No. __-____

In the Supreme Court of the United States

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

v.

NOVO NORDISK A/S AND NOVO NORDISK, INC., RESPONDENTS

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

When the Food & Drug Administration (FDA) approves a drug for multiple uses, the Hatch-Waxman Act allows generic drug makers to avoid contested patent litigation by marketing generic versions of the drug solely for non-patented uses. The FDA lacks the authority and expertise needed to verify the patent information submitted by name-brand drug companies, however, so it defers to their descriptions of the scope of their patents. Such companies can therefore block the approval of generic drugs by submitting overbroad patent descriptions to the FDA, effectively extending their patents to cover non-infringing uses.

To combat this problem, the Act allows a "counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information submitted by the holder * * * on the ground that the patent does not claim * * * an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). In a 2-1 decision that conflicts with this Court's precedents and recent D.C. Circuit authority, the Federal Circuit held that the counterclaim provision effectively authorizes only "delet[ing]" improperly listed patents, but not "correct[ing]" information that misrepresents the scope of the approved uses claimed by a patent. That ruling expressly invalidates longstanding FDA regulations defining "patent information," which the FDA deems "essential" to administering the Act, without seeking the agency's views. The question presented is:

> Whether this counterclaim provision applies where (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) the brand submits "patent information" to the FDA that misstates the patent's scope, requiring "correct[ion]."

PARTIES TO THE PROCEEDINGS

Petitioners are Caraco Pharmaceutical Laboratories, Ltd., a publicly traded company, and Sun Pharmaceutical Industries, Ltd., a publicly traded company that owns a majority of Caraco's shares. Sun has no parent corporation.

Respondents are Novo Nordisk A/S and Novo Nordisk, Inc. Upon information and belief, Novo A/S owns more than 10 percent of the stock of Novo Nordisk A/S and Novo A/S, in turn, is fully owned by the Novo Nordisk Foundation.

The amici curiae in support of rehearing or rehearing en banc below were the Generic Pharmaceutical Association; Apotex, Inc.; the Consumer Federation of America; the National Legislative Association on Prescription Drug Prices; Mylan Pharmaceuticals Inc.; and Teva Pharmaceuticals USA, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND REGULATIONS

OTHER AUTHORITIES

GLOSSARY OF ABBREVIATIONS

Act	Hatch-Waxman Act
ANDA	Abbreviated New Drug Application
Counterclaim	21 U.S.C. § 355(j)(5)(C)(ii)(I)
FDA	Food & Drug Administration
NDA	New Drug Application
Orange Book	FDA Orange Book Approved Products With Therapeutic Equivalence Evaluations
Paragraph IV	21 U.S.C. § 355(j)(2)(A)(vii)(IV)
Section viii	21 U.S.C. § 355(j)(2)(A)(viii)

INTRODUCTION

Petitioners ("Caraco") seek review of a splintered Federal Circuit decision raising issues of recurring importance under the Hatch-Waxman Act.[1] This ruling enables name-brand manufacturers to use their patents to block generic manufacturers from marketing drugs that *concededly* do not infringe.

The question presented is vitally important to the $300 billion pharmaceutical industry and the FDA, which administers the statute. In conflict with this Court's precedents and recent D.C. Circuit authority, the decision below effectively nullifies both a critical provision of the Act and related FDA regulations—which Congress ratified in 2003—without calling for the FDA's views. Each panel member, and the dissent from the denial of en banc review, recognized that the decision "tip[s] the [Act's] careful balance in the favor of pioneering manufacturers." Pet. 14a (Rader, J.); Pet. 20a-21a (Clevenger, J., concurring); Pet. 40a (Dyk, J., dissenting); Pet. 59a (Gajarsa and Dyk, JJ., dissenting from denial of rehearing). This extraordinary result compels review, particularly under a law designed to *expedite* generic competition.

Here is the problem. When a drug has multiple FDA-approved uses and a patent claims at least one, but not all, of those approved uses, "Section viii" of the statute allows generics to obtain FDA approval to market the drug with a "carve-out label" that omits

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[1] The "Hatch-Waxman Act" refers to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

reference to infringing uses. Pet. 6a. Caraco seeks FDA approval to market generic repaglinide—a diabetes drug manufactured by respondents ("Novo")—for two uses that Novo *concedes* do not infringe its patent. Every panel member agreed that Caraco qualifies for a Section viii carve-out label.

Over a forceful dissent, however, the Federal Circuit held that Novo could block approval of Caraco's product by deliberately providing the FDA with a description of its patent erroneously indicating that it *does* cover Caraco's proposed uses. Shortly after the FDA rejected Novo's challenge to Caraco's carve-out label, Novo submitted a newly broadened description of its patent to the agency. As the district court held, Novo's new description "seriously misrepresents" the patent's scope. Pet. 70a. But the FDA—which lacks the requisite legal authority and expertise to substantively review patents—defers to the brand's patent description, known as a "use code." Novo's newly minted use code thus caused the FDA to reverse itself and reject Caraco's carve-out label—thereby barring Caraco from marketing its drug for uses that everyone agrees are non-infringing.

The question presented boils down to whether the Act remedies such gamesmanship. It does. It authorizes counterclaims to "correct or delete the patent information submitted by the [patent] holder" whenever there is "an approved method of using the drug" that "the patent does not claim," and the brand's "patent information" is inaccurate, requiring "correct[ion]." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

Yet contrary to the Act's text, structure, legislative history, and interpretation by the FDA, a divided Federal Circuit panel held that Caraco has no rem-

edy. By the majority's lights, no counterclaim is available because (1) Novo's patent claims *one* approved use, even though it "does not claim" two *other* "approved method[s] of use"; and (2) the counterclaim is effectively limited to "delet[ing]" wrongly-listed patents, when Congress also authorized "correct[ing]" patent information. Pet. 12a. The majority reached this result by announcing that the phrase "an approved method of us[e]" *really* means "*any* approved method of us[e]." *Ibid.* But that rewriting of the Act violated this Court's precedents—not least because the word "any" appears elsewhere in the same provision. Moreover, the majority read the term "patent information" as limited to "an erroneous patent number or expiration date"—*i.e.*, to exclude "use codes"—invalidating the FDA's contrary interpretation, which Congress ratified. Pet. 16a.

Accordingly, brands may now craft highly generalized use codes (*e.g.*, "a method for treating diabetes"), which "effectively allows [them] to extend [their] monopol[ies] to unpatented uses." Pet. 62a (Gajarsa, J., dissenting). In other words, brands can "insulat[e] themselves from generic competition and render[] Section viii"—"a critical provision" that "facilitates the approval and marketing of lower-cost generic drugs for uses no longer protected by a patent"—"a dead letter." Pet. 62a, 59a. Not surprisingly, the FDA's counsel has publicly stated that, since the ruling below, a solution to the problem of overbroad use codes has eluded the agency.

If Hatch-Waxman is to be read as leaving generics without any remedy to address this manipulation of FDA approval, that result should come from a decision of this Court—not from a dubious Federal Circuit ruling that split three ways, conflicts with this

Court's precedents and D.C. Circuit authority, and threatens the FDA's administration of the Act. The petition should therefore be granted.

OPINIONS BELOW

The Federal Circuit's opinion (Pet. 1a-52a) is reported at 601 F.3d 1359. The Federal Circuit's decision denying rehearing and rehearing en banc (Pet. 53a-64a) is reported at 615 F.3d 1374. The relevant decisions of the District Court for the Eastern District of Michigan (Cohn, J.) (Pet. 65a-103a) are reported at 649 F.Supp.2d 661 and 656 F.Supp.2d 729.

JURISDICTION

The Federal Circuit entered judgment on April 14, 2010, and denied a timely rehearing petition on July 29, 2010. On October 18, 2010, the Chief Justice extended the time to petition for certiorari to December 23, 2010. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUORY AND REGULATORY PROVISIONS INVOLVED

Relevant statutory and regulatory provisions are set forth at Pet. 104a-210a.

STATEMENT

A. The structure of the Hatch-Waxman Act

The Hatch-Waxman Act governs FDA approval of new and generic drugs. 21 U.S.C. § 355. The Act is designed to "strike 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) (citations

and brackets omitted), cert. denied, 129 S. Ct. 1316 (2009). Because new drugs are often protected by patents, the Act stands at the intersection of patent law and the FDA drug approval process.

Notwithstanding the Act's importance, this Court has addressed its application just twice. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661 (1990). Moreover, the Court has never addressed the Act's provisions governing approval of generic marketing, at issue in hundreds of cases annually.

As detailed below, the Act provides different ways for generic manufacturers to obtain FDA approval to market generic drugs. Most relevant here are the "Paragraph IV" process, which facilitates resolution of patent infringement disputes between name-brand and generic companies; and the "Section viii" process, which avoids such litigation and speeds market entry when generics seek to sell drugs for uses *not* covered by any patent. In both instances, "Congress sought to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

1. Abbreviated New Drug Applications

To expedite FDA approval, the Act allows generic manufacturers to submit to the FDA an abbreviated new drug application (ANDA) instead of a full-blown new drug application (NDA). 21 U.S.C. § 355(j)(2)(A). An ANDA may rely on safety and efficacy studies previously submitted by brands. The timing of an ANDA's approval, however, depends largely on the scope of the patents covering the name-brand drug and, if necessary, resolution of litigation over patent infringement. Accordingly, NDA filings must identify

all non-process patents that arguably protect the new drug. *Id*. § 355(b)(1), (c)(2). The FDA lists these patents in its book of "Approved Products With Therapeutic Equivalence Evaluations"—the "Orange Book"—which alerts generics to the scope of claimed patent rights. Pet. 4a-5a.

a. Paragraph IV applications

As relevant here, the Act provides two distinct means of obtaining FDA approval of an ANDA. If a generic manufacturer seeks to market a drug arguably covered by an unexpired patent listed in the Orange Book, "the generic is generally required to certify that the patent * * * is invalid or will not be infringed by the sale or use of the [generic] drug." Pet. 24a. This is called a "Paragraph IV" certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[2]

The Act treats a Paragraph IV certification as an artificial act of patent infringement, permitting the brand to sue the generic. 35 U.S.C. § 271(e)(2).[3] If the generic wins and its ANDA otherwise qualifies, the FDA must approve the ANDA on the "date" when the district court enters judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(I). And if the generic is the first to file a Paragraph IV certification for that drug (a "first

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[2] Alternatively, a generic may certify that: (I) the required patent-related information has not been filed; (II) the patent has expired; or (III) the patent will soon expire. *Id*. § 355(j)(2)(A)(vii)(I-III).

[3] If the NDA holder does not sue within 45 days, the FDA may approve the ANDA; if the NDA holder sues, approval is automatically stayed for 30 months or until a court holds each listed patent not infringed or invalid, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii).

filer"), it receives 180 days of market exclusivity. *Id.* § 355(j)(5)(B)(iv).

b. Section viii applications

The Act also offers an alternative means of obtaining approval of an ANDA—a "Section viii" statement. "Section viii addresses scenarios where a patent claims at least one, but not all, approved methods of using a drug." Pet. 13a-14a. Section viii applies when the patent on a chemical compound used in a drug has expired, and the Orange Book lists a "method" patent—one covering a specific method of using the compound—that "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii); *Purepac Pharm. Co.* v. *Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

Section viii allows a generic to "submit a proposed label to the FDA that does not contain [*i.e.*, carves out] the patented method of using the listed drug." Pet. 5a.[4] By obtaining approval to "delet[e] patented use[s] from its proposed label," generics "avoid infringement." Pet. 60a.

Importantly, however, the FDA lacks both institutional "expertise in patent matters" and a "statutory basis" to interpret patents. *Applications for FDA Approval to Market a New Drug*, 68 Fed. Reg. 36676, 36682 (June 18, 2003). Thus, "[the FDA's] role in listing patents in the Orange Book is 'ministerial'; it simply lists the patent information that it receives from brand manufacturers, expecting those parties to

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[4] Normally, the generic's label must be identical to the brand's. 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 314.94(a)(8)(iv).

properly abide by the statutory and regulatory mandates." Pet. 60a-61a n.4.

This brand-authored patent information is known as a "use code narrative," or simply a "use code." Pet. 4a. "The FDA approves the section viii statement only where there is no overlap between the proposed carve-out label * * * and the [brand's] use code." Pet. 6a. Thus, accurate use codes are "essential to the [Act's] operation." Pet. 29a.

B. The Act's counterclaim provision and the *Mylan* decision

Aware of brands' efforts to "block generic competition by making unwarranted claims to patent coverage" (Pet. 25a), Congress enabled generics "in a Paragraph IV suit to assert a counterclaim challenging the accuracy of the 'patent information' submitted to the FDA" (Pet. 6a). As Congress provided:

> (I) In general.—If * * * the [NDA] 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 [ANDA] applicant, the [ANDA] 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.

21 U.S.C. § 355(j)(5)(C)(ii)(I).

This provision was not always part of the Act; and in 2002 the Federal Circuit ruled in *Mylan Pharma-*

ceuticals, Inc. v. *Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), that Hatch-Waxman did not authorize private actions to correct inaccurate patent listings. The generic there (Mylan) had filed a Section viii statement representing that a listed patent did not claim a use for which Mylan sought approval. When the FDA asked for clarification of the patent's scope, the brand responded that its patent *did* claim that use, prompting rejection of Mylan's Section viii statement. Mylan then sued, alleging that the brand's patent information was inaccurate. Describing Mylan's claim as "analogous to those barred in [a] long line of cases precluding private rights of action," the court rejected it. *Id.* at 1332. The decision, however, prompted both regulatory and legislative action.

C. The FDA's Regulations

The FDA acted first, amending its regulations in June 2003 to clarify the "need for accurate and detailed information related to the approved methods of use claimed in [listed] patent[s]." 68 Fed. Reg. at 36682. These "*Submission of Patent Information*" regulations contain special rules for method patents that claim one or more approved methods of using the listed drug. 21 C.F.R. § 314.53. Brands must submit a description of each approved method of using the drug (or, if appropriate, the labeled indication specifying the recommended use) claimed by its patent:

> (P) Information on each method-of-use patent including the following:
>
> > (1) Whether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted;

> (2) Identification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and
>
> (3) *The description of the patented method of use as required for publication*.

Id. § 314.53(c)(2)(ii)(P) (emphasis added).[5]

FDA "Form 3542," whereby NDA holders submit such patent descriptions, confirms that use codes must track the method patent's scope:

> The use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist * * * ANDA applicants in determining whether a listed method of use patent claims a use for which the * * * ANDA applicant is not seeking approval.

Pet. 211a-214a; 68 Fed. Reg. at 36682-36683.

Acting on comments from the Federal Trade Commission (FTC), the FDA also required brands to attest to the accuracy of patent information under penalty of perjury, cautioning them that knowingly filing false information violates 18 U.S.C. § 1001. 68 Fed. Reg. at 36686. But even criminal sanctions are insufficient to deter some companies. Accordingly, just months later, Congress undertook to "close loopholes in the law and end the abusive practices in the pharmaceutical industry * * * which have cost con-

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[5] Before 2003, the FDA merely requested a declaration that the NDA holder's patent covered a drug or approved use thereof. 59 Fed. Reg. 50338, 50363 (Oct. 3, 1994).

sumer billions," by allowing generics sued for infringement "to file a counterclaim to have the brand drug company * * * correct the patent information in FDA's Orange Book." 149 Cong. Rec. 31200 (Nov. 23, 2003) (Sen. Schumer).

Congress acted "with full awareness of the agency's interpretation of ['patent information']." Pet. 37a. The FDA's chief counsel twice testified concerning those regulations.[6] And as Senator Schumer, a leading sponsor, stated: "The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing, but it goes much further." *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hrg. Before S. Comm. on Judiciary*, 108th Cong. 19 (2003); accord 149 Cong. Rec. S8690 (daily ed. June 26, 2003) (Sen. Hatch); *id.* at S8197 (daily ed. June 19, 2003) (Sen. Frist). Thus, in late 2003—six months after the FDA published its final rule—Congress enacted the counterclaim provision quoted above, employing the term "patent information" defined in the regulations.

D. Novo's New Drug Application and Caraco's Abbreviated New Drug Application

Novo holds an NDA for repaglinide, a diabetes drug sold as PRANDIN. Novo's patent on the repaglinide compound expired in 2009. Pet. 7a.

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[6] *FTC Study: Generic Drug Entry Prior to Patent Expiration: Hrg. Before S. Comm. on Judiciary*, 108th Cong. 5-20 (June 17, 2003) (statement of D. Troy, Chief Counsel for FDA); *Examining the Senate And House Versions of the "Great Access to Affordable Pharmaceuticals Act": Hrg. Before S. Comm. on Judiciary*, 108th Cong. 7-10 (Aug. 1, 2003) (statement of D. Troy, Chief Counsel for FDA).

The patent-in-suit (the '358 patent), which expires in 2018, claims the use of "repaglinide in combination with metformin," another diabetes drug, to treat patients with type 2 diabetes. *Ibid.* This is one of three FDA-approved uses of repaglinide; the others include repaglinide by itself (monotherapy); and repaglinide combined with thiazolidinediones (TZDs). *Ibid.* But "Novo does not own patents claiming the other two approved methods of using repaglinide." Pet. 8a. And until 2009, Novo's use code described its patent as covering *only* the "use of repaglinide in combination with metformin to lower blood glucose." Pet. 45a.

In February 2005, Caraco became the first ANDA applicant seeking to sell generic repaglinide. *Ibid.* Because Caraco initially filed a Paragraph IV certification, its proposed label had to list all FDA-approved uses of repaglinide. *Supra* n.4. In June 2005, Novo sued Caraco for patent infringement.

E. Novo's revised use code and the FDA's ruling on Caraco's Section viii application

Novo originally alleged that any generic label that referenced the repaglinide-metformin combination would induce infringement. At the FDA's urging, however, Caraco invoked Section viii, "declaring that Caraco was not seeking approval for the repaglinide-metformin combination therapy" and asking to carve out of the label any reference thereto. Pet. 8a.[7]

Based on Novo's first use code, the FDA ruled that Caraco's carve-out label would be proper. Pet. 8a. But in "'response to th[is] section viii ruling,'" Novo

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[7] Caraco filed a "split certification"—a Paragraph IV certification as to the non-method claims and a Section viii certification as to the method claims. Pet. 45a n.16.

amended its code to read: "a method for improving glycemic control in adults with type 2 diabetes mellitus." Pet. 49a, 45a. As "Novo admitted," "[t]he FDA did not direct or request that Novo change its use code"; "nor was [this] required under FDA regulations." Pet. 47a-48a (citing Novo's counsel).[8]

Based on Novo's new use code, the FDA "reversed itself and rejected Caraco's proposed labeling carveout"—requiring Caraco to include the patented repaglinide-metformin combination on its label. Thus, by misrepresenting the scope of its patent, Novo manufactured a claim that Caraco's label would induce infringement—effectively extending its patent on the repaglinide *compound*, which expired in 2009, to *unpatented uses* of that compound until 2018.

Caraco thus filed a counterclaim, seeking partial summary judgment and an injunction. Noting that its use code "seriously misrepresents the approved method of use covered by" the '358 patent, the district court enjoined Novo to restore its original use code. Pet. 70a. Novo's new use code is "so broad as to incorrectly suggest that the '358 patent generically covers three (3) different FDA-approved methods of use of repaglinide," the court explained, when "the first two (2) uses are not covered." Pet. 68a. The parties then agreed to postpone trial on issues of patent validity and enforceability, pending resolution of Novo's appeal.[9]

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[8] The FDA requested a new *label* for Novo's product; the use code describes the *patent*, not the label. *Ibid*.

[9] After the ruling below, the parties tried those issues before Judge Cohn. The district court has not yet ruled, but the outcome will not affect the suitability of this case for certiorari. See *infra* Part I.

F. The Federal Circuit's divided ruling

In a ruling that spawned three opinions, a divided Federal Circuit panel (Rader, Clevenger, Dyk, JJ.) reversed.

First, reading the phrase "*an* approved method of use" to mean "*any* approved method of use," the majority (per Rader, J.) held that a counterclaim is available "only if the listed patent does not claim *any* approved methods of using the listed drug." Pet. 12a (emphasis added). Although the word "any" appears elsewhere in the same provision (§ 355(j)(5)(C)(ii)(II)), the court never discussed this language, finding "no ambiguity in the statut[e]." Pet. 12a. Second, the majority held that the term "patent information" is limited to "an erroneous patent number or expiration date" and "does not extend to the use code narrative." Pet. 15a-16a.

In Judge Rader's view, a generic can use "a Paragraph IV lawsuit" to prove that its "use will not overlap with * * * the patented use." Pet. 14a. But Judge Clevenger, who concurred, was "not as certain" that "Paragraph IV litigation will cleanly resolve the dispute." Pet. 19a. As he recognized, "Caraco can no longer assert that its proposed labeling does not infringe." Pet. 20a. And although he blamed the FDA for purportedly creating the problem—on the mistaken understanding that "FDA's request that Novo change its labeling" required changing the *use code*—he acknowledged that the outcome "upset the careful balance of interests" embodied in the Act. *Ibid.*

Judge Dyk dissented, explaining that "the text is clear" in light of "the overall operation of the statutory scheme." Pet. 41a. "[I]nterpreting 'an approved method' * * * to mean 'any' approved method," he ob-

served, is "fundamentally inconsistent with the Supreme Court's admonition * * * that '[u]ltimately, context determines meaning.'" Pet. 39a.

On the "patent information" issue, Judge Dyk believed the majority's reading was contrary to the text, the FDA's interpretation, and *Chevron*—"even if the language of the statute is ambiguous, and not (as I urge) plainly contrary to the majority's interpretation." Pet. 30a, 33a. Further, because "Congress utilized the FDA's interpretation of 'patent information' * * * with full awareness," he believed that interpretation was "binding." Pet. 37a-38a.

Judge Dyk also clarified that the FDA did not cause "Caraco's predicament"—citing Novo's admission that "FDA did not require [a new use code]" and explaining that "absolutely nothing in the statute or regulations * * * required Novo to change the use code to track [its label]." Pet. 47a-48a. But he agreed with Judge Clevenger that generics are "left without any remedy to correct an erroneous Orange Book listing" for "a method of use patent." Pet. 51a. Moreover, he found the majority's approach to be "notably inconsistent with the approach adopted by our sister circuit in another recent Hatch-Waxman Act case, *Teva Pharms. USA, Inc.* v. *Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010)." Pet. 51a.

G. The dissent from the denial of rehearing

Over Judges Gajarsa's and Dyk's dissent, en banc review was denied. As Judge Gajarsa explained, "[b]oth constructions" adopted by the majority—its "overly narrow construction of 'patent information' and [its] overly broad construction of 'an approved method of using the drug'"—"are irreconcilable with

pre-existing FDA regulations, the text of the [Act], and Congressional intent." Pet. 59a.

Furthermore, brands now have "every incentive to follow Novo's lead and draft exceedingly broad use codes"—thus "subverting Section viii carve-out statements." Pet. 62a, 60a. By "leav[ing] generic drug manufacturers without a remedy to challenge inaccurate listings with respect to method of use patents," Judge Gajarsa explained, the majority's ruling "render[s] section viii a dead letter." Pet. 59a, 62a.

Judge Gajarsa also objected that, "[w]ithout even requesting the views of the FDA, the majority opinion refuses to give effect to [its] interpretation of an important statutory term." Pet. 63a. This was "especially troubling given Congress's explicit approval of those regulations." *Ibid.*

In sum, holding "that counterclaim relief is not available because the [patent in suit] covered at least one approved use * * * effectively allows a patent holder to extend its monopoly to unpatented uses." Pet. 62a. This "absurd result * * * contravenes the intent of Congress in adopting the counterclaim"—"a critical provision of the [Act]." Pet. 63a, 59a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's fractured 2-1 ruling compels immediate review. The question presented is not only recurring, but critically important to the $300 billion pharmaceutical industry, to consumers needing low-cost drugs, and to the FDA—whose longstanding interpretation of "patent information" was ratified by Congress in 2003, but invalidated below without the agency's input. In one fell swoop, the Federal Circuit: read Section viii out of existence (Part I); overruled the FDA's definition of "patent information," ignoring *Chevron* and placing the FDA in an intractable administrative bind (Part II); created a critical inconsistency with the D.C. Circuit on how to read the counterclaim provision (Part III); and violated numerous precedents of this Court, including precedent interpreting Hatch-Waxman itself (Part IV). This Court's review is urgently needed.

I. The decision below threatens FDA approval for myriad generics that seek to market their products solely for non-patented uses under Section viii.

When Congress passed the Hatch-Waxman Act, it established two principal means of obtaining FDA approval to market generic drugs: Paragraph IV certifications, which assert that any Orange Book-listed patents are invalid or not infringed by the generic's product, prompting full-blown litigation; and Section viii statements, which seek to *avoid* such litigation where the generic asks to market its product solely for uses *not* covered by any patent. As Judges Dyk and Gajarsa understood, the decision below leaves generics "without any remedy to correct an erroneous Orange Book listing with respect to a method of use

patent"—"rendering Section viii a dead letter." Pet. 51a, 62a.

1. When a generic files a Paragraph IV certification, that filing constitutes an artificial act of patent infringement that obligates the brand either to sue or risk FDA approval of generic marketing. 35 U.S.C. § 271(e)(2). If the brand sues, FDA approval is stayed for 30 months or until the generic prevails—in which case the agency may approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Further, if the generic was the first filer, it receives 180 days of market exclusivity before other generics can go to market. *Id.* § 355(j)(5)(B)(iv). But generics must generally prevail in court to obtain FDA approval under Paragraph IV.

Section viii, by contrast, is designed to avoid litigation. It "facilitates the approval and marketing of lower-cost generic drugs for uses no longer protected by a patent." Pet. 59a. "[W]here a patent claims at least one, but not all, approved methods of using a drug" (Pet. 13a-14a), Section viii allows the generic to certify that the patent "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). The generic submits a carve-out label that does not refer to the patented uses (Pet. 6a); and if the FDA approves it, litigation is unnecessary. But even if it is the first Section viii filer, a generic cannot obtain 180 days of marketing exclusivity under Section viii.

Paragraph IV and Section viii thus offer tradeoffs. Prevailing in Paragraph IV suits holds the promise of a non-infringement or invalidity ruling—enabling the generic to sell its drug for *all* approved uses—and for first filers 180 days of marketing exclusivity. Section viii offers only the ability to market drugs for *some*

approved uses, with no prospect of marketing exclusivity. Yet section viii avoids the delays and "hazard[s] of sparking costly litigation." *Teva*, 595 F.3d at 1305. It is therefore "essential to the [Act's] operation." Pet. 29a.

2. "The majority opinion * * * eviscerates Section viii." Pet. 62a (Gajarsa, J., dissenting). It creates "every incentive" for brands "to follow Novo's lead and draft exceedingly broad use codes," "thereby insulating themselves from generic competition." *Ibid.*

First, the ruling forces generics to defend costly and protracted patent litigation, when they should be free to sell their drugs for non-infringing uses without setting foot in court. Still worse, generics must fight with one hand tied behind their backs. That is because the unavailability of Section viii requires generics to use the same label as the brand—which includes the patented use, and is by definition infringing.[10] Thus, to prevail in Paragraph IV litigation, generics that seek approval only for non-infringing uses must prove *invalidity*—a much higher burden—when they should not even have to litigate.

The ruling below therefore gives brands "the advantage of [stalling generic approval under Paragraph IV]" without "the disadvantage of [Section viii's carve-out label]"—which would preclude any showing of infringement. See *Eli Lilly*, 496 U.S. at 671-672. It is "most implausible that Congress" would intend this, and there is no evidence—let alone "strong evidence"—that it did. *Id.* at 672-673. Indeed, the majority's interpretation is "at odds with one of the most basic interpretive canons, that '[a] statute should be

[10] Caraco therefore stipulated to infringement.

construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'" *Corley* v. *United States*, 129 S. Ct. 1558, 1566 (2009).

It is no answer to say that some generics might overcome these hurdles, reaching the market by winning a Paragraph IV suit. Some may win, some may lose, but the point of Section viii is that *no* generic should have to litigate whether an unexpired method patent is valid whenever there are other approved and unpatented uses of the drug. Being forced to litigate is a direct affront to Congress's aim of speeding the introduction of generic drugs where, if a carve-out label *were* available, there could be no infringement. Yet the ruling below, and Novo's actions, force Caraco to litigate validity, greatly delaying Caraco's ability to sell *concededly* non-infringing drugs.[11]

Nor does a generic wrongly denied a carve-out label possess an adequate remedy in suing the FDA. Such a suit would likely fail, since the FDA lacks any "statutory basis for a substantive review of patents," and courts have repeatedly "upheld [the agency's] determination that [its] role with respect to patent listings is ministerial." 68 Fed. Reg. at 36683 (collecting decisions); accord Pet. 50a-51a. But again, subjecting generics to the delay and expense involved in bringing such suits undermines Section viii's purpose—*avoiding* litigation where non-infringement is indisputable. It also undermines the Act's ultimate goal:

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[11] That being forced to defend Paragraph IV litigation itself eviscerates Section viii is one of many reasons why review of this case is needed now, and why the interlocutory nature of the decision below should not stand in the way of certiorari.

"get[ting] generic drugs into the hands of patients at reasonable prices—fast." *Barr Labs.*, 930 F.2d at 76.

Second, by eliminating the Act's check on allowing brands to overstate their patents, the decision below "effectively allows a patent holder to extend its monopoly to unpatented uses." Pet. 62a. This would be problematical in any context, but it is especially troubling under Hatch-Waxman. In other markets, competitors that wish to sell allegedly infringing products can launch at risk and litigate later. But selling drugs requires FDA approval. *Eli Lilly*, 496 U.S. at 670-671. Thus, if brands can bottle up the approval process, generics are excluded from the market even absent risk of infringement (due to a carve-out label). The counterclaim serves as a critical check on such (well-documented) "gam[ing] of the system," but the ruling below renders that provision "a virtual nullity." Pet. 59a; see Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* 46, 52 (July 2002) (identifying multiple "categories of patents listed in the Orange Book rais[ing] significant listability issues").

3. This problem is not isolated. It arises every time generics file Section viii ANDAs for drugs with more than one FDA-approved use.

This is increasingly common, as patents on blockbuster drug compounds expire and brands seek to extend their monopolies via method patents—a process known as "evergreening." Bouchard, et al., *Empirical Analysis of Drug Approval-Drug Patenting Linkage for High-Value Pharmaceuticals*, 8 Nw. J. Tech. & Intel. Prop. 174, 182 (2010) ("that pharmaceutical companies are focusing more on evergreening older products and on incremental drug development rather

than breakthrough drug development suggests that firms may be leveraging legal loopholes favouring enhanced patent protection for drugs with low innovative value"). And consumers are directly affected. As the Department of Health and Human Services notes: "In 2010 to 2014, a number of blockbusters are projected to go off patent," and "[t]he greatest and most certain potential for increased savings [to consumers] * * * lies in the increased availability of generic drugs through patent expirations." *ASPE Issue Brief: Expanding the Use of Generic Drugs* 2, 13 (Dec. 1, 2010).[12]

The importance of the question presented is confirmed by recent statistical analysis. For example, in the wake of "the hubbub over Patent Use Codes ('PUCs') since the [decision below]," one study "analyze[d] the growth of [use codes]." Karst, *Analysis Shows Patent Use Codes Have Doubled Since August 2003* (July 8, 2010).[13] As this study found, only "25 [use codes] were listed" in the Orange Book in 1988, when use codes were initiated. *Ibid.* But today, "a grand total of 1062 [use codes]" have been listed; and "532 new [use codes] have been designed by NDA holders" since 2003. *Ibid.* "[A]lthough free to use 'old' [use codes]," brands "appear to be favoring the creation of new [ones]," which lets them "tailor" the code to their liking. *Ibid.*

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[12] Available at: http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf.

[13] Available at: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/07/analysis-shows-patent-use-codes-have-doubled-since-august-2003--by-kurt-r-karst-httpwwwhpmcomvattorneycfmrid22.html.

The number of new use codes created by brands has doubled since 2003. *Ibid.* And there is every reason to expect use codes to grow exponentially if the decision below is left undisturbed. As Judge Gajarsa observed, brands "have found another way to game the system"—"by submitting overbroad and inaccurate use codes." Pet. 60a. "With the majority's blessing [brands] now have every incentive to follow Novo's lead"—"subverting Section viii carve-out statements" and "rendering Section viii a dead letter." Pet. 60a, 62a.

Not surprisingly, the Federal Circuit's ruling "has grabbed the attention of the drug industry"—a $300 billion industry. Sandburg, *Patent Use Codes May Still Block Generics as FDA Looks for Alternatives*, The Pink Sheet 18 (Oct. 18, 2010); Clinton & Mozeson, *The Pharm Exec 50* 71, Pharmaceutical Executive (May 2010). As one leading practitioner, who "emphasized the significance of the Novo case," noted: "'This is an issue that is reverberating through the industry and through all our practices.'" Sandburg, *supra*, at 18; see also Sandburg, *"The Next Best Way to Block Generics" May Be Novo's Patent Use Code Switch*, The Pink Sheet 28-29 (June 7, 2010).

Review is therefore needed *now*.

II. By invalidating the FDA's "patent information" regulations, the ruling below undercut the FDA's ability to administer the Act.

Review is likewise warranted because the Federal Circuit's ruling threatens the FDA's administration of the Act. Without soliciting the agency's views, the court invalidated pre-existing regulations governing the submission of "patent information"—regulations Congress ratified in 2003. That throws a wrench in

the FDA's ability to enforce provisions "essential to the [Act's] operation." Pet. 29a. And the FDA's counsel has publicly cited these enforcement problems, confirming the urgency of review.

1. In 2003, when considering how to implement the Act's "patent information" requirement, the FDA took extensive public comments and considered three main responses to the use code problem. *First*, it considered substantively reviewing use codes, by means "rang[ing] from hiring patent lawyers" to "development of a full administrative hearing process." 68 Fed. Reg. at 36683. *Second*, it considered "permit[ting] each ANDA * * * applicant to make its own independent decision on whether a listed method-of-use patent claims the use for which the ANDA applicant seeks approval." *Id.* at 36682. *Third*, it considered "requir[ing] the NDA applicant * * * to identify specifically the approved uses claimed by the method of use patent"—the approach ultimately adopted. *Ibid.*

The FDA favored the third approach for several reasons. For instance, it lacked any "statutory basis" for conducting substantive patent analysis. *Id.* at 36683. The Act imposes "short time frames" for publishing Orange Book listings, and these mandates "do not contemplate a substantive agency review of the scope of the patent." *Ibid.* Further, the FDA "lack[s] both the resources and the expertise to resolve [patent] matters." *Ibid.* Indeed, "[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"—since they "have the experience, expertise, and authority." *Ibid.*

Deferring to *generics'* Section viii submissions, by contrast, could create inappropriate incentives in the opposite direction. If generics "could always avoid the possibility of a 30-month stay [of FDA approval] by asserting in a section viii statement that certain labeling for which the applicant is seeking approval is not protected by a listed method-of-use patent," "there would be little reason for any [ANDA] applicant to submit a paragraph IV certification for a method-of-use patent." *Id.* at 36682. Furthermore, requiring brands to submit use code information is "more efficient and accurate," since brands have better access to relevant information. *Id.* at 36683.

Whatever approach it took, however, the FDA was clear that "accurate and detailed information related to the approved methods of use" was "essential" to fulfilling its statutory duty to "expedite [its] review of ANDA * * * applications that do not seek approval for all the approved uses." 68 Fed. Reg. at 36682, 36685. Citing the "case law" and prior "questions about what aspects of the approved drug was claimed by a listed use patent," the FDA recognized that "submission of inappropriate patent information" had "led to confusion and then to litigation over an ANDA applicant's obligation to submit either a paragraph IV certification * * * or a 'section viii' statement." *Id.* at 36682. "To effectively implement the [Paragraph IV] certification and section viii statement provisions," the FDA concluded, "it is necessary that an NDA holder submit more specific information on the approved methods of use protected by a submitted patent. *Only with this information* can we determine what submission is required of [generics]." *Id.* at 36682, 36683 (emphasis added). The final rule therefore required

brands to submit use code information. 21 C.F.R. § 314.53(c)(2)(ii)(P)(1).

Congress not only ratified the FDA's approach; it went "much further," "provid[ing] a critical complement to the work the FDA has done in clarifying its regulations on patent listing" by empowering courts to resolve disputes concerning overbroad use codes. *Barriers to Entry Hearing, supra* , at 19.

2. The ruling below ignores all of this, sending the FDA back to square one. "Patent information" is now limited to the "patent number or expiration date," and the counterclaim is limited to "suits to correct or delete" such numbers and dates. Pet. 15a-16a. This reading, however, deprives the agency of information it "must have" to "expedite [its] review of ANDA * * * applications that do not seek approval for all the approved uses." 68 Fed. Reg. at 36682. Whereas the FDA's 2003 changes sought to "reduce confusion and help curb [brands'] attempts to take advantage of this [approval] process" (*ibid.*), invalidating those changes will have the opposite effect.

Since the decision below, while "the FDA is assessing ways to alter how it handles patent use codes following charges they are being used to derail the approval of generics," "a straightforward solution so far has eluded the agency." Sandburg, *supra*, at 18. Indeed, the FDA's own counsel has publicly cited "the significance of the case" and expressed concern about the enforcement problems it creates. *Ibid.* As Elizabeth Dickinson, senior counsel in the FDA's Office of Chief Counsel, recently explained, the difficulty created by the Federal Circuit "is going to be complicated to resolve." *Ibid.* As she recounted, the FDA is considering "the best way forward," but the alterna-

tive approaches have drawbacks and implementing them is "a recipe for marketplace confusion, in addition to complications in terms of intellectual property rights." *Ibid*.

FTC Commissioner Thomas Rosch has likewise cited the decision, stating that Judge Dyk's dissent "took a view that was more consistent with promoting competition."[14] As these statements of public officials confirm, review is needed now.

III. The decision below is inconsistent with recent D.C. Circuit precedent.

Review is also warranted because, as Judge Dyk noted, the ruling below is "notably inconsistent with the approach adopted by [the D.C. Circuit] in another recent Hatch-Waxman case, *Teva Pharmaceuticals USA, Inc.* v. *Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010)." Pet. 51a.

Teva analyzed a Hatch-Waxman provision allowing generics to *forfeit* their 180-day exclusivity rights. The FDA argued that Hatch-Waxman allows *brands* to trigger forfeiture when generics do not market their products within a certain time after "patent information * * * is withdrawn by the [brand]." 21 U.S.C. § 355(j)(5)(D)(i)(I). Under this view, "after a generic has filed a paragraph IV certification," the brand may "announce that in fact the challenged patent is not one that protects the drug," and "ask the FDA to 'delist' the patent, thus purporting to pull the

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[14] *The Antitrust/Intellectual Property Interface: Thoughts on How To Best Wade Through the Thicket in the Pharmaceutical Context Before the World Generic Medicine Congress* 13 (Nov. 17, 2010), available at: http://www.ftc.gov/speeches/rosch/101117roschworldspeech.pdf.

rug from under the paragraph IV certification." 595 F.3d at 1305.

The FDA approved this maneuver, but the D.C. Circuit rejected it, holding that a brand cannot "unilaterally deprive the generic of its exclusivity." *Id*. at 1317. In support, the court cited both the counterclaim provision and the overall "statutory structure." *Id*. at 1315, 1316.

"*The FDA may not * * * change the incentive structure adopted by the Congress*," the court explained, "for the agency is bound not only by the ultimate purposes Congress has selected but by the means it has deemed appropriate." *Id*. at 1316 (quotation omitted). Finding "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger [forfeiture] by withdrawing a challenged patent, outside the counterclaim scenario," the court held that "[n]o forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement." *Id*. at 1317. This result promoted Hatch-Waxman's purpose of providing generics "'the certainty of receiving a period of marketing exclusivity.'" *Id*. at 1316 (citation omitted).

The decision below is in serious tension with *Teva*, which turns on the counterclaim's role in providing "certainty" for generics. Like the brand in *Teva*, Novo seeks "to pull the rug from under" Caraco's Section viii statement. The difference is that here the brand maneuver was not *de-listing* the patent, but *changing its description*. And it worked. The FDA reversed itself and rejected Caraco's carve-out label.

In holding that no counterclaim is available, the majority below not only flouts the counterclaim's text, which allows generics both to "correct" *and* "delete" patent information (21 U.S.C. § 355(j)(5)(C)(ii)(I)); it also "*change*[*s*] *the incentive structure adopted by the Congress*." 595 F.3d at 1316. Courts are "bound not only by the ultimate purposes Congress has selected" (providing certainty), but "by the means it has deemed appropriate" (providing a counterclaim to "correct" patent information). *Ibid.* And this is especially clear absent any "cogent reason why Congress might have" precluded brands from improperly listing patents, but not from describing them too broadly—either way, extending them beyond their scope.

The inconsistency between *Teva* and the ruling below—on a matter of great importance to the FDA, industry, and consumers—confirms the need for review.

IV. Certiorari is warranted because the panel's splintered decision rewrites a key provision of the Hatch-Waxman Act.

In addition to nullifying Section viii and the FDA's "patent information" regulations—inviting manipulation of FDA drug approval and delaying competition—the statutory construction employed below violates myriad precedents of this Court. *First*, it substitutes the word "any" for "an"—rewriting the text, which authorizes counterclaims whenever there is "an approved method of using the drug" that the listed patent "does not claim." *Second*, it ignores the FDA's definition of "patent information," which Congress ratified and in all events warrants *Chevron* deference. These errors—on a recurring issue "essential to the [Act's] operation" (Pet. 29a)—underscore the importance of review.

A. The majority misconstrued the Act's plain text and ignored the cardinal rule that statutory language must be read in context.

1. As countless decisions hold, "'[t]here is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has * * * specifically enacted.'" *Lamie* v. *United States Trustee*, 540 U.S. 526, 538 (2004) (citation omitted). Yet the majority below rewrote the statute by "read[ing] 'an approved method' as 'any approved method.'" Pet. 12a. That was flatly incorrect, particularly in light of "the structure of the * * * Act taken as a whole." *Eli Lilly*, 496 U.S. at 669.

Novo admits that there is "an approved method of using the drug" that its patent "does not claim." Yet the majority ignored this sensible reading of the plain text. Instead, it "detect[ed] no ambiguity" because, "[w]hen an indefinite article is preceded and qualified by a negative, standard grammar generally provides that 'a' means 'any.'" Pet. 12a.

The majority believed that substituting "any" for "an" left the Act unchanged. But the fact that "an," when qualified by a negative, *can* mean "any" does not mean it *generally* means "any." As Judge Dyk noted, the majority invoked *secondary* definitions of "an." Pet. 41a. And as one leading commentator on English usage has observed, use of "any" in "negative assertions * * * creates an *emphatic* negative, meaning 'not at all' or 'not even one.'" Garner, *A Dictionary of Modern American Usage* 45 (1998) (emphasis added). Indeed, "any" is "an expansive word" demanding an "expansive reading." *New York* v. *EPA*, 443 F.3d 880, 887 (D.C. Cir. 2006). Inserting "any"

into the text, therefore, was not a neutral interpretive decision; it changed the statute's meaning. Moreover, as discussed below, Congress used "any" elsewhere in the same provision, confirming that it did *not* intend "an" to mean "any" here.

2. This reveals the deeper problem with the ruling below: It ignores the cardinal rule that "[u]ltimately, context determines meaning." *Johnson* v. *United States*, 130 S. Ct. 1265, 1270 (2010). It is a "fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used." *Deal* v. *United States*, 508 U.S. 129, 132 (1993). By ignoring this principle, the majority ran through no fewer than five contextual "stop signs."

First, the phrase "an approved method" appears in a provision entitled "[c]ounterclaim to infringement action," which affords relief to a generic able to show that "the patent does not claim" a certain method of use. By design, this provision asks not whether the *brand* can show that its patent *claims* "an approved method," but whether the *generic* can point to "an approved method" that the patent "*does not* claim." This error led the majority to read the statute backwards—as if the brand raised the counterclaim. That violated this Court's teaching that, "'[i]n ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.'" *Household Credit Servs.* v. *Pfennig*, 541 U.S. 232, 239 (2004).

An illustration confirms this. Suppose A writes to B with news that she had another child. In relating

the challenges of having more children, A adds that "my taxes are higher than they should be because I did not claim an exemption." Read in context, this statement does not suggest that A did not claim *any* exemption—only that she did not claim an exemption *for the latest child*. If B ignored the context and concluded that A did not claim *any* exemptions, we would not say A's use of the phrase "did not claim an exemption" was ambiguous. We would say B read it in isolation. The same is true of the majority's reading of "an approved method."

Second, to read "an" as "any" is particularly inappropriate given that "any" appears elsewhere in the same provision. 21 U.S.C. § 355(j)(5)(C)(ii)(II) ("any civil proceeding"). So "Congress knew how" to express other meanings. *Central Bank* v. *First Interstate Bank*, 511 U.S. 164, 176-177 (1994). And as the bill's lead sponsor explained: "[T]o close the loopholes * * * the devil is in the details. * * * Change an 'and' to an 'a,' to a 'the' and you go from huge savings to huge costs." *Hrg. Before Cmte. on Judiciary*, *supra*, 108 Cong. 15 (Sen. Schumer).

Third, the Act authorizes counterclaims "to *correct or* delete patent information," but the majority "render[ed] superfluous" the term "correct." See *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 112 (1991). That is, brands may list only patents that claim the drug or an approved method of using it; and under the majority's view, a counterclaim is available only where the patent claims *neither*—the problem in *Mylan*. But in cases like *Mylan*, the patent should not have been listed *at all*, and the proper remedy is "deleting" it. Pet. 32a (Dyk, J., dissenting).

Thus, "[v]iewing [Congress's] overruling of *Mylan* as limited to complete delisting would be inconsistent with the explicit statutory language, which provides for correction of Orange Book information" as well. *Ibid.* And even if "[*Mylan*] prompted the *proposal* of [the counterclaim provision]," "whether that alone accounted for its *enactment* is quite a different question." *Eli Lilly*, 496 U.S. at 670. The counterclaim provision's broad text confirms that Congress meant to close other "loopholes in the law and end abusive practices * * * by allowing a generic applicant * * * to file a counterclaim to * * * correct the patent information." 149 Cong. Rec. 31200 (2003) (Sen. Schumer).

Fourth, Section viii and the counterclaim provision work together and use similar language—one refers to a patent that "does not claim *a* use" approved for the branded drug, the other to a patent that "does not claim *an* approved method of us[e]." There is no reason to read these provisions inconsistently, such that the counterclaim means "*any*" use and Section viii means "*a*" use.

Finally, even if the Act were viewed as reflecting "legislative imprecision" (*Eli Lilly*, 496 U.S. at 679), there is no reason why Congress would want courts to "delete" misleading patent information when brands' patents claim *no* approved use, but not to "correct" misleading patent descriptions used to block marketing for *some subset of* non-infringing uses. Under this Court's Hatch-Waxman precedent, it takes "strong evidence to persuade [the Court] that" Congress "should enact provisions" that "create an effective extension of the patent term." *Id.* at 670, 672, 673. Such evidence of "implausible substantive intent" is lacking here. *Id.* at 679. And that is especially clear when the counterclaim is read in light of Section viii

and "the structure of the 1984 Act taken as a whole." *Id*. at 669.

B. In contravention of *Chevron*, the majority erroneously invalidated the FDA's settled interpretation of "patent information."

The majority's ruling that the Act's undefined use of "patent information" is limited to "the patent number and expiration date," not "use codes" (Pet. 15a-16a) is also contrary to the FDA's considered interpretation—and violates *Chevron* v. *NRDC, Inc*., 468 U.S. 867 (1984).

In 2003, the "FDA promulgated a regulation [entitled '*Submission of Patent Information*'] * * * requir[ing] a [brand] to submit not only the patent number and the expiration date, but also the use code narratives." Pet. 16a. Congress then acted "with full awareness of the agency's interpretation," yet the majority ignored this "compelling evidence of legislative adoption." Pet. 37a & n.11.

The majority dismissed the fact that the FDA defined "patent information" before the counterclaim was enacted as an "'opaque timing observation[].'" Pet. 16a. But there was nothing opaque about it. If Congress meant to overrule the published definition of "patent information," it would have said so. "Congress * * * does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not * * * hide elephants in mouseholes." *Whitman* v. *Am. Trucking Ass'ns, Inc*., 531 U.S. 457, 468 (2001). The counterclaim thus *implements* the FDA's definition.

Even apart from *Chevron*, the FDA's interpretation is correct. By filing a counterclaim, what a generic can "correct or delete" is "patent information

submitted by the holder under [§ 505](b) or (c)." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Because § 505(b) and (c) mention only the patent number and expiry, the majority read "patent information" as limited to those items. But this rewrites the text, which speaks of "patent information *submitted* * * * *under* subsection (b) or (c)," not "patent information *referenced in*" those subsections.

By using the term "under," Congress anticipated that the agency would require additional patent information to administer the statute. And as the FDA stated shortly before Congress acted, "accurate and detailed information related to the approved methods of use" is "essential" to its ability to "expedite [its] review of ANDA * * * applications that do not seek approval for all the approved uses"—a statutory mandate. 68 Fed. Reg. at 36682, 36685. Far from being "at odds with the [statute's] plain language" (Pet. 16a), the FDA's interpretation tracks it. But at a minimum, its interpretation is reasonable, warranting *Chevron* deference. Pet. 33a-36a.

In sum, the majority failed to see that "[s]licing a statute into phrases while ignoring their contexts—the surrounding words, the setting of the enactment, the function a phrase serves in the statutory structure—is a formula for disaster." *Herrmann* v. *Cencom Cable Assocs.*, 978 F.2d 978, 982 (7th Cir. 1992). This Court's review is needed to avert that disaster.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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