SUPREME COURT OF THE UNITED STATES

No. 10–844

CARACO PHARMACEUTICAL LABORATORIES, LTD., ET AL., PETITIONERS *v.* NOVO NORDISK A/S ET AL.

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

[April 17, 2012]

JUSTICE KAGAN delivered the opinion of the Court.

When the Food and Drug Administration (FDA) evaluates an application to market a generic drug, it considers whether the proposed drug would infringe a patent held by the manufacturer of the brand-name version. To assess that matter, the FDA requires brand manufacturers to submit descriptions of the scope of their patents, known as use codes. The FDA does not attempt to determine if that information is accurate. Rather, the FDA assumes that it is so and decides whether to approve a generic drug on that basis. As a result, the breadth of the use code may make the difference between approval and denial of a generic company's application.

In this case, we consider whether Congress has authorized a generic company to challenge a use code's accuracy by bringing a counterclaim against the brand manufacturer in a patent infringement suit. The relevant statute provides that a generic company "may assert a counterclaim seeking an order requiring the [brand manufacturer] to correct or delete the patent information [it] submitted . . . under [two statutory subsections] on the

ground that the patent does not claim . . . an approved method of using the drug." 117 Stat. 2452, 21 U. S. C. §355(j)(5)(C)(ii)(I). We hold that a generic manufacturer may employ this provision to force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using the drug in question.

I

A

The FDA regulates the manufacture, sale, and labeling of prescription drugs under a complex statutory scheme. To begin at the beginning: When a brand manufacturer wishes to market a novel drug, it must submit a new drug application (NDA) to the FDA for approval. The NDA must include, among other things, a statement of the drug's components, scientific data showing that the drug is safe and effective, and proposed labeling describing the uses for which the drug may be marketed. See §§355(b)(1), (d). The FDA may approve a brand-name drug for multiple methods of use—either to treat different conditions or to treat the same condition in different ways.

Once the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version pursuant to legislation known as the Hatch-Waxman Amendments. See Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. Those amendments allow a generic competitor to file an abbreviated new drug application (ANDA) piggybacking on the brand's NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug. See §§355(j)(2)(A)(ii), (iv). As we have previously recognized, this process is designed to speed the introduction of low-cost generic drugs to market. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 676 (1990).

Because the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug. Those patents come in different varieties. One type protects the drug compound itself. Another kind—the one at issue here—gives the brand manufacturer exclusive rights over a particular method of using the drug. In some circumstances, a brand manufacturer may hold such a method-of-use patent even after its patent on the drug compound has expired.

To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents. The statute mandates that a brand submit in its NDA "the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug." §§355(b)(1). And the regulations issued under that statute require that, once an NDA is approved, the brand provide a description of any method-of-use patent it holds. See 21 CFR §§314.53(c)(2)(ii)(P)(3), (e) (2011). That description is known as a use code, and the brand submits it on FDA Form 3542. As later discussed, the FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply. It simply publishes the codes, along with the corresponding patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations).

After consulting the Orange Book, a company filing an ANDA must assure the FDA that its proposed generic drug will not infringe the brand's patents. When no patents are listed in the Orange Book or all listed patents have expired (or will expire prior to the ANDA's approval), the generic manufacturer simply certifies to that effect.

See 21 U. S. C. §§355(j)(2)(A)(vii)(I)–(III). Otherwise, the applicant has two possible ways to obtain approval.

One option is to submit a so-called section viii statement, which asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents. See §355(j)(2)(A)(viii). A section viii statement is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. If the ANDA applicant follows this route, it will propose labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use. See 21 CFR §314.94(a)(8)(iv). The FDA may approve such a modified label, see §314.127(a)(7), as an exception to the usual rule that a generic drug must bear the same label as the brand-name product, see 21 U. S. C. §§355(j)(2)(A)(v), (j)(4)(G). FDA acceptance of the carve-out label allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents.

Of particular relevance here, the FDA will not approve such an ANDA if the generic's proposed carve-out label overlaps at all with the brand's use code. See 68 Fed. Reg. 36682–36683 (2003). The FDA takes that code as a given: It does not independently assess the patent's scope or otherwise look behind the description authored by the brand. According to the agency, it lacks "both [the] expertise and [the] authority" to review patent claims; although it will forward questions about the accuracy of a use code to the brand,[1] its own "role with respect to patent listing is

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[1] Under the FDA's regulations, any person may dispute the accuracy of patent information listed in the Orange Book by notifying the agency in writing. See 21 CFR §314.53(f). The FDA will then request that the brand verify the information, but will make no changes "[u]nless the [brand] withdraws or amends" the listing. *Ibid.*

ministerial." *Id.,* at 36683; see *ibid.* ("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").[2] Thus, whether section viii is available to a generic manufacturer depends on how the brand describes its patent. Only if the use code provides sufficient space for the generic's proposed label will the FDA approve an ANDA with a section viii statement.

The generic manufacturer's second option is to file a so-called paragraph IV certification, which states that a listed 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)(IV). A generic manufacturer will typically take this path in either of two situations: if it wants to market the drug for all uses, rather than carving out those still allegedly under patent; or if it discovers, as described above, that any carve-out label it is willing to adopt cannot avoid the brand's use code. Filing a paragraph IV certification means provoking litigation. The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue. See 35 U. S. C. §271(e)(2)(A). Assuming the brand does so, the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed. See 21 U. S. C. §355(j)(5)(B)(iii). Accordingly, the paragraph IV process is likely to keep the generic drug off the market for a lengthy period, but may eventually enable the generic company to market its drug for all approved uses.

In the late 1990's, evidence mounted that some brands

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[2] Several courts have affirmed the FDA's view of its ministerial role. See, *e.g., Apotex, Inc.* v. *Thompson*, 347 F. 3d 1335, 1349 (CA Fed. 2003); *aaaiPharma* v. *Thompson*, 296 F. 3d 227, 242–243 (CA4 2002). That question is not before us, and we express no view on it.

were exploiting this statutory scheme to prevent or delay the marketing of generic drugs, and the Federal Trade Commission (FTC) soon issued a study detailing these anticompetitive practices. See FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, pp. iii–vi (July 2002) (hereinafter FTC Study). That report focused attention on brands' submission of inaccurate patent information to the FDA. In one case cited by the FTC, *Mylan Pharmaceuticals, Inc.* v. *Thompson*, 268 F. 3d 1323 (CA Fed. 2001), a brand whose original patent on a drug was set to expire listed a new patent ostensibly extending its rights over the drug, but in fact covering neither the compound nor any method of using it. The FDA, as was (and is) its wont, accepted the listing at its word and accordingly declined to approve a generic product. The generic manufacturer sued to delete the improper listing from the Orange Book, but the Federal Circuit held that the Hatch-Waxman Amendments did not allow such a right of action. See *id.,* at 1330–1333. As the FTC noted, that ruling meant that the only option for generic manufacturers in Mylan's situation was to file a paragraph IV certification (triggering an infringement suit) and then wait out the usual 30-month period before the FDA could approve an ANDA. See FTC Study 40–45.

Congress responded to these abuses by creating a mechanism, in the form of a legal counterclaim, for generic manufacturers to challenge patent information a brand has submitted to the FDA. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2452. The provision authorizes an ANDA applicant sued for patent infringement to

> "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of §355] on the ground that the patent does not claim

either—

"(aa) the drug for which the [brand's NDA] was approved; or

"(bb) an approved method of using the drug." 21 U. S. C. §355(j)(5)(C)(ii)(I).

The counterclaim thus enables a generic competitor to obtain a judgment directing a brand to "correct or delete" certain patent information that is blocking the FDA's approval of a generic product. This case raises the question whether the counterclaim is available to fix a brand's use code.

B

The parties to this case sell or seek to sell the diabetes drug repaglinide. Respondents (collectively Novo) manufacture Prandin, the brand-name version of the drug. The FDA has approved three uses of Prandin to treat diabetes: repaglinide by itself; repaglinide in combination with metformin; and repaglinide in combination with thiazolidinediones (TZDs). Petitioners (collectively Caraco) wish to market a generic version of the drug for two of those uses.

Novo originally owned a patent for the repaglinide compound, known as the '035 patent, but it expired in 2009. In 2004, Novo also acquired a method-of-use patent for the drug, called the '358 patent, which does not expire until 2018. That patent—the one at issue here—claims a "method for treating [diabetes by] administering . . . repaglinide in combination with metformin." 601 F. 3d 1359, 1362 (CA Fed. 2010). Thus, Novo currently holds a patent for one of the three FDA-approved uses of repaglinide—its use with metformin. But Novo holds *no* patent for the use of repaglinide with TZDs or its use alone.

In 2005, Caraco filed an ANDA seeking to market a generic version of repaglinide. At that time, the Orange Book entry for Prandin listed both the '035 patent (the

drug compound) and the '358 patent (the use of the drug with metformin). Caraco assured the FDA that it would not market its generic drug until the '035 patent expired, thus making that patent irrelevant to the FDA's review of the ANDA. Caraco filed a paragraph IV certification for the remaining, '358 patent, stating that it was "invalid or [would] not be infringed." §355(j)(2)(A)(vii)(IV); see *supra,* at 5. In accord with the patent statute, Novo treated this filing as an act of infringement and brought suit.

When Caraco filed its ANDA, Novo's use code for the '358 patent represented that the patent covered "'[u]se of repaglinide in combination with metformin to lower blood glucose.'" 601 F. 3d, at 1362–1363. The FDA therefore advised Caraco that if it did not seek to market repaglinide for use with metformin, it could submit a section viii statement. That would allow Caraco, assuming its ANDA was otherwise in order, to market its generic drug for the other two uses. Caraco took the FDA's cue and in 2008 submitted a section viii statement, with proposed labeling carving out Novo's patented metformin therapy. See App. 166–176.

Before the FDA took further action, however, Novo changed its use code for the '358 patent. The new use code describes "'[a] method for improving glycemic control in adults with type 2 diabetes.'"[3] 601 F. 3d, at 1363. Because that code indicates that the '358 patent protects all three approved methods of using repaglinide to treat diabetes, Caraco's proposed carve-out of metformin therapy was no longer sufficient; even with that exclusion,

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[3] Novo asserts that it made the change so that its use code would mirror its label, which the FDA had just asked it to alter. See Brief for Respondents 14. But the FDA, in calling for new labeling, neither requested nor required Novo to amend its use code. And indeed, Novo's counsel conceded before the Federal Circuit that Novo modified its use code in part as "'a response to the [FDA's] section viii'" suggestion. 601 F. 3d, at 1380–1381.

Caraco's label now overlapped with Novo's use code on the other two uses. And Caraco could not carve out those uses as well, because at that point nothing would be left for it to market. The FDA has approved repaglinide for only three uses, and Novo's use code encompassed them all. The FDA accordingly informed Caraco that it could no longer employ section viii to bring its drug to market.

Caraco responded to Novo's new, preclusive use code by filing a statutory counterclaim in the ongoing infringement suit. The counterclaim sought an order requiring Novo to "correct" its use code "on the ground that [the '358] patent does not claim" two approved methods of using repaglinide—alone and in combination with TZDs. §355(j)(5)(C)(ii)(I); see *supra,* at 6–7. That order would permit the FDA to accept Caraco's proposed carve-out label and approve the company's ANDA. The District Court granted summary judgment to Caraco, enjoining Novo to "correct . . . its inaccurate description of the '358 patent" by submitting a new Form 3542 to the FDA that would "reinstat[e] its former" use code. App. to Pet. for Cert. 65a–66a.

The Court of Appeals reversed, holding that Caraco lacked "a statutory basis to assert a counterclaim." 601 F. 3d, at 1360. The court first read the statutory phrase "the patent does not claim . . . an approved method of using the drug" to require Caraco to demonstrate that the '358 patent does not claim *any* approved method of use. See *id.*, at 1365 ("'[A]n approved method' means 'any approved method'"). Because the patent covers one approved method of use—repaglinide in combination with metformin—the counterclaim was unavailable. The court further ruled that the counterclaim provision does not reach use codes because they are not "patent information submitted by the [brand] under subsection (b) or (c)." On the Federal Circuit's view, that information consists only of the patent number and expiration date. See *id.*, at

1366–1367. Judge Dyk dissented. He would have read the phrase "the patent does not claim . . . an approved method of using the drug" to include situations where, as here, the use code wrongly indicates that the patent covers one or more particular approved methods of use. See *id.*, at 1376–1378. And he would have construed "patent information submitted . . . under subsection (b) or (c)" to include use codes. See *id.*, at 1370–1376.[4]

We granted certiorari, 564 U. S. ___ (2011), and now reverse.

II

We begin "where all such inquiries must begin: with the language of the statute itself." *United States* v. *Ron Pair Enterprises, Inc.*, 489 U. S. 235, 241 (1989). This case requires us to construe two statutory phrases. First, we must decide when a "patent does not claim . . . an approved method of using" a drug. Second, we must determine the content of "patent information submitted . . . under subsection (b) or (c)" of §355. We consider both of those questions against the backdrop of yet a third statutory phrase, providing that the remedy for a prevailing counterclaimant is an order requiring the brand "to correct or delete" that patent information. And we consider each question in the context of the entire statute. See *Robinson* v. *Shell Oil Co.*, 519 U. S. 337, 341 (1997) (Statutory interpretation focuses on "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"). We cannot say that the counterclaim clause is altogether free of ambiguity. But when we consider statutory text and context together, we conclude that a generic manufacturer in Caraco's position

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[4] On remand from the Federal Circuit's decision, the District Court determined that the '358 patent was invalid and unenforceable. See 775 F. Supp. 2d 985 (ED Mich. 2011). The Federal Circuit stayed Novo's appeal from that judgment pending the decision here.

can use the counterclaim.[5]

A

An ANDA applicant sued for patent infringement may bring a counterclaim "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). The parties debate the meaning of this language. Novo (like the Federal Circuit) reads "not an" to mean "not any," contending that "the counterclaim is available only if the listed patent does not claim *any* (or, equivalently, claims *no*) approved method of using the drug." Brief for Respondents 29 (internal quotation marks omitted). By that measure, Caraco may not bring a counterclaim because Novo's '358 patent claims the use of repaglinide with metformin. In contrast, Caraco reads "not an" to mean "not a particular one," so that the statute permits a counterclaim whenever the patent does not claim a method of use for which the ANDA applicant seeks to market the drug. On that view, the counterclaim is available here—indeed, is available twice over—because

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[5] Before proceeding to the merits, we dispose of a recently raised jurisdictional argument. Novo now contends that the federal courts lost subject-matter jurisdiction over this infringement action (including the counterclaim) at the moment Caraco filed its section viii statement. On Novo's theory, such a statement (unlike a paragraph IV certification) does not count as an act of infringement under the patent statute, see 35 U. S. C. §271(e)(2)(A), and so cannot provide a jurisdictional basis for the suit. But that argument is wrong even assuming (as Novo contends) that Caraco's section viii filing terminated its paragraph IV certification and that a section viii filing is not an act of infringement. The want of an infringing act is a merits problem, not a jurisdictional one. Nothing in the section of the statute defining certain filings as acts of infringement suggests anything to the contrary. And "we are not inclined to interpret statutes as creating a jurisdictional bar when they are not framed as such." *Stern* v. *Marshall*, 564 U. S. ___, ___ (2011) (slip op., at 13). In the absence of such a bar, the federal courts have jurisdiction over this suit for a single, simple reason: It "ar[ose] under a[n] Act of Congress relating to patents." 28 U. S. C. §1338(a).

the '358 patent does not claim the use of repaglinide with TZDs or its use alone.

Truth be told, the answer to the general question "What does 'not an' mean?" is "It depends": The meaning of the phrase turns on its context. See *Johnson* v. *United States*, 559 U. S. ___, ___ (2010) (slip op., at 5) ("Ultimately, context determines meaning"). "Not an" sometimes means "not any," in the way Novo claims. If your spouse tells you he is late because he "did not take a cab," you will infer that he took no cab at all (but took the bus instead). If your child admits that she "did not read a book all summer," you will surmise that she did not read any book (but went to the movies a lot). And if a sports-fan friend bemoans that "the New York Mets do not have a chance of winning the World Series," you will gather that the team has no chance whatsoever (because they have no hitting). But now stop a moment. Suppose your spouse tells you that he got lost because he "did not make a turn." You would understand that he failed to make a particular turn, not that he drove from the outset in a straight line. Suppose your child explains her mediocre grade on a college exam by saying that she "did not read an assigned text." You would infer that she failed to read a specific book, not that she read nothing at all on the syllabus. And suppose a lawyer friend laments that in her last trial, she "did not prove an element of the offense." You would grasp that she is speaking not of all the elements, but of a particular one. The examples could go on and on, but the point is simple enough: When it comes to the meaning of "not an," context matters.[6]

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[6] For this reason, we find Novo's reliance on the occasional dictionary definition of "a[n]" unconvincing. Although "an" sometimes means "any" when used in negative structures, see, *e.g.,* Microsoft Encarta College Dictionary 1 (2001) (fifth definition), it sometimes does not. Cf. *FCC* v. *AT&T Inc.*, 562 U. S. ___, ___ (2011) (slip. op., at 3–5) (rejecting a proposed definition of "personal" because it did not always hold in

And the statutory context here supports Caraco's position. As described earlier (and as Congress understood), a single drug may have multiple methods of use, only one or some of which a patent covers. See, *e.g.,* 21 U. S. C. §355(b)(1) (requiring that an NDA applicant file information about "any patent which claims the drug . . . or which claims *a* method of using such drug" (emphasis added)). The Hatch-Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market. The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones. Within that framework, the counterclaim naturally functions to challenge the brand's assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue. That assertion, after all, is the thing blocking the generic drug's entry on the market. The availability of the counterclaim thus matches the availability of FDA approval under the statute: A company may bring a counterclaim to show that a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii.

Consider the point as applied to this case. Caraco wishes to market a generic version of repaglinide for two (and only two) uses. Under the statute, the FDA could approve Caraco's application so long as no patent covers those uses, regardless whether a patent protects yet a third method of using the drug. Novo agrees that Caraco could bring a counterclaim if Novo's assertion of patent protection for repaglinide lacked any basis—for example, if Novo held no patent, yet claimed rights to the pair of uses for

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ordinary usage and the statutory context suggested it did not apply).

which Caraco seeks to market its drug. But because Novo has a valid patent on a *different* use, Novo argues that Caraco's counterclaim evaporates. And that is so even though, once again, Caraco has no wish to market its product for that patented use and the FDA stands ready, pursuant to the statute, to approve Caraco's product for the other two. To put the matter simply, Novo thinks the counterclaim disappears because it has a patent for a method of use in which neither Caraco nor the FDA is interested at all. "It would take strong evidence to persuade us that this is what Congress wrought." *Eli Lilly*, 496 U. S., at 673. That "not an" sometimes (but sometimes not) means "not any" is not enough.

Novo argues that our reading must be wrong because Congress could have expressly "impose[d] additional . . . qualifications" on the term "an approved method of us[e]"—and indeed did so in another place in the statute. Brief for Respondents 31; 21 U. S. C. §355(j)(5)(C)(ii)(I). Novo points here to section viii itself, which applies when the brand's patent "does not claim a use *for which the [ANDA] applicant is seeking approval*." §355(j)(2)(A)(viii) (emphasis added). But the mere possibility of clearer phrasing cannot defeat the most natural reading of a statute; if it could (with all due respect to Congress), we would interpret a great many statutes differently than we do. Nor does Congress's use of more detailed language in another provision, enacted years earlier, persuade us to put the counterclaim clause at odds with its statutory context. That is especially so because we can turn this form of argument back around on Novo. Congress, after all, could have more clearly expressed Novo's proposed meaning in the easiest of ways—by adding a single letter to make clear that "not an" really means "not any." And indeed, Congress used a "not any" construction in the very next subclause, enacted at the very same time. See §355(j)(5)(C)(ii)(II) ("Subclause (I) does not authorize the

assertion of a claim . . . in any [other] civil action"). So if we needed any proof that Congress knew how to say "not any" when it meant "not any," here we find it. We think that sees, raises, and bests Novo's argument.

Our more essential point, though, has less gamesmanship about it: We think that the "not any" construction does not appear in the relevant counterclaim provision because Congress did not mean what Novo wishes it had. And we think that is so because Congress meant (as it usually does) for the provision it enacted to fit within the statutory scheme—here, by facilitating the approval of non-infringing generic drugs under section viii.

B

Novo contends that Caraco's counterclaim must fail for another, independent reason: On its view (as on the Federal Circuit's), the counterclaim does not provide a way to correct use codes because they are not "patent information submitted by the [brand] under subsection (b) or (c)" of §355. Once again, we disagree.

The statute does not define "patent information," but a use code must qualify. It describes the method of use claimed in a patent. See 21 CFR §§314.53(c)(2)(ii)(P)(3), (e). That fits under any ordinary understanding of the language.[7]

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[7] Novo's only counter is to redefine a use code. Novo argues that a use code need not be tied to the patent at all—that "[t]he relevant regulation requires [NDA] applicants to provide [only] 'a description of each approved method of use *or indication*.'" Brief for Respondents 48 (quoting 21 CFR §314.53(c)(2)(ii)(P)(1)). Because an "indication" refers generally to what a drug does (here, treat diabetes), see §201.57(c)(2), Novo claims that a use code may sweep more broadly than the patent. But that is incorrect. First, Novo does not cite the regulations that specify the information required for publication—*i.e.,* use codes. See §314.53(c)(2)(ii)(P)(3) (requiring a "description of the patented method of use as required for publication"); §314.53(e) ("[F]or each use patent," FDA will publish "the approved indications or other conditions of use

The more difficult question arises from the "submitted under" phrase. The subsections mentioned there—(b) and (c) of §355—require an NDA applicant to submit specified information: "the patent number and the expiration date of any patent" claiming the drug or a method of its use. 21 U. S. C. §§355(b)(1), (c)(2). According to Novo, only that information comes within the counterclaim provision. But subsections (b) and (c) as well govern the regulatory process by which brands provide additional patent information to the FDA, both before and after an NDA is approved. In particular, those subsections provide the basis for the regulation requiring brands to submit use codes, see 21 CFR §314.53; in issuing that regulation, the FDA noted that "[o]ur principal legal authority . . . is section 505 of the act [codified at §355], in conjunction with our general rulemaking authority." 68 Fed. Reg. 36697–36698 (specifically referring to subsections (b) and (c)). And the form (Form 3542) on which brands submit their use codes states that the information appearing there is "provided in accordance with Section [355](b) and (c)." App. 97. So use codes fall within the counterclaim's ambit if the phrase "submitted under" reaches filings that not only subsections (b) and (c) themselves, but also their implementing regulations require.

Several of our cases support giving "under" this broad meaning. For example, in *Eli Lilly*, 496 U. S., at 665–668, we examined a similar statutory reference to the "submission of information under a Federal law which regulates

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covered by a patent"). Those provisions (whether referring to methods of use, conditions of use, or indications) all demand a description of the patent. And second, even the provision Novo cites—which mandates the submission of additional material, not listed in the Orange Book—ties information about indications to patent coverage; that regulation requires (when quoted in full) that the brand provide "a description of each approved method of use or indication and related patent claim of the patent being submitted." §314.53(c)(2)(ii)(P)(1).

the manufacture, use, or sale of drugs," 35 U. S. C. §271(e)(1). We noted there that submitting information "under a Federal law" suggests doing so "in furtherance of or compliance with a comprehensive scheme of regulation." 496 U. S., at 667. Likewise, in *Ardestani* v. *INS*, 502 U. S. 129, 135 (1991), we held that a regulatory proceeding "under section 554," 5 U. S. C. §504(b)(1)(C)(i), meant any proceeding "subject to," "governed by," or conducted "by reason of the authority of" that statutory provision.

So too here. "Patent information submitted . . . under subsection (b) or (c)" most naturally refers to patent information provided as part of the "comprehensive scheme of regulation" premised on those subsections. *Eli Lilly*, 496 U. S., at 667. It includes everything (about patents) that the FDA requires brands to furnish in the proceedings "subject to," "governed by," or conducted "by reason of the authority of" §§355(b) and (c). *Ardestani*, 502 U. S., at 135. The breadth of the term "under" becomes particularly clear when compared with other phrases—"described in" and "prescribed by"—appearing in neighboring provisions. See, *e.g.,* 21 U. S. C. §355(c)(2) ("patent information described in subsection (b)"); §355(d)(6) ("patent information prescribed by subsection (b)"). Those phrases denote a patent number and expiration date and nothing more. In contrast, the word "under" naturally reaches beyond that most barebones information to other patent materials the FDA demands in the regulatory process.

Once again, that congressional choice fits the broader statutory context. Use codes are pivotal to the FDA's implementation of the Hatch-Waxman Amendments—and no less so because a regulation, rather than the statute itself, requires their submission. Recall that those Amendments instruct the FDA (assuming other requirements are met) to approve an ANDA filed with a section viii statement when it proposes to market a drug for only

unpatented methods of use. To fulfill that charge, the FDA must determine whether any patent covers a particular method of use; and to do that, the agency (which views itself as lacking expertise in patent matters, see *supra,* at 4–5, and n. 2) relies on the use codes submitted in the regulatory process. See 68 Fed. Reg. 36682–36683. An overbroad use code therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates. So it is not surprising that the language Congress used in the counterclaim provision sweeps widely enough to embrace that filing.

C

Another aspect of the counterclaim provision—its description of available remedies—dispatches whatever remains of Novo's arguments. According to the statute, a successful claimant may obtain an order requiring the brand to "correct or delete" its patent information. §355(j)(5)(C)(ii)(I). Our interpretation of the statute gives content to both those remedies: It deletes a listing from the Orange Book when the brand holds no relevant patent and corrects the listing when the brand has misdescribed the patent's scope. By contrast, Novo's two arguments would all but read the term "correct" out of the statute.

Consider first how Novo's an-means-any contention would accomplish that result. Recall that on Novo's view, a counterclaim can succeed only if the patent challenged does not claim either the drug or any approved method of using it. See *supra,* at 11. But when a generic manufacturer makes that showing, the remedy must be to "delete" the listing; no correction would be enough. Novo agrees with that proposition; "[a]t bottom," Novo avers, "the counterclaim is a delisting provision." Brief for Respondents 20. But that raises the obvious question: Why did Congress also include the term "correct" in the statute?

Novo can come up with just one answer: The counter-

claim, it proposes, can correct erroneous patent numbers. Imagine, for example, that Novo mistakenly entered the number '359, instead of '358, when submitting information about its repaglinide patent for publication in the Orange Book. Then, Novo suggests, Caraco could bring a counterclaim to challenge the inaccurate listing (on the ground that '359 does not claim any method of use), and the remedy would be "correct[ion]" (substituting an 8 for a 9). But we think Novo's admission that this scenario would be "unusual," Tr. of Oral Arg. 41, considerably understates the matter. As Novo concedes, brands have every incentive to provide the right patent number in the first place, and to immediately rectify any error brought to their attention. See *id.,* at 40–41. By doing so, they place both generic companies and the FDA on notice of their patents and thereby prevent infringement. And conversely, generics have little or no incentive to bring a counterclaim that will merely replace one digit in the Orange Book with another. So we doubt Congress created a legal action to "correct" patent information just to fix such scrivener's errors. See, *e.g., TRW Inc.* v. *Andrews*, 534 U. S. 19, 31 (2001) (refusing to adopt an interpretation of a statute that would render a piece of it "insignificant, if not wholly superfluous" (internal quotation marks omitted)). That would have been, in the most literal sense, to make a federal case out of nothing.

The same problem afflicts Novo's alternative contention—that "patent information submitted . . . under subsection (b) or (c)" includes only numbers and expiration dates (and not use codes). Once again, we cannot think Congress included the remedy of "correct[ion]" so that courts could expunge typos in patent numbers. And not even Novo has proffered a way for the counterclaim to "correct" an erroneous expiration date. Suppose, for example, that a brand incorrectly lists the expiration date of a valid patent as 2018 rather than 2015. The counter-

claim would be useless: It authorizes a remedy only "on the ground that" the listed patent does not claim the drug or an approved method of using it—and notwithstanding the wrong expiration date, this patent does so. Alternatively, suppose the brand lists a patent as having a 2018 expiration date when in fact the patent has already lapsed. Then, a generic manufacturer could bring a counterclaim alleging that the patent no longer claims the drug or a method of using it—but the appropriate remedy would be deletion, not correction, of the brand's listing. Novo's reading of "patent information," like its reading of "not an," effectively deletes the term "correct" from the statute.

III

Novo finally advances two arguments relating to the counterclaim's drafting history. Neither contention, however, overcomes the statutory text and context. Indeed, consideration of the provision's background only strengthens our view of its meaning.

A

Novo first contends that our interpretation of the statute "effectively resurrect[s] the scheme rejected by Congress." Brief for Respondents 44 (quoting *Smith* v. *United States*, 507 U. S. 197, 203, n. 4 (1993)). In 2002, Novo notes, Congress failed to pass a bill that would have required brands to file specified "patent information," including, for method-of-use patents, a description of "the approved use covered by the [patent] claim." S. 812, 107th Cong., 2d Sess., §103(a)(1), p. 7 (engrossed bill). That bill would have allowed a generic company to bring its own civil action—not merely a counterclaim in ongoing litigation—to "delete" or "correct" the information filed. *Id.,* at 8. The Senate approved the bill, but the House of Representatives took no action on it. Novo argues that because

this failed legislation would have allowed a generic company to challenge overbroad descriptions of a patent, we cannot read the statute Congress eventually enacted as doing so.

We disagree. We see no reason to assume, as Novo does, that Congress rejected S. 812 because it required brands to submit patent information beyond a number and expiration date. Indeed, Novo's argument highlights the perils of relying on the fate of prior bills to divine the meaning of enacted legislation. "A bill can be proposed for any number of reasons, and it can be rejected for just as many others." *Solid Waste Agency of Northern Cook Cty.* v. *Army Corps of Engineers*, 531 U. S. 159, 170 (2001)). S. 812 contained numerous items, including a title on importing prescription drugs (no controversy there!), that may have caused its failure. See S. 812, Tit. II. Moreover, what criticism there was of the bill's mechanism for challenging brands' patent claims focused not on the specification of "patent information," but instead on the creation of an independent cause of action—stronger medicine than the counterclaim Congress ultimately adopted.[8] And finally, Novo ignores a likely cause for the redrafting of the provision on submitting information. Between S. 812's demise and the counterclaim's enactment, the FDA issued a rule requiring brands to supply material concerning method-of-use patents, including use codes. The drafters of the counterclaim provision knew about that rule,[9] and

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[8] See, *e.g.,* 148 Cong. Rec. 15424 (2002) (remarks of Sen. Gregg) ("Probably the most significant issue is the fact that it creates a new cause of action"); *id.,* at 15431–15432 (remarks of Sen. Grassley) (similar); *id.,* at 14434 (remarks of Sen. Hatch) (similar).

[9] See, *e.g.*, Hearings on Barriers to Entry in the Pharmaceutical Marketplace before the Senate Committee on the Judiciary, 108th Cong., 1st Sess., 5–8 (2003) (statement of Daniel Troy, Chief Counsel to the FDA); *id.,* at 19 (statement of Sen. Schumer) ("The bill provides a critical complement to the work FDA has done in clarifying its regulations on patent listing, but it goes much further").

had no need to duplicate its list of mandated filings. So the drafting history does not support Novo's conclusion. If anything, the statute's evolution indicates that Congress determined to enforce the FDA's new listing provisions, including its use-code requirement, through the new counterclaim.

B

Novo next argues that Congress established the counterclaim only to solve the problem raised by the Federal Circuit's decision in *Mylan*, 268 F. 3d 1323—the impossibility of deleting an improperly listed patent from the Orange Book. In *Mylan*, as earlier described, a generic company alleged that a brand had listed a patent that covered neither the approved drug nor any method of using it, and brought an action seeking delisting. See *supra,* at 6. The Federal Circuit held that no such action was available, even assuming the allegation was true. Because several legislators saw *Mylan* as "exemplif[ying]" brands' "perceived abuse" of the FDA's patent listing practices, Brief for Respondents 35, Novo contends that we should construe the counterclaim provision to aid only a generic company that "finds itself in the same position as Mylan was in *Mylan*," Supp. Brief in Opposition 5–6.

Once again, we think not. Maybe *Mylan* triggered the legislative effort to enact a counterclaim, or maybe it didn't: By the time Congress acted, it also had at hand an FTC study broadly criticizing brands' patent listings and an FDA rule designed to address the very same issue. See *supra,* at 6, 21. But even assuming *Mylan* "prompted the proposal" of the counterclaim, "whether that alone accounted for its enactment is quite a different question." *Eli Lilly*, 496 U. S., at 670, n. 3 (emphasis deleted). Here, we think *Mylan* alerted Congress to a broader problem—that generic companies generally had no avenue to challenge the accuracy of brands' patent listings, and that the

FDA therefore could not approve proper applications to bring inexpensive drugs to market. The proof of that lies in the statute itself (where the best proof of what Congress means to address almost always resides). As we have described, the statute's text and context demonstrate that the counterclaim is available not only (as in *Mylan*) when the patent listing is baseless, but also (as here) when it is overbroad. See *supra,* at 10–20. In particular, Congress's decision to allow a counterclaimant to seek "correct[ion]" of patent information explodes Novo's theory, because the remedy for a *Mylan*-type impropriety is complete delisting.

And to make matters still easier, Congress's equation of the two situations—the one in *Mylan* and the one here—makes perfect sense. Whether a brand lists a patent that covers no use or describes a patent on one use as extending to others, the brand submits misleading patent information to the FDA. In doing so, the brand equally exploits the FDA's determination that it cannot police patent claims. And the brand's action may in either case delay or block approval of a generic drug that infringes no patent—and that under the statute should go to market. See *supra,* at 4. That is the danger Caraco faces here, as much as it was the threat in *Mylan*: Novo seeks to preclude Caraco from selling repaglinide for unpatented uses until 2018, when Novo's patent on a *different* use expires.

Indeed, the need for the counterclaim is greater here than in *Mylan*. When a brand lists a patent that covers no use, a generic company has a pathway aside from the counterclaim to challenge the listing. As described earlier, the company may make a paragraph IV certification stating that the listed patent "is invalid or will not be infringed" by the generic drug. 21 U. S. C. §355(j)(2)(A)(vii)(IV); see *supra,* at 5. If the brand sues, the generic company can argue that its product would not infringe the patent. Using the counterclaim may enable a generic manufacturer to obtain delisting more quickly, see

Tr. of Oral Arg. 54; but even without it, the company can eventually get a judgment of non-infringement enabling the FDA to approve its ANDA. In contrast, where (as here) a brand files an overbroad use code, a generic company cannot use paragraph IV litigation to that end. A paragraph IV certification (unlike a section viii statement) requires the generic company to propose labeling identical to the brand's; it cannot carve out any uses. See *supra,* at 4. And that proposed label will necessarily infringe because it will include the use(s) on which the brand does have a patent. So here, a paragraph IV suit cannot lead to a judgment enabling FDA approval; the counterclaim offers the *only* route to bring the generic drug to market for non-infringing uses. Novo's view eliminates the counterclaim where it has the greatest value.

IV

The statutory counterclaim we have considered enables courts to resolve patent disputes so that the FDA can fulfill its statutory duty to approve generic drugs that do not infringe patent rights. The text and context of the provision demonstrate that a generic company can employ the counterclaim to challenge a brand's overbroad use code. We accordingly hold that Caraco may bring a counterclaim seeking to "correct" Novo's use code "on the ground that" the '358 patent "does not claim . . . an approved method of using the drug"—indeed, does not claim two.

The judgment of the Court of Appeals is reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 10–844

CARACO PHARMACEUTICAL LABORATORIES, LTD., ET AL., PETITIONERS *v.* NOVO NORDISK A/S ET AL.

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

[April 17, 2012]

JUSTICE SOTOMAYOR, concurring.

The Court today interprets the counterclaim set forth in 21 U. S. C. §355(j)(5)(C)(ii)(I) to permit generic manufacturers to force brand manufacturers to "correct" inaccurate use codes. While I too find the counterclaim not "free of ambiguity," *ante,* at 10, I join the Court's opinion because I agree this is the most sensible reading in light of the existing regulatory scheme. I write separately to add the following observations.

I

I first underscore that the counterclaim can only lessen the difficulties created by an overly broad use code; it cannot fix them. The statutory scheme is designed to speed the introduction of low-cost generic drugs to market. See *ante,* at 2 (citing *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 676 (1990)). To that end, the statute provides for the rapid approval of a drug that a generic manufacturer seeks to market for unpatented methods of use. The manufacturer need only submit an abbreviated new drug application (ANDA) with a section viii statement and a proposed label that "carves out" from the brand manufacturer's label any patented methods of use. See *ante,* at 4. So long as the use code is not overly broad (and all else is in order), FDA may approve the application without re-

quiring any further steps relating to the patent, and the generic drug may reach the public without undue delay. See *ibid*.

An overly broad use code "throws a wrench" into that scheme. *Ante,* at 18. The reason why is simple: FDA relies on use codes in determining whether to approve an ANDA, but it refuses to evaluate the accuracy of those use codes. See *ante,* at 4–5. Thus, if the use code overlaps with the generic manufacturer's proposed carve-out label (*i.e.*, if the use code is overly broad), FDA will not approve an ANDA with a section viii statement. See *ibid*.

After today's opinion, the generic manufacturer can respond to this situation by taking the following steps: submit an ANDA with a paragraph IV certification (which requires a proposed label materially identical to the brand manufacturer's label, see *ante,* at 24), wait for the brand manufacturer to institute suit, file a counterclaim, litigate the counterclaim, and, if successful in securing the correction of the use code, return to the start of the process and do what it always wanted to do—file an ANDA with a section viii statement and a carve-out label.

The problem with this process is twofold. First, it results in delay and expense the statutory scheme does not envision. Second, there is no guarantee the process will work. It depends on the brand manufacturer initiating paragraph IV litigation, but it is not obvious the brand will have any incentive to do so. In light of today's holding, the upshot of such litigation will be the correction of the use code through the assertion of a counterclaim—an outcome that is desirable, to be sure, for the generic manufacturer, but perhaps less so for the brand manufacturer.

Meanwhile, it is not clear what happens if the brand manufacturer does not file suit. FDA may approve the generic manufacturer's application, see 21 U. S. C. §355(j)(5)(B)(iii), "without prejudice to infringement claims the patent owner might assert when the ANDA applicant

produces or markets the generic drug." Brief for United States as *Amicus Curiae* 6 (hereinafter United States Brief). But the generic manufacturer, having been forced to proceed with a paragraph IV certification, will have secured approval to market a drug with a label materially identical to the brand manufacturer's. That is not a position I imagine a generic manufacturer wants to be in: As the Solicitor General's Office informed us at argument, "[i]t would be inducement of infringement to sell a product with labeling that suggests that the product be used for a patented method of use." Tr. of Oral Arg. 24; see also United States Brief 32 (noting that in this situation, if a generic manufacturer proceeded with a paragraph IV certification, "[s]o long as the [new drug application (NDA)] holder's patent covers some approved method of using the approved drug, the proposed labeling will be infringing").

In short, the counterclaim cannot restore the smooth working of a statutory scheme thrown off kilter by an overly broad use code. At best, it permits the generic manufacturer to do what the scheme contemplates it should do—file an ANDA with a section viii statement—but only after expensive and time-consuming litigation. A fix is in order, but it must come from Congress or FDA.

II

Precisely because the regulatory scheme depends on the accuracy and precision of use codes, I find FDA's guidance as to what is required of brand manufacturers in use codes remarkably opaque. The relevant regulation states simply that a brand manufacturer must provide "[t]he description of the patented method of use as required for publication." 21 CFR §314.53(c)(2)(ii)(P)(3). The form on which brand manufacturers submit that information provides some additional detail, explaining that "[e]ach approved use claimed by the patent should be separately identified . . .

and contain adequate information to assist . . . applicants in determining whether a listed method of use patent claims a use for which the . . . applicant is not seeking approval." App. to Pet. for Cert. 214a. But it also provides that brand manufacturers may "us[e] no more than 240 total characters including spaces," *id.*, at 213a, and elsewhere FDA acknowledges "that in some cases 240 characters may not fully describe the use as claimed in the patent." 68 Fed. Reg. 36683 (2003); see also *ibid.* (indicating for this reason that use codes "are not meant to substitute for the applicant's review of the patent").

Indeed, in some respects we are here today because of FDA's opacity in describing what is required of brand manufacturers. In its initial NDA filing, Novo submitted a use code for the '358 patent that was not "overly broad": It described narrowly the single patented method of use. App. 54–55, 99. Some years later FDA required that Novo amend its label to "[r]eplace all the separate indications" "with the following sentence: 'Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.'" *Id.*, at 163–164, 215. Novo then amended its use code to track the new label, *id.,* at 482–486, explaining that the amendment "correspond[ed] with the change in labeling required by FDA," *id.*, at 483. Novo understood its amended use code to comply with FDA regulations, likely on the ground it pressed before us: that the regulations permit a brand manufacturer to submit for publication in the Orange Book a description of *either* the patented method of use *or* the indication (which refers to "what a drug does," *ante*, at 15, n. 7). Brief for Respondents 10, 22, 48–50.

For the reasons explained by the Court, see *ante,* at 15, n. 7, Novo is mistaken. But the company can hardly be faulted for so thinking. The regulations also require submission of "a description of each approved method of use or indication," 21 CFR §314.53(c)(2)(ii)(P)(1), and the form

on which brand manufacturers submit use codes requires "information on the indication or method of use for the Orange Book 'Use Code' description." App. to Pet. for Cert. 213; see also *ibid.* (explaining brand manufacturers should "[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"). Those sources at the least suggest (as Novo thought) that a method of use here is distinct from an indication and that either suffices as a use code.

Prior to enactment of the counterclaim provision, Congress considered a bill that required brand manufacturers to submit a "description of the approved use covered by the [patent] claim," and that allowed a generic manufacturer to bring a civil action to correct that information. See *ante,* at 20. Congress rejected the bill, in part over criticism that it would encourage excess litigation.* Absent greater clarity from FDA concerning what is required of brand manufacturers in use codes, Congress' fears of undue litigation may be realized.

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*See, *e.g.,* 148 Cong. Rec. 13481 (2002) (remarks of Sen. Hatch); *id.*, at 15433 (remarks of Sen. McCain); Office of Management and Budget, S. 812—Greater Access to Affordable Pharmaceuticals Act (July 18, 2002) (statement of administration policy), online at http://www.whitehouse.gov/omb/legislative_sap_107-2_S812-S (as visited Apr. 13, 2012, and available in Clerk of Court's case file).