. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (a justiciable controversy must exist at all stages of a lawsuit). Novo moved to dismiss on that basis. *See* D.E. 92, 478.

The district court recognized that “a section viii statement, unlike a Paragraph IV certification, does not constitute an act of infringement sufficient to invoke subject matter jurisdiction.” Opp. App. 7a. It concluded, however, that Caraco “was pursuing *both* a paragraph IV certification *and* a section viii statement with respect to the '358 patent.” *Id.* at 10a (emphases added). This ruling contravenes the controlling regulation, which provides that “[o]nce an

amendment ... is submitted, the application will no longer be considered to contain the prior certification.” 21 C.F.R. § 314.94(a)(12)(viii). And the regulation accords with common sense: An ANDA filer logically cannot certify both that it is seeking approval for a use *not claimed* by an Orange-Book-listed patent (section viii) and that the same use *is claimed* by a listed patent that is invalid or not infringed (Paragraph IV). *See* 59 Fed. Reg. 50,338, 50,347 (Oct. 3, 1994). Thus, as the government explains (and Caraco does not dispute), “FDA does not ... permit a simultaneous paragraph IV certification and section viii statement to the same claim of a particular patent.” U.S. Cert. Br. 8 n.1; *see also Purepac*, 354 F.3d at 880 (“patent ANDA applicants use either a paragraph IV certification or a section viii statement—they may not use both”).

Since Caraco amended its ANDA in April 2008, more than a year *before* filing its counterclaim, there has been no case or controversy between Novo and Caraco within the meaning of Article III; Caraco’s ANDA does not constitute an “artificial act of infringement” (*Eli Lilly*, 496 U.S. at 678) on which statutory jurisdiction could be predicated under 35 U.S.C. § 271(e)(2)(A); and there is therefore no “patent infringement suit” that could support a counterclaim under the 2003 amendments.³

³ The government has previously implied that, if a counterclaim were filed while there is a pending Paragraph IV certification, jurisdiction would not be lost by a *later* conversion to section viii. U.S. Cert. Br. 22. Assuming, *dubitante*, that could be right, here Caraco converted to section viii *before* filing the counterclaim. It is perhaps for this reason that the government’s merits brief, like Caraco’s, is silent on jurisdiction.

This result should not surprise. As Caraco itself acknowledges, section viii “is designed to avoid litigation.” Caraco Br. 43. The counterclaim is *never* available if an ANDA applicant chooses to proceed under section viii rather than Paragraph IV, as Caraco did, because by definition there is no patent infringement litigation. *See* note 7, *infra*. Caraco’s initiation and maintenance of the counterclaim, including in this Court, founders on that barrier—yet Caraco does not even address it.

II. THE FEDERAL CIRCUIT CORRECTLY CONSTRUED THE SCOPE OF THE COUNTERCLAIM

The Hatch-Waxman counterclaim provides that, if the ANDA applicant proves in a Paragraph IV lawsuit that “the patent does not claim ... an approved method of using the drug,” then the court may order the NDA holder “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).⁴

As the Federal Circuit correctly concluded, Caraco’s attempt to invoke this counterclaim provision is foreclosed by the statutory language in two separate—and independently dispositive—respects. *First*, the counterclaim is unavailable where, as here, the patent-in-suit *does* claim “an approved method of using the drug.” This is true even if the patent does not claim *all* approved methods. Pet. App. 11a-14a. *Second*, even where the counterclaim is available, the “patent information” subject to correction or deletion is limited to the patent number and expiration

⁴ The counterclaim and “complementary” provisions of Section 505 (*see Eli Lilly*, 496 U.S. at 673) are excerpted in the statutory addendum, *infra*.

date, and thus does not include the use code narrative. *Id.* at 11a-16a.

**A. THE COUNTERCLAIM IS NOT AVAILABLE
WHERE, AS HERE, THE PATENT CLAIMS
AN APPROVED METHOD OF USE**

The counterclaim provision requires the generic competitor to prove that the listed patent “does not claim ... an approved method of using the drug.” 21 U.S.C. § 355(j)(5)(C)(ii); *see also* U.S. Br. 18-19. Caraco concedes, however, that Novo’s patent “*does* claim an approved method of use.” J.A. 688-89; *see also id.* at 396 (acknowledging that Novo’s patent “covers an FDA-approved method of using the referenced drug”). The counterclaim is therefore unavailable.

1. A patent either “claim[s] an approved method” of using a particular drug, or it does not. This dichotomy is at the heart of the Hatch-Waxman Act’s patent listing requirements, and was expressly adopted by Congress in the counterclaim. A patent that “claim[s] an approved method of use” for a drug cannot simultaneously be said “not [to] claim an approved method of use” for that drug; the two modes are dichotomous.

Caraco asserts that this straightforward reading of the statutory language “rests on a logical fallacy” because, in its view, “whether the patent claims an approved method of use” is not “necessarily an either-or-proposition.” Caraco Br. 29. Indeed, an *essential* component of Caraco’s argument is that “it can simultaneously be true that the patent *both* (1) ‘claims an approved method of use’ *and* (2) ‘does not claim an approved method of use.’” *Id.* at 29-30. Nonsense. To be sure, as a matter of quantum mechanics, “[e]lementary particles can both exist and not exist at the same time.” *Kusay v. United States*, 62 F.3d 192, 194 (7th Cir. 1995). But “[j]udicial pow-

er needs a more predictable basis” (*ibid.*), and patent claims, unlike Schrödinger’s cat, cannot be in multiple, inconsistent states at once.

The language enacted by Congress means that the counterclaim is available only if “the listed patent does not claim *any*” (or, equivalently, claims *no*) “approved method of using the drug.” Pet. App. 12a. Caraco protests that “Congress did not say ‘any’; it said ‘an.’” Caraco Br. 23. But what Congress *actually* said was “not ... an.” As the Federal Circuit correctly recognized, “[w]hen an indefinite article is preceded and qualified by a negative, standard grammar generally provides that [it] means ‘any.’” Pet. App. 12a. That is because the construction “not ... an” equates to “none.” *Shorter Oxford English Dictionary* (5th ed. 2002) (defining “an” with a “preceding negative” to mean “none at all of, no—of any kind; not even one”); *see also, e.g., American Heritage Dictionary of the English Language* 1 (4th ed. 2000) (“not a drop to drink”). Contemporaneous dictionaries consistently include this definition of “a” or “an” in the context of a negative formulation.⁵ While Caraco dismisses these as “secondary definitions” (Caraco Br. 26), they are the *only* definitions applicable where, as here, the article is preceded and qualified by a negative (“does not claim”), and Caraco does not cite a single definition or other authority

⁵ *See, e.g., Random House Webster’s Unabridged Dictionary* (2d ed. 2001) (“any; a single: not a one”); *Oxford American College Dictionary* (2002) (“[with negative] one single; any: I haven’t a thing to wear”); *Microsoft Encarta College Dictionary* (2001) (“ANY used in negative structures to emphasize a complete absence of something,” as in “He doesn’t have a hope!”); *Webster’s II New Collegiate Dictionary* (3d ed. 2005) (“Any < not a bite to eat>”); *Oxford American Dictionary and Thesaurus with Language Guide* (2003) (“one single (not a thing in sight)”).

that disagrees with this construction or states a contrary rule.

Caraco, implicitly acknowledging that it cannot satisfy the statutory requirement as written, is forced to concoct strained (and irrelevant) hypotheticals. *See* Caraco Br. 26-28; *see also* U.S. Br. 22 n.2 (same). They serve only to confirm that, on Caraco’s reading, an ANDA applicant may invoke the counterclaim if it can identify *any* “approved method’ that the patent ‘does not claim.’” Caraco Br. 29 (emphasis omitted). That would bring the counterclaim into play unless the patent claimed “*all* approved methods” of use. Pet. App. 12a. The statute, however, says no such thing.

To make its proposed construction work, Caraco has to invert the statutory language: According to Caraco, the counterclaim is available if “the generic can point to ‘an approved method’ that the patent ‘does not claim.’” Caraco Br. 29 (emphasis omitted). This inversion, however, requires substituting a definite article (“the”) for the indefinite article (“an”) that Congress actually used. As Caraco admits, it reads the statute as referring to “a single approved method of using the drug”—that is, *the* “*particular* approved method of use” invoked by the ANDA filer. *Id.* at 27 (emphasis added). Caraco repeatedly reminds the Court that “[c]hang[ing] an ‘an’ to a ‘the’ ... go[es] from huge savings to huge cost.” *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”: Hearing Before the Senate Comm. on the Judiciary, 108th Cong. 119 (2003) (Sen. Schumer)*. But that is *precisely* what Caraco is attempting to do.

The government, for its part, claims that the relevant statutory inquiry is whether the patent “does not claim ... *the approved use* for which [the generic company] seeks carve-out labeling under section

viii.” U.S. Br. 15 (emphasis added). As with Caraco’s formulation, the government would impermissibly convert the article from indefinite to definite. Moreover, where Congress intended to impose additional limitations or qualifications on “approved use,” it did so expressly. Thus, section viii statements are appropriate only “[i]f ... information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use *for which the applicant is seeking approval.*” 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added).⁶ Congress’s decision to include such “language in one section of a statute but omi[t] it” elsewhere must be presumed “intentiona[l] and purpose[ful].” *Bates v. United States*, 522 U.S. 23, 29-30 (1997). And adding the language to a provision “from which it is conspicuously absent,” of course, “more closely resembles inventing a statute rather than interpreting one.” *Hardt v. Reliance Standard Life Ins. Co.*, 130 S. Ct. 2149, 2156 (2010) (internal quotation marks omitted).

2. The Federal Circuit’s interpretation of the counterclaim provision is also consistent with this Court’s requirement that the Hatch-Waxman Act be “taken as a whole.” *Eli Lilly*, 496 U.S. at 669. The Hatch-Waxman Act requires listing of patents that

⁶ FDA interprets “does not claim a use” in this provision as referring to *any* use covered by the patent. See 21 C.F.R. § 314.94(a)(12)(iii)(A) (allowing section viii statement if “the labeling for the drug product for which the applicant is seeking approval does not include *any* indications that are covered by the use patent” and requiring “a statement explaining that the method of use patent does not claim *any* of the proposed indications” (emphases added)). Caraco does not explain why the same construction should not be applied to the counterclaim’s similar language.

claim “a method of using such drug” (21 U.S.C. § 355(b)(1)), and the counterclaim is available if the owner of a patent “for the drug ... a use of which is claimed by the patent” initiates an infringement action (*id.* § 355(j)(5)(C)(ii)(I)). In both instances it is clear from context that the indefinite article “a” means any—as Caraco has previously admitted. Pet. C.A. Br. 38 n.2 (“an NDA holder may list a patent if it covers any approved use”). Reading “an approved method” the same way is the only way to harmonize the statute as a whole. *See, e.g., Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) (“identical words and phrases within the same statute should normally be given the same meaning”).

The Hatch-Waxman Act’s listing provisions provide a particularly compelling parallel with the counterclaim. For a method-of-use patent to be properly listed in the Orange Book, it must “clai[m] ... a method of using such drug.” 21 U.S.C. § 355(b)(1). An Orange Book listing is improper, therefore, if the patent *does not* “clai[m] ... a method of using such drug.” Thus, the counterclaim provision operates to remove from the Orange Book those method-of-use patents that were not properly listed in the first place, and puts the burden on the counterclaimant to prove that the listing is improper. *See Caraco Br. 29* (acknowledging that the generic company “bears the burden of proof under the statute”). A patent is either correctly listed in the Orange Book or it is not—as with the counterclaim provision, the listing requirement turns on the dichotomy between patents that “claim ... an approved method of use” and those that do not. It *is* an either-or proposition.

This is, moreover, how the listing requirements have consistently been applied by FDA. Form 3542 asks simply: “Does the patent ... claim an approved method of use of the approved drug product?” J.A. 98. There are only two possible answers to this ques-

tion: “Yes” and “No.” *Ibid.* Dichotomous again. The patent holder cannot answer, as Caraco’s theory would require, “Both” (or “Yes, but not all”). And if the patent holder checks “No,” then the patent cannot be listed in the Orange Book at all. *Id.* at 99.

Eli Lilly—this Court’s only previous foray into the wilds of the Hatch-Waxman Act—recognized that the Act’s provisions should be construed in a “complementary” manner. 496 U.S. at 673. Contrary to Caraco’s assertion (at 42-45), this does not mean that the counterclaim should be harmonized with section viii; the counterclaim has *nothing to do* with section viii.⁷ Rather, the complementariness principle demands that the counterclaim be construed in parallel with the listing requirements of Section 505(b) and (c)—which, unlike section viii, are actually cross-referenced in the counterclaim itself.

As Caraco concedes, Novo’s patent was properly listed in the Orange Book because it “[d]oes ... claim an approved method of use of the approved drug product.” J.A. 98; *see also id.* at 396 (Caraco’s concession that the ’358 patent is “properly listed in the Orange Book”). Accordingly, Caraco’s assertion that, for purposes of the counterclaim provision, the patent “does not claim ... an approved method of us[e]”

⁷ Caraco’s suggestion that “Section viii and the counterclaim were meant generally to be complementary” (Caraco Br. 47 (internal quotation marks omitted)), like the government’s view that the counterclaim “facilitate[s] the section viii process” (U.S. Br. 21), overlooks that the statute makes them mutually exclusive: If an ANDA applicant elects to proceed through section viii, the counterclaim is categorically unavailable. Consequently, Caraco’s lament that the decision below “eviscerate[s]” section viii (Caraco Br. 41) is meaningless.

(21 U.S.C. § 355(j)(5)(C)(ii)) is at war with the statutory scheme.

3. The drafting history of the counterclaim further confirms that it is unavailable here. The counterclaim was enacted to “correct the specific issue raised” in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001)—that is, “to deter pioneering manufacturers from listing patents that were not related at all to the patented product or method.” Pet. App. 13a.

a. In *Mylan*, the Federal Circuit held that a generic competitor could not seek a court order requiring a patentee to delist an improperly listed patent because it “did not claim ... an approved method of using [the drug].” 268 F.3d at 1331. Because a delisting cause of action was not explicitly authorized by the Hatch-Waxman Act, the court reasoned that Mylan’s suit was “an impermissible attempt by a private party to enforce the FDCA.” *Id.* at 1329-30 (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001)). Congress responded with the counterclaim, which (echoing the language of *Mylan*) is available only where “the patent does not claim ... an approved method of using the drug.” 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb); *see also* Pet. App. 21a (Clevenger, J., concurring) (“The counterclaim statute ... was designed to cure the situation presented in *Mylan*”).

Caraco concedes that the Federal Circuit’s interpretation of the counterclaim fully accounts for “the problem in the *Mylan* case.” Caraco Br. 31. It claims, however, that the counterclaim was designed to remedy a broader range of “improper Orange Book listings” and that “[t]he legislative history contains no significant discussion of *Mylan*.” *Id.* at 31-32. This grossly mischaracterizes the historical record.

In the debates leading to enactment of the counterclaim provision, Members of Congress were focused on several publicized instances of perceived abuse. *See Kelly, supra*, at 435-39 (summarizing legislative background). As the initial patent for a drug's active ingredient neared expiration, and after the generic had filed its ANDA and certified to the patents previously listed in the Orange Book for a particular drug, some branded companies would list one or more additional patents in the Orange Book related to relatively minor aspects of the underlying drug—such as, for example, “the color or the design of the packaging or the scoring of the pill that really did not indicate a different or improved use for the product.” 148 Cong. Rec. S6844 (July 16, 2002) (Sen. Collins). Whether these late-listed, additional patents actually claimed the approved drug or an approved use of the drug was questionable, but their inclusion in the Orange Book would nonetheless require the ANDA applicant to provide a Paragraph IV certification that would lead to a 30-month stay. And because, at that time, there was no limit on the number of 30-month stays, some branded companies could take advantage of this strategy indefinitely—thus “evergreening” their patents. *Id.* at S6828-29 (Sen. Kennedy).

According to several legislators, the *Mylan* litigation exemplified this perceived abuse. *See, e.g.*, 148 Cong. Rec. S7637 (July 31, 2002) (Sen. Schumer) (“Problems caused by th[e] [multiple 30-month stay] provision are illustrated by the facts of the Buspar litigation”); 148 Cong. Rec. S7344 (July 25, 2002) (Sen. Hatch) (“We all know of the now infamous case of the drug, Buspar”). The NDA holder owned an Orange-Book-listed patent for BuSpar, an FDA-approved anti-anxiety medication that contained the ingredient buspirone. 268 F.3d at 1327. Hours before the BuSpar patent expired, the branded compa-

ny submitted to FDA a new patent, which claimed a process for treating anxiety by introducing an active metabolite of buspirone into the body. *Id.* at 1328. This patent was not properly listed because it claimed only a metabolite of buspirone rather than the drug itself. *Ibid.* But existing law, the Federal Circuit held, did not provide Mylan with any opportunity to seek a judicial order delisting the patent on the ground that it “did not claim ... an approved method of using [the drug].” *Id.* at 1331.

Congress’s primary response to *Mylan* and like cases was to reform the 30-month stay provision, eliminating repeated stays with respect to the same drug. *See* 21 U.S.C. § 355(j)(5)(B). Congress also adopted a narrow counterclaim provision to address the specific problem in *Mylan*: patents that should never have been listed in the Orange Book.

Caraco suggests, erroneously, that the “abusive practices in the pharmaceutical industry” addressed by Congress included use code narratives. Caraco Br. 10 (quoting 149 Cong. Rec. S15,745 (Nov. 24, 2003) (Sen. Schumer)). According to Caraco, for instance, “FDA ... urged that, to resolve problems with the scope of patent use codes, ‘the courts are the appropriate mechanism.’” *Id.* at 32 (quoting 68 Fed. Reg. 36,676, 36,683 (June 18, 2003)). What FDA *actually* said was that “[a] fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism *for the resolution of disputes about the scope and validity of patents.*” 68 Fed. Reg. at 36,683 (emphasis added). Similarly, although Caraco implies (at 33) that Senator Gregg’s reference to “those issues” (149 Cong. Rec. S8193 (June 19, 2003)) had something to do with use code narratives, he was instead referring to “interminable [30-month] stays” and *generic* companies “tak[ing] advantage of the 180-day exclusivity clause”—both of which were “addresse[d] ... very conscientiously” by

the statute. *Ibid.* No Member of Congress *ever* discussed use code narratives in connection with the 2003 amendments, and Caraco’s contrary suggestion is unadulterated revisionism.

Indeed, until August 2003, FDA *itself* wrote use code narratives. *See* 68 Fed. Reg. at 36,683. Neither Caraco nor the government explains how, when Congress passed the counterclaim provision in June 2003, it could have intended to “combat” a “sort of manipulation”—*i.e.*, “submitting to FDA an overbroad description of [a] method-of-use patent” (U.S. Br. 17)—that was not even *possible*. Again, neither the statute nor the legislative history contains even a *single* reference to the issue of use code narratives; Congress was, instead, focused on improperly listed patents, and the solution it adopted was narrowly tailored to solve that specific problem.

Caraco would prefer that Congress have adopted a broader provision that addressed other purported (but unidentified) “abuses,” but this is nothing more than a policy-based plea to extend the counterclaim beyond the *Mylan* situation that Congress set out to address—and, indeed, to resurrect a bill that Congress was unwilling or unable to pass. If the counterclaim is to be extended beyond *Mylan*, then such an extension is a task for Congress, not this Court. *See Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 457 (2007) (any such “loophole’ ... is properly left for Congress to consider, and to close if it finds such action warranted”); *see also 62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951).

b. Caraco contends, however, that reading the counterclaim provision as limited to the *Mylan* situation would “render superfluous’ the term ‘correct.’” Pet. 32 (citing *Astoria Fed. Sav. & Loan Ass’n v. Solimino*, 501 U.S. 104, 112 (1991)). Not so: If a patent is improperly listed because it does not claim an ap-

proved method of using the drug, then the court may order *either* delisting *or* correction of the statutory patent information.

In most cases in which a generic competitor proves that the listed patent does not claim an approved method, the appropriate remedy will be delisting. But if an error were made in listing a patent—for example, the wrong patent number were submitted—the Hatch-Waxman counterclaim authorizes the court to order correction of the statutory patent information without requiring a resubmission by the NDA holder. This could have important consequences (including benefits for generic challengers) under the various stay provisions of the Act. *See Kelly, supra*, at 446-50.

Moreover, even if the statutory term “correc[t]” has little or no independent work to do under the Federal Circuit’s reading of the counterclaim, this Court should not distort the remainder of the statute to accommodate that single word. “Surplusage does not always produce ambiguity,” and this Court’s “preference for avoiding surplusage constructions is not absolute.” *Lamie v. U.S. Trustee*, 540 U.S. 526, 536 (2004); *see also Chickasaw Nation v. United States*, 534 U.S. 84, 94 (2001).

The statutory term “correct” is an artifact of the earlier, failed bills that would have required submission of a much broader range of “patent information” and permitted a suit to correct that information. S. 812, 107th Cong. § 103(a)(2)(C), (E) (2002). When Congress eliminated the submission requirements to achieve legislative consensus, it modified the counterclaim provision by adding the word “correct” to the “delete” clause. At the same time, Congress confirmed its understanding that the counterclaim is—primarily, if not exclusively—a delisting provision. *See H.R. Rep. No. 108-391*, at 836 (counterclaim

available to “ANDA applicant *seeking removal* of a patent listed in the Orange Book” (emphasis added)).

Where, as here, the patent is properly listed, the counterclaim never comes into play. There is nothing to delete—or correct.

B. THE COUNTERCLAIM DOES NOT REACH USE CODE NARRATIVES

Caraco seeks a judicial order requiring Novo to withdraw its current use code narrative and replace it with one selected by Caraco. Even if the Hatch-Waxman counterclaim were available, however, it would not allow the remedy sought by Caraco. Rather, the only remedy authorized by statute is correcting or deleting the “patent information submitted by the [patent] holder under subsection (b) or (c)” of Section 505. 21 U.S.C. § 355(j)(5)(C)(ii)(I). The only such “patent information” is “the patent number and the expiration date of any patent” covering the drug or a method of use. *Id.* § 355(b)(1), (c)(2). It does not extend to the use code narrative.

1. Section 505(b) requires NDA filers to submit “the *patent number* and the *expiration date* of any patent which claims the drug ... or which claims a method of using such drug” and directs the Secretary to “publish [the] *information submitted under*” this clause. 21 U.S.C. § 355(b)(1) (emphases added). Section 505(c) states that “[i]f the *patent information* described in subsection (b) of this section could not be filed with the submission of an application,” the holder of an approved application “shall file with the Secretary the *patent number* and the *expiration date* of any patent which claims the drug ... or which claims a method of using such drug.” *Id.* § 355(c)(2) (emphases added).

Section 505 therefore makes clear that the “patent information” submitted under subsection (b) or

(c)—the very phrase used in the counterclaim provision—is limited to the patent number and expiration date. *See IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005) (applying “the normal rule of statutory interpretation that identical words used in different parts of the same statute are generally presumed to have the same meaning”).

Caraco wants to rewrite the statute, arguing that the “patent information submitted by the holder under subsection (b) or (c)” really means any “patent information submitted under FDA regulations.” Caraco Br. 35; *see also* U.S. Br. 24 (“[p]atent information” subject to the counterclaim “includes everything FDA requires NDA holders to submit”). But the only textual hook it asserts is that the counterclaim “says ‘submitted ... under’” rather than “‘specified in’ or ‘described in.’” Caraco Br. 34; *see also* U.S. Br. 24. This distinction is perfectly understandable; after all, the counterclaim is referring to the content of a patent holder’s *submission* to FDA, whereas the provisions using “specified in” or “described in” involve information that has not been “submitted.”⁸ But it is, in any event, a distinction without a difference: The counterclaim refers to information “submitted ... under” two specific provisions, each of which provides for submission only of the patent

⁸ Section 505(c)(2) refers to “patent information described in subsection (b),” for instance, because that provision is triggered only if the information “could *not* be filed with the submission of an application under subsection (b) of this section.” 21 U.S.C. § 355(c)(2) (emphasis added). Similarly, Section 505(d)(6) discusses the statutory remedy “[i]f the Secretary finds ... the application *failed* to contain the patent information prescribed by subsection (b).” *Id.* § 355(d)(6) (emphasis added); *see also id.* § 355(e)(4) (“the patent information prescribed by subsection (c) of this section was not filed within thirty days”).

number and expiration date—and not other information, even if required by FDA regulation. *See, e.g.*, 21 C.F.R. § 314.53(c)(2)(ii)(J) (requiring NDA holders to provide e-mail addresses for agents or representatives); Pet. App. 211a (same).

Nor is Caraco correct that other provisions of the Hatch-Waxman Act “us[e] the phrase ‘submitted under’ ... when referring to patent information submitted under FDA regulations.” Caraco Br. 35 (citing 21 U.S.C. § 355(c)(2), (j)(5)(D)(i)(I)(bb)(CC)). In both of the examples it cites, as in the counterclaim provision at issue here, the statute says absolutely nothing about FDA regulations.

One of Caraco’s examples provides for forfeiture of the exclusivity period otherwise available to the first generic company to file a Paragraph IV certification if that company fails to market its drug within 75 days after “[t]he patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.” 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). There is no basis in the text of this provision to interpret it as referring to any information other than patent number and expiration date. (Otherwise, the NDA holder could precipitate a forfeiture merely by “withdraw[ing]” the e-mail address of its agent or representative.) To the contrary, the provision is designed to avoid delay by the generic applicant after removal of the patent from the Orange Book *altogether*.

Caraco’s other example provides that, “[u]pon the submission of patent information under this subsection, the Secretary shall publish it.” 21 U.S.C. § 355(c)(2). But Caraco provides no reason to believe that this publication requirement extends to whatever additional information FDA chooses to require by regulation; indeed, such an interpretation would

mean, implausibly, that FDA would be in violation of its *statutory* obligations if it were by *regulation* to require, but then decline to publish, information (such as the e-mail addresses of agents or representatives—which FDA does not in fact publish). The proper view is that FDA “publishes th[e] patent information” submitted under Section 505(b) and (c) “along with *other information* about the drug.” *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1297 (11th Cir. 2003) (emphasis added).

Indeed, Caraco’s wishful reading of “submitted under” is refuted by Section 505(b) itself. After requiring submission of the patent number and expiration date, Section 505(b)(1)(G) provides that, “[u]pon approval of the [NDA], the Secretary shall publish information *submitted under the two preceding sentences.*” 21 U.S.C. § 355(b)(1)(G) (emphasis added). This narrow reference to the “two preceding sentences” cannot reasonably be read to incorporate the full range of information that FDA has elected to request (including e-mail addresses), rather than the specific patent information identified in those “two preceding sentences.” And FDA *itself* has explained that “[t]he statute and regulation require the NDA holder to submit, and in turn FDA to publish, only the patent number and expiration date.” FDA Br. 16, *Teva Pharms. USA Inc. v. Leavitt*, No. 08-5141 (D.C. Cir. June 18, 2008). Caraco’s interpretation of “submitted under” conflicts with the agency’s own.⁹

⁹ Caraco’s reliance on *Ardestani v. INS*, 502 U.S. 129 (1991), is misplaced. The Court did not hold, as Caraco claims, that “‘under,’ followed by a statutory provision” necessarily “refers to regulatory proceedings subject to, or governed by, that provision.” Caraco Br. 35-36. On the contrary, this Court recognized that “[t]he word ‘under’ has many dictionary definitions and

The remainder of the statute shows that Congress knows perfectly well how to invoke FDA’s implementing regulations when it so wishes. In Section 505(q), for instance, Congress provided that ANDA approval may be delayed when a citizen petition is “submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations).” 21 U.S.C. § 355(q); *see also id.* § 355(i), (k), (o) (referring to regulations as establishing standard of conduct). And even where Congress did not include chapter and verse, it nonetheless understood how to incorporate regulatory (as opposed to statutory) requirements. *See id.* § 343(r)(2)(A)(i) (providing that certain nutrient claims “may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary”); *see also, e.g., id.* §§ 352n, 354(b), 356a(c). Indeed, the FDCA contains *more than 100* express references to FDA regulations.

But even though—as Caraco repeatedly reminds the Court—FDA had long “required brands to submit more than patent numbers and expiries” (Caraco Br. 40 n.11), Congress did not even hint *in the counterclaim* that it was referring to those regulations, let alone expressly invoke them. *See Kucana v. Holder*, 130 S. Ct. 827, 837 (2010) (“If Congress wanted the jurisdictional bar to encompass decisions specified as discretionary by regulation along with those made discretionary by statute, ... Congress could easily have said so”).

[Footnote continued from previous page]

must draw its meaning from its context.” 502 U.S. at 135. The context here has nothing to do with FDA regulations.

2. Even if the statutory text and structure were otherwise open to Caraco’s interpretation, the drafting history conclusively forecloses the theory that “submitted ... under subsection (b) or (c)” includes FDA’s regulatory requirements. Indeed, Caraco is attempting to obtain through judicial reimagination of the counterclaim provision a result that Congress considered but declined to adopt.

a. Before Congress passed the counterclaim provision at issue here, it considered several proposals that would have required NDA holders to provide an expanded list of statutory patent information, including, “if the patent claims a method of use, the approved use covered by the claim.” S. 812, 107th Cong. § 103(a)(2)(C)(iv) (2002). And the generic company would have been permitted to “bring a civil action ... seeking an order requiring that the holder of the application amend the application ... to correct patent information filed” under the expanded submission requirements. *Id.* § 103(a)(2)(E).

These bills would have been broad enough to authorize what Caraco seeks here: a judicial challenge to the use code narrative. But the backers of such a right (including Representative Waxman) lacked sufficient votes to move it through Congress—at least seven bills containing this provision failed to pass. The ensuing legislative compromise explains why the counterclaim provision, as enacted, is far narrower than any of these earlier bills. Yet Caraco and all of its *amici*, including the United States, fail even to inform the Court of these predecessor bills, let alone attempt to analyze their impact on the issues before the Court.

Simply put, Caraco’s interpretation of the counterclaim provision “would effectively resurrect the scheme rejected by Congress.” *Smith v. United States*, 507 U.S. 197, 203 n.4 (1993). Yet Congress’s

“rejection of the very language that would have achieved the result” urged by Caraco “weighs heavily against [that] interpretation.” *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006); *see also, e.g., Doe v. Chao*, 540 U.S. 614, 622-23 (2004) (same). Indeed, “[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.” *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987).

In this case, the drafting history of the counterclaim provision provides an “unusually clear indication” (*Thompson v. Thompson*, 484 U.S. 174, 183-84 (1988)) that Congress did not intend the enacted provision to reach things, including use code narratives, that Congress declined to require by statute.

b. The drafting history is also a complete answer to Caraco’s speculation that, since FDA revised its Form 3542 regulation a few months before the counterclaim was enacted, Congress “must” have intended the counterclaim to reach the requirements of the new form. Caraco Br. 39-41. Since Congress declined to impose these requirements directly, it is ludicrous to suggest that the same Congress did so indirectly.

According to Caraco, “FDA explained” that “its ‘principal legal authority for the final rule [revising Form 3542] is section 505 of the act’—in particular, ‘the patent submission ... requirements’ of ‘Section 505(b) and (c).’” Caraco Br. 36 (quoting 68 Fed. Reg. at 36,697-98). What FDA *actually* said is simply: “Section 505(b) and (c) of the act describes the contents of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements.” 68 Fed. Reg. at 36,698. Elsewhere in the final rule FDA acknowledged the limited scope of

those subsections. *Id.* at 36,676. In fact, FDA’s authority to promulgate regulations is found in another provision of the FDCA. 21 U.S.C. § 371(a).

When later challenged on its authority to require NDA holders to provide a use code narrative, FDA did *not* reference the pertinent parts of subsections (b) or (c); rather, it described the submission of use code narratives as a “regulatory requirement” that “provides for effective implementation of the patent certification and ‘section viii statement’ provisions” in subsection (j). 72 Fed. Reg. 21,266, 21,268-69 (Apr. 30, 2007). Because FDA has expressly disclaimed that its Form 3542 requirements rest on a construction of the statutory term “patent information,” Caraco’s plea for deference (Caraco Br. 38) is so baseless that not even the Solicitor General—typically quick to defend the prerogatives of client agencies—invokes deference in this case.

FDA’s regulation requiring the submission of use code narratives, among other information, was offered as an *alternative* to the proposed legislation that could not pass the House. As part of the legislative compromise, the executive branch agreed to require additional information from NDA holders. But as part of that same compromise, the legislative branch agreed not to make that same information statutorily required or subject to the counterclaim. The judicial branch, of course, has no warrant to upset that compromise—yet that is precisely what Caraco is asking this Court to do.

III. CARACO IS NOT ENTITLED TO AN ORDER COMPELLING NOVO TO CHANGE ITS USE CODE NARRATIVE

Even if Caraco could invoke the counterclaim, the injunction it seeks would be inappropriate. *First*, because Novo’s use code narrative is fully compliant with all regulatory requirements, there is nothing to

“correct” under the counterclaim provision. *See* Pet. App. 21a (Clevenger, J., concurring) (“there is nothing illegal, or even incorrect, about Novo’s current use code”). *Second*, although the relief afforded by the counterclaim is discretionary, Caraco has never even attempted to satisfy the traditional four-factor test for injunctive relief. *See eBay Inc. v. Merc Exchange, L.L.C.*, 547 U.S. 388, 391 (2006).

A. NOVO’S CURRENT USE CODE NARRATIVE IS “CORRECT”

The counterclaim authorizes courts to order the “correct[ion] or delet[ion]” of statutorily submitted patent information. 21 U.S.C. § 355(j)(5)(C)(ii)(I). Caraco does not seek the “delet[ion]” of Novo’s patent from the Orange Book but instead claims that the use code narrative should be “correct[ed].” Caraco Br. 48-49. Caraco’s request must fail because it cannot establish that Novo’s existing narrative is *incorrect*.

1. Caraco makes the assumption—repeated almost 20 times in its brief—that the use code narrative must “describe the patent’s scope, so FDA and generics can determine whether infringing uses may be carved out from the generic’s labeling.” Caraco Br. 50; *see also* GPhA Br. 26 (“the NDA applicant [must] tailor its use code to correspond to the legitimate scope of the patent”); U.S. Br. 22 (criticizing “disparit[ies] between the NDA holder’s use code and the patent’s actual coverage”). That assumption, however, is not just unsupported, but flat wrong.

The patent itself—not the use code narrative—“must describe the exact scope of an invention.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). The precise boundaries of patent claims, which this Court has “likened to the description in a deed” (*Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917)), are de-

fined by a complicated series of rules. *See* 35 U.S.C. §§ 101-103, 112; *see also* Manual of Patent Examining Procedure § 608.01(1)-(n). Moreover, “claims are to be construed in the light of the specifications” (*United States v. Adams*, 383 U.S. 39, 49 (1966)) and “with reference to the file wrapper or prosecution history in the Patent Office” (*Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966)), and the “patent’s scope is not limited to its literal terms, but embraces all equivalents to the claims described.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 723 (2002). These nuances, and many more, are governed by a different statute (the Patent Act) and overseen by a different agency (the Patent and Trademark Office).

The Hatch-Waxman Act does not create a junior-variety patent system in which all of these intricacies must be distilled down to a 240-character “tweet” in an FDA database. Rather, FDA’s requirement of a use code narrative is simply “intended to alert ANDA ... applicants to the existence of a patent that claims an approved use.” 68 Fed. Reg. at 36,683. As FDA has emphasized, it is “not meant to substitute for the applicant’s review of the patent and the approved labeling.” *Ibid.* And there is no dispute that Caraco is fully apprised of the scope of the ’358 patent, as claimed in the patent itself. *See, e.g.*, J.A. 322, 338-39 (Caraco’s arguments on patent scope).

For this reason, it is unsurprising that FDA has *never* required the use code narrative to replicate the “approved method[s] of using the drug” covered by the patent, as Caraco maintains. Caraco Br. 49-50. The relevant regulation requires applicants to provide “a description of each approved method of use *or indication.*” 21 C.F.R. § 314.53(c)(2)(ii)(P)(1) (emphasis added); *see also* 59 Fed. Reg. at 50,346 (“for a use patent, FDA includes in the Orange Book a code identifying the indication covered by the patent”).

Similarly, Form 3542 itself permits NDA holders to “[s]ubmit 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 (emphasis added).

FDA’s guidance is expressly written in the alternative: An applicant may describe *either* the indication or the method of use. See, e.g., *Garcia v. United States*, 469 U.S. 70, 73 (1984) (“terms connected in the disjunctive” must “be given separate meanings”). A use code that tracks the approved indication thus complies with the FDA’s own regulation and instructions. See J.A. 424 ¶ 29.

FDA’s decision to permit use code narratives based on approved indications makes perfect sense considering that FDA regulates *drugs*, not *patents*. The central focus of its regulatory oversight is to determine whether a drug or method is safe and effective for the treatment of a particular disease or condition. Prescription drug labels must contain an “indications” section stating that the drug (or a use of the drug) is “indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition.” 21 C.F.R. § 201.57(c)(2). FDA’s focus on indications is entirely consistent with the statutory scheme—including section viii carve-outs. See H.R. Rep. No. 98-857, Part I, at 21 (1984) (“The [ANDA] applicant need not seek approval for all of the *indications* for which the listed drug has been approved” (emphasis added)). Unsurprisingly, no court has *ever* rejected or disapproved a use code narrative that incorporates an FDA-approved indication.

2. It is undisputed that Novo’s current use code narrative (“[a] method for improving glycemic control in adults with type 2 diabetes mellitus”) correctly recites the approved indication for the drug

(“PRANDIN is indicated ... to improve glycemic control in adults with type 2 diabetes mellitus”)—an indication required by FDA in its 2007 directive. All of the listed patents in Novo’s portfolio have indication-based use code narratives, and Novo’s amendment of the PRANDIN[®] narrative comports with that corporate practice.

Moreover, Novo’s use code narrative is consistent with the one created for PRANDIN[®] by FDA itself. In 1997, when repaglinide was first approved, there were two approved methods of use for PRANDIN[®]: use in monotherapy and use in combination therapy with metformin. FDA’s use code (U-214) did not distinguish between the two approved uses, nor did it define the scope of the patent then at issue (U.S. Patent No. 5,312,924). Rather, the U-214 use code narrative stated: “Use as a blood glucose-lowering agent.” J.A. 425 ¶ 34. If this indication-based use code created by FDA was proper (and here *is* an appropriate place for deference), then Novo’s current use code narrative must be proper as well.¹⁰

“FDA will not list the patent in the Orange Book [if] the [use code] information requested ... is not provided in full.” Pet. App. 213a; *see also* 21 C.F.R. § 314.53(c)(2)(ii) (FDA may “notify an applicant that a declaration form is incomplete or shows that the patent is not eligible for listing”). Yet FDA has never informed Novo that its amended use code narrative

¹⁰ FDA has also accepted use codes for at least two other diabetes drugs that, like Novo’s amended use code, describe the approved indication of the drug: U-827 (“Use for treatment of diabetes, particularly type 2 diabetes”) and U-412 (“Treatment of type 2 diabetes”). J.A. 425-26 ¶¶ 35-36. The relevant patents—Nos. 6,559,188 and 6,303,146—do not expressly claim approved combination therapies.

was “not provided in full,” or that its disclosure was “incomplete.” And although FDA has not appeared in this Court, the Justice Department does *not* take the position that Novo’s use code narrative is incorrect in any way. *See* U.S. Br. 33.

3. Caraco maintains that Novo’s use code narrative *must* be incorrect because Novo is purportedly “blocking Caraco’s Section viii carved-out labeling by describing its patent in an overbroad manner.” Caraco Br. 48-49. Caraco is thereby accusing Novo of committing a federal crime, but it cannot back up this outrageous accusation: Caraco does not identify *any* statute or regulation that Novo’s current use code narrative transgresses, because there is none. On the contrary, Novo’s use code complies with *all* applicable guidance—including FDA’s *express* authorization of indication-based use codes. *See* J.A. 423-24. Indeed, a brief perusal of the Orange Book reveals dozens of such use codes, many broader than the one here, including many drafted by FDA itself. *See* U-118 (“Method of lowering blood sugar level”); U-185 (“Method of treating hypertension”); U-279 (“Method of use of the approved product”); U-305 (“Methods for using the drug product”). Caraco’s position, if accepted, would require rewriting (and greatly expanding) the Orange Book.

Just as “there is nothing sinister in so arranging one’s affairs as to keep taxes as low as possible (*Comm’r of Internal Revenue v. Newman*, 159 F.2d 848, 850-51 (2d Cir. 1947) (Hand, J., dissenting)), nor is there anything wrong with Novo’s election to frame its use code in a manner that complies with all applicable statutory and regulatory guidance while channeling infringement disputes into pre-approval Paragraph IV litigation rather than post-approval litigation after the generic drug goes to market with a section viii carve-out label. *See* Pet. App. 21a (Clevenger, J., concurring). Given the choice be-

tween a use code narrative tied to the indication or one tied to the method of use—a choice expressly permitted by FDA—Novo was under no obligation to adopt the use code that would most benefit Caraco. Complying with a regulatory regime is not “gam[ing]” it, as Caraco insinuates. Caraco Br. 45.

Caraco’s misguided insistence that use code narratives must “describe the patent’s scope” (Caraco Br. 50) is just a collateral attack on FDA’s longstanding decision to permit a drug’s approved indication to serve as a use code—and, more particularly, its decision to accept Novo’s use code narrative over Caraco’s objection. The proper forum for such an attack is not a counterclaim against Novo but instead a lawsuit against FDA under the APA. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378-79 (Fed. Cir. 2002) (“the APA provides an appropriate mechanism for reviewing the lawfulness of the FDA’s action”). That is entirely consistent with the background rule that submissions to FDA may *not* be challenged in private litigation. *See Buckman*, 531 U.S. at 353. Indeed, Caraco conceded at the petition stage that it could have challenged FDA’s refusal to authorize its section viii carve-out but failed to do so. *See* Pet. 20. Yet neither Caraco nor its *amici*, including the government, even *acknowledge* the APA in their merits submissions to this Court.

At almost every turn, Caraco challenges FDA’s decisions—to allow NDA holders to propose use code narratives, to allow use code narratives based on methods *or* indications, to allow only limited challenges to use code narratives, to base section viii determinations on use code narratives. *See* 68 Fed. Reg. at 36,682-83. The counterclaim should not be distorted to allow such collateral attacks on agency decisions in the context of private litigation to which FDA is not even a party. Rather, Caraco (or any other allegedly aggrieved party) must proceed directly

against FDA, in an appropriate forum, under the APA.¹¹

**B. ENJOINING NOVO WOULD BE
INEQUITABLE**

Caraco asks this Court to “reinstate” the district court’s injunction (Caraco Br. 47), but that court did not require Caraco to demonstrate (1) “that it has suffered an irreparable injury”; (2) “that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted”; (3) “that remedies available at law, such as monetary damages, are inadequate to compensate for that injury”; and (4) “that the public interest would not be disserved by a permanent injunction.” *eBay*, 547 U.S. at 391. These prerequisites to equitable relief each point in a single direction here: Caraco is not “entitled” to an injunction.

1. Caraco cannot establish any irreparable injury that would occur in the absence of an injunction, for the simple reason that Caraco’s goods have been seized for failure to comply with safe manufacturing practices, and Caraco is enjoined from making additional drug products until FDA is satisfied that it has fixed these problems. J.A. 642-73. Even if Caraco were permitted to pursue a section viii statement,

¹¹ The Obama Administration’s support for Caraco’s position, albeit lukewarm, is perplexing because most if not all of the concerns raised could be addressed by FDA, prospectively, through notice-and-comment rulemaking. See U.S. Cert. Br. 17-18; see also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011) (“Congress and the FDA retain the authority to change the law and regulations if they so desire”). That FDA has not done so indicates that the concerns raised by Caraco and its *amici* are either illusory or countermanded by competing considerations.

and even if it were to obtain FDA approval to market generic repaglinide, it could not go to market. And that alone is sufficient to preclude the injunctive relief sought by Caraco.

2. At the same time, requiring Novo to change its use code narrative would cause irreparable harm. As noted above, FDA has permitted use code narratives based on either the approved indication or the method of use. The counterclaim provision gives Caraco no license to enlist a federal judicial officer to force Novo to choose between these two equally permissible alternatives. Indeed, if the statute were so construed it would give rise to serious constitutional problems. See *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group*, 515 U.S. 557, 579 (1995). “[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems.” *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); see *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 78 (1994).

3. Caraco has several adequate alternative remedies. FDA rejected Caraco’s request for a labeling carve-out based on its previous acceptance of Novo’s use code and denied Caraco’s administrative challenge to that use code. 21 C.F.R. § 314.53(f). While Caraco complains about the robustness of FDA’s review procedures, all agencies must make decisions on how to allocate their resources and expertise. Yet again, Caraco is really complaining about FDA—a non-party—rather than Novo. But Caraco never sought judicial review of FDA’s denial of administrative relief under the APA, even though the conceded *availability* of such review establishes another alternative remedy that could have vindicated the interests Caraco now seeks to assert. It similarly puts to

rest any argument that judicial review under the counterclaim is “necessary.” Caraco Br. 38.

4. Finally, the public interest favors Novo. Caraco suggests that allowing its counterclaim could lower the price of prescription medication by making generic drugs more widely available. Caraco Br. 44. This is, however, only one-half of the relevant inquiry. The Hatch-Waxman Act “strike[s] a balance between two *competing* policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.” *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008); *see also, e.g., Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) (“Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market”).

Without pharmaceutical innovation, the generic manufacturers would have nothing to copy. The patent system “encourage[s] the creation and disclosure of new, useful, and nonobvious advances,” in medicine as well as other areas, by providing inventors with “the exclusive right to practice the[ir] invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). Particularly in pharmaceutical development, where the costs of research and testing are so high, strong protection of patent rights is “necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market.” Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1617 (2003); *cf. Verizon Commc’ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 407 (2004).

Novo, which developed at great expense an innovative method for treating diabetes that has benefited millions of patients, has complied at all times with the detailed and reticulated regulatory regime governing prescription drugs. This meticulous compliance includes its current use code narrative, which tracks the FDA-mandated indication. A judicial order requiring Novo to change that narrative, as requested by Caraco, would upset the statutory balance to the detriment of the public.

CONCLUSION

The judgment of the court of appeals should be affirmed or, alternatively, vacated and remanded with instructions to dismiss for lack of jurisdiction.

Respectfully submitted.

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ADDENDUM

**Section 505 of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585,
codified as amended at 21 U.S.C. § 355, provides in relevant part regarding methods of use:**

Section 505(b)(1) [Listing]	Section 505(b)(2) [Certification]	Section 505(c)(2) [Listing]	Section 505(j)(2)(A)(vii) [Certification]	Section 505(j)(2)(A)(viii) [Section viii]	Section 505(j)(5)(C)(ii) [Counterclaim]
<p>The applicant shall 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 of using such drug and with respect to which a claim of patent infringement could reasonably be asserted</p>	<p>[An NDA] ... shall also include— (A) a certification ... with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval ... and (B) if with respect to the drug for which investigations ... were conducted information was filed ... for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, [the NDA shall contain] a statement that the method of use patent does not claim such a use.</p>	<p>If the patent information described in subsection (b) ... could not be filed ... [the NDA holder] ... shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted</p>	<p>[An ANDA] shall contain ... a certification ... with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval ... and for which information is required to be filed under subsection (b) or (c)</p>	<p>[I]f with respect to the listed drug ... information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, [the ANDA shall contain] a statement that the method of use patent does not claim such a use.</p>	<p>If an owner of the patent or the [ANDA] holder ... 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) of this section 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.</p>

Section 505 of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, codified as amended at 21 U.S.C. § 355, provides in relevant part regarding patent information:

<p align="center">Section 505(b) [Listing]</p>	<p align="center">Section 505(c)(2) [Listing]</p>	<p align="center">Section 505(j)(5)(C)(ii) [Counterclaim]</p>
<p>(1) The applicant shall file with the [NDA] 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 of 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. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences....</p> <p>(2) An application submitted under paragraph (1) ... shall also include—</p> <p>(A) a certification ... with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—</p> <p>(i) that such patent information has not been filed</p>	<p>If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.</p>	<p>If an owner of the patent or the [ANDA] holder ... 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) of this section on the ground that the patent does not claim either—</p> <p>(aa) the drug for which the application was approved; or</p> <p>(bb) an approved method of using the drug.</p>