No. 10-844

In the Supreme Court of the United States

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

v.

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

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

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

By Congress's design, courts may order a brand-name drug maker to "correct or delete the patent information" it "submitted under [Section 505(b) or (c)] on the ground that [its] patent does not claim * * * an approved method of using the drug." 21 U.S.C. § 355 (j)(5)(C)(ii)(I). Novo's method patent "does not claim" repaglinide administered alone, "an approved method of us[e]." Yet the "description of the patented method of use" (21 C.F.R. § 314.53(c)(2)(ii)(P)(3)) that Novo submitted "in accordance with Section 505(b) and (c)" (JA97) says otherwise. It requires correction.

Novo says the statute is but a "delisting provision" under which "an" means "any," "patent information" means "the patent number and expiration date," and "correct" is an "artifact" of "failed bills." Br. 20, 38. But to support that claim, Novo (astonishingly) substitutes the dictionary definition of "*any*" for the definition of "*an*." Compare Resp. Br. 29 with *Shorter Oxford English Dictionary* 94 (5th ed. 2002) (reprinted *infra* at 1a). And Novo ignores that "any" appears 34 times in surrounding provisions, including in a negative assertion in the very next sentence.

Congress authorized courts to "correct *or* delete" inaccurate "patent information." Yet Novo's reading admittedly leaves "correct"—the first of two available remedies—with "little or no independent work to do." Br. 38. Novo cannot say why Congress would create a counterclaim to correct typos in patent numbers. Nor can Novo explain why Congress would exchange FDA's definition of "patent information" for a definition limited to two things—dates, which cannot be reached by the counterclaim; and numbers, which brands already have incentives to state correctly.

In fact, Congress remedied not only cases where listed patents claim *no* approved use (warranting "deletion"), but cases where overbroad patent descriptions block generic marketing for *a subset* of approved uses (warranting "correction"). Novo's reading rests on the "implausible" notion that Congress handed brands "an effective extension of the patent," enabling them to block sales of concededly non-infringing products. See *Eli Lilly and Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 670, 679 (1990).

ARGUMENT

I. Novo's eleventh-hour jurisdictional argument lacks merit.

Facing difficulties on the merits, Novo attempts to change the subject. This Court lacks "jurisdiction," Novo says, because Caraco "amended its ANDA" to assert a Section viii statement—as opposed to a Paragraph IV certification—as to one claim of the patent-in-suit. Br. 23. But Novo did not question jurisdiction in the Federal Circuit, and in granting certiorari without supplementing the question presented this Court "necessarily considered and rejected" Novo's position. *Stolt-Nielsen S.A.* v. *AnimalFeeds Int'l Corp.*, 130 S. Ct. 1758, 1767 n.2 (2010). And for good reason. The statutes that Novo invokes are nonjurisdictional, and in any event are satisfied.

A. Article III

Caraco meets each Article III case-or-controversy requirement—"injury in fact, causation, and redressability." *Steel Co.* v. *Citizens for a Better Env't*, 523 U.S. 83, 103 (1998). "[A] barrier that makes it more difficult" to "compete" creates an injury. *Northeastern Fla. Chapter, Assoc. Gen. Contractors* v. *Jacksonville*, 508 U.S. 656, 666 (1993). Novo's revised use

code blocks approval of Caraco's ANDA. And ordering Novo to reinstate its earlier use code will facilitate FDA approval, redressing Caraco's injury. See U.S. Invitation Br. 19.

Without addressing these core requirements, Novo says Caraco's Section viii statement "represent[ed] that there is no controversy between the parties regarding patent infringement." Br. 24. In truth, Caraco's Section viii statement stated only that there *ought not* be any controversy under Novo's *prior* use code. When Novo revised its use code, FDA rejected Caraco's Section viii statement—compelling Caraco to maintain a Paragraph IV certification "under protest" (JA724) and litigate accordingly. Cf. *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 130-131 (2007). Article III is satisfied.

B. Statutory jurisdiction

1. Statutory jurisdiction is provided by 28 U.S.C. § 1338(a), which grants district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents," and 28 U.S.C. § 1331, which provides jurisdiction over federal civil actions.

Ignoring these statutes, Novo says the infringement statute (35 U.S.C. § 271(e)(2)) and the counterclaim grant "jurisdiction" "only if the generic applicant maintains a Paragraph IV certification." Br. 23. But "when Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as nonjurisdictional." *Stern* v. *Marshall*, 131 S. Ct. 2594, 2607 (2011) (quotation omitted). Novo's statutes fail this test.

Section 271, entitled "Infringement of patent," makes it "an act of infringement to submit * * * an application under section 505(j) * * * for a drug

claimed in a patent or the use of which is claimed in a patent * * * if the purpose of such submission is to obtain approval" to market the drug commercially. 35 U.S.C. § 271(e)(2). Because nothing in § 271(e)(2) "clearly state[s]" that these terms are "jurisdictional," they are not. *Arbaugh* v. *Y&H Corp.*, 546 U.S. 500, 515-516 (2006).

The same is true of § 355(j)(5)(C)(ii), which permits filing a counterclaim if a brand "brings a patent infringement action." This is a claim-processing requirement. For example, *Reed Elsevier, Inc.* v. *Muchnick*, 130 S. Ct. 1237, 1245-1247 (2010), deemed nonjurisdictional the requirement that "no civil action for infringement of the copyright in any United States work shall be instituted until preregistration or registration of the copyright claim has been made in accordance with this title." *Reed* governs here.

Because neither statute is jurisdictional, and Novo did not press this issue in the Federal Circuit, it is waived. *Stern*, 131 S. Ct. at 2608 (citing "the consequences" of "'sandbagging'").

2. Even if these statutes were jurisdictional, Novo's position would fail. *First*, the only requirement for bringing a Hatch-Waxman counterclaim is that a "patent infringement action" be pending; no Paragraph IV certification is necessary. 21 U.S.C. § 355(j)(5)(C)(ii)(I).

Novo's position thus rests on the premise that its own claim *should have been* dismissed when Caraco invoked Section viii. Even if this were correct (and it is not), jurisdiction does not turn on "events that did not occur." *Rumsfeld* v. *Padilla*, 542 U.S. 426, 448-449 (2004). Nor would dismissing Novo's claim now defeat jurisdiction. Absent contrary language in the

governing statute, "'[a]s long as a court has jurisdiction, it may hear and render a separate judgment on a counterclaim even if the opposing party's claim has been (or should have been) dismissed.'" U.S. Invitation Br. 22-23 (citation omitted).

Second, Novo errs in suggesting that infringement suits may be filed before FDA approves ANDAs "only" where there is "a Paragraph IV certification." Br. 24. To the contrary, the Act makes it "an act of infringement to submit * * * an application under section 505(j) * * * for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). Certainly, ANDAs challenged under § 271(e)(2)(A) frequently include Paragraph IV certifications. But unlike other Hatch-Waxman provisions,[1] § 271(e)(2)(A) nowhere mentions Paragraph IV. Congress made the infringing act the attempt "to obtain approval" for a patented drug or use.

To be sure, Section viii should permit Caraco to carve out the patented use. But Novo's revised use code caused FDA to *reject* Caraco's Section viii statement. JA724. Novo cannot have it both ways. Having blocked FDA approval of Caraco's ANDA, Novo cannot now insist that the ANDA does not seek approval for a patented use. Indeed, in another case involving the same patent, Novo condemned the position it now takes as "perverse." *Novo Nordisk, Inc.* v. *Mylan Pharm. Inc.*, 2009 WL 7847269, *9 (D.N.J. Sept. 8, 2009) (Novo brief).

Today, Novo invokes dictum from *Eli Lilly* stating that the infringing act under § 271(e)(2) is "submit-

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[1] *E.g.*, 35 U.S.C. § 271(e)(5); 21 U.S.C. §§ 355(j)(2)(B), 355(j)(5)(B)(iii)-(iv), 355(j)(5)(D).

ting an ANDA * * * containing the fourth type of certification." 496 U.S. at 678. The Court there, however, was not addressing § 271(e)(2)'s precise scope in drug cases; it was explaining why § 271(e)(2) and (4) are inapplicable to devices.

Third, even if § 271(e)(2)(A) required a Paragraph IV certification, Caraco had one when Novo sued—and "subject-matter jurisdiction 'depends on the state of things at the time of the action brought.'" *Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457, 473 (2007) (citation omitted). It is irrelevant that Caraco later invoked Section viii.

II. Novo misreads the counterclaim.

According to Novo, "the counterclaim is available only if 'the listed patent does not claim *any*' (or, equivalently, claims *no*) approved method of using the drug." Br. 29 (quoting Pet. 12a). That is, the Court must substitute "*any*" for the term Congress chose—"*an*"—because "[a] patent either 'claim[s] an approved method' of using a particular drug, or it does not." Br. 28. Accordingly, the counterclaim is merely "a delisting provision" and the remedy of "correct[ing]" inaccurate patent information a useless "artifact" of "failed bills." *Id.* at 20, 34, 38. This interpretation is textually and logically unsupportable.

A. Novo's view that "an" and "any" are interchangeable contravenes the Act's text, its context, and ordinary usage.

Novo does not deny that "any" is an "unqualified" and "sweeping" term, or that Congress used "any" 34 times in surrounding provisions—including in a *negative assertion* in the *very next sentence*. Pet. Br. 24-25. Nonetheless, invoking dictionaries and "standard grammar," Novo insists that "an" and "any" are effec-

tively interchangeable in negative formulations. Br. 29. Novo is mistaken.

1. Dictionaries and "standard grammar"

As to dictionaries, Novo cites an unspecified page of the Shorter Oxford English Dictionary as "defining 'an' with a 'preceding negative' to mean 'none at all of, no—of any kind; not even one.'" Br. 29. Initially we could not find this definition. But eventually we did—*under the entry for "any." Shorter Oxford English Dictionary* 94 (5th ed. 2002); see *infra* at 1a-3a (reprinting definitions). Novo thus defines the term it *wishes* appeared in the counterclaim ("any"), not the term that *does* appear ("an"). Indeed, one might say that Novo did not cite an applicable definition.

Which is not to say that Novo did not cite *any* applicable definition. Br. 29 n.5 (definitions of "an"). But Novo misconstrues its other definitions as creating a grammatical rule, when at most they show that "an" often means "any" in negative assertions. No grammatical imperative holds that "not an" necessarily "equates to 'none.'" Br. 29. That raises a question of *usage*. See *FCC* v. *AT&T Inc.*, 131 S. Ct. 1177, 1181-1182 (2011) (rejecting a so-called "'grammatical imperativ[e]'" that did "not always" hold "in ordinary usage") (citation omitted).

The definition of "*an*" in Novo's leading dictionary is quite different from its definition of "*any*," and confirms that its meaning depends upon the context:

> one, some, any, (the oneness or indefiniteness being implied rather than asserted).

Shorter Oxford English Dictionary 1 (reprinted *infra* at 2a). Here, the context confirms that "an" does not mean "any" approved use, but rather "one" or "some"

approved uses. Pet. Br. 30. The Dictionary Act points to the same result. 1 U.S.C. § 1; Pet. Br. 30 n.6.[2]

2. Usage of "an"

Nor is this an unusual use of "an." Novo mocks as "irrelevant" our examples of "an" in ordinary usage. Br. 30; see Pet. Br. 26-28. But as our examples show, "an" is commonly used in negative assertions to refer to a discrete object—be it a particular tax exemption, element of an offense, recipe ingredient, prescribed medicine, assigned text, driving direction, or judicial precedent. When a judge tells a lawyer that his brief "does not address an applicable precedent" (Pet. Br. 27), that does not ordinarily mean the lawyer failed to address *any* applicable precedent—only that he did not address a particular case.

So too with drug patents and FDA-approved uses —and one need not understand "quantum mechanics" (Resp. Br. 28) to see why. Drugs often have multiple approved uses, and related patents often claim some such uses but not others. Novo's patent claims repaglinide administered with metformin ("an approved use"), not repaglinide administered alone ("an approved use") or repaglinide administered with TZDs

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[2] Usage guides—which precisely differentiate closely related terms—typically treat "*an*" and "*any*" as separate terms, with distinct senses, having discrete entries and no cross-references. *E.g.*, Garner, *Garner's Modern American Usage* 1 (*an*), 52-53 (*any*) (3d ed. 2009); *Merriam-Webster's Concise Dictionary of English Usage* 1 (*an*), 75-76 (*any*) (2002); Morris & Morris, *Harper Dictionary of Contemporary Usage* 1 (*an*), 40 (*any*) (1975); Fowler, *A Dictionary of Modern English Usage* 1 (*an*), 31 (*any*) (2d ed. 1965); Evans & Evans, *A Dictionary of Contemporary American Usage* 3 (*an*), 36 (*any*) (1957).

("an approved use"). This does not mean that Novo's patent exists, like "Schrödinger's cat," in "multiple, inconsistent states at once." Br. 29. It means that what a patent claims must be analyzed on a use-by-use basis.

3. The counterclaim's structure

This is confirmed by the counterclaim's structure, which Novo ignores. The counterclaim requires the "*ANDA applicant*" to establish that the patent-in-suit "*does not* claim * * * an approved method of using the drug." Novo cannot explain why, that being so, courts adjudicating counterclaims should focus on what the *brand* can show its patent *does* claim. To be sure, where there is one approved use, whether a patent "does" or "does not" claim that use is one and the same inquiry. But where (as here) there are multiple approved uses, whether the patent claims an approved use is not an either/or proposition.

4. FDA Form 3542

Quoting a question from FDA Form 3542—"Does the patent * * * claim an approved method of use of the approved drug product?"—Novo says the answers ("Yes" or "No") confirm its either/or position. Br. 32. But that is a threshold question on a worksheet that becomes much more specific. The first question keeps brands from listing patents that do not belong in the Orange Book—like the counterclaim's "delete" function. But Form 3542 later states: "Each approved use claimed by the patent should be separately identified." Pet. 214a. It is this information that the counterclaim may "correct."

Our reading does not require "invert[ing]" the text or "substituting a definite article." Resp. Br. 30. Having shown that Novo's patent "does not claim

* * * *an* approved method," Caraco should prevail. Novo's insistence that "[a] patent either 'claim[s] an approved method' of using a particular drug, or it does not" (Br. 28), by contrast, presents a false choice and requires substituting "any" for "an."

5. Hatch-Waxman as a whole

By Novo's lights, the counterclaim must be "harmonized with" Hatch-Waxman's "listing provisions," but "has *nothing to do* with section viii." Br. 32, 33. Yet the counterclaim and Section viii provide remedies to *generics*, whereas the listing provisions govern *brands*. Moreover, Novo's counsel hailed the decision below as an "important decision construing the Hatch-Waxman counterclaim and section viii carve-outs"—a decision that would "benefit" brands "in the method of use context, where the FDA looks to use codes * * * in evaluating requests by ANDA applicants for section viii carve-outs." Mark A. Perry, *Federal Circuit Issues Important Decision Construing the Hatch-Waxman Counterclaim and Section viii Carve-Outs*.[3]

Our reading of the counterclaim complements both the listing provisions and Section viii. Novo's, by contrast, directly contravenes the text, which authorizes courts not only to "delete" (*delist*) patents, but to "correct" overbroad patent descriptions. That alone forecloses Novo's suggestion (at 34) that Congress intended only to address *Mylan*. Pet. Br. 31-33; U.S. Br. 30-33.

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[3] http://www.gibsondunn.com/publications/pages/FederalCircuitDecisionConstruingHatchWaxmanCounterclaim.aspx.

Novo also errs in contending that "an" must mean "any" in the counterclaim because (they say) we "admitted" below that "the indefinite article 'a' means 'any'" in the listing provisions. Br. 33. Not so. We simply recognized that patents claiming "any" use necessarily claim "a" use. C.A. Br. 38 n.2 (brands should "list a patent if it covers any approved use"). As in the counterclaim, the listing provision uses the word "any" ("any patent") just before the term "a" ("which claims a method of using such drug"), confirming that "an" (or "a") does not *mean* "any." Yet "an" is necessarily satisfied if "any" is satisfied.

Novo cannot dispute that its reading would effectively "eviscerate" Section viii. Br. 33 & n.7. Novo's amici are still more brazen, describing "carving out the approved use" and "heading to market"—as authorized by Section viii—as a "glaring 'loophole'" that promotes "premature entry of generic drugs" and "induce[s]" infringement. Allergan Amicus Br. 4, 20.

Allergan's quarrel is with Section viii itself, which expedites generic entry only where the patent "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). Indeed, by authorizing labels that omit patented uses, Section viii *avoids* the "active" promotion that induced infringement requires. 35 U.S.C. § 271(b). And if it did not, brands would have a remedy. *Ibid.*

Without carve-outs, however, brands whose compound patents have long expired could easily leverage method patents claiming a sliver of the market into control of the whole market—"creat[ing] an effective extension of the patent term." *Eli Lilly*, 496 U.S. at 670. Without the counterclaim, generics would have no remedy for *that*. And the notion that Congress

viewed misrepresenting patents as integral to Hatch-Waxman's "careful balance" (Allergan Br. 27) is absurd.[4]

6. Section viii

Novo also lacks a convincing response to the fact that Section viii and the counterclaim 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]."

Novo attempts to justify reading these provisions inconsistently by noting that a phrase in Section viii —"a use for which the applicant is seeking approval" —is absent in the counterclaim. Br. 31. But this phrase would be superfluous in the counterclaim, as Article III supplies the same limitation. Courts may not order "correction" of use codes where generics are *not* seeking approval for uses purportedly claimed by the patent. That would be rendering an advisory opinion. U.S. Br. 28-29 (the counterclaim applies "only when a generic manufacturer genuinely seeks to market the drug"). By contrast, Section viii governs

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[4] Amicus Allergan says Hatch-Waxman always "requires [filing] *both* a [Paragraph IV] certification *and* a section viii statement." Br. 22. Like Novo (Br. 23), however, FDA rightly disagrees. 68 Fed. Reg. 36676, 36682 (June 18, 2003). Section viii is *conditional*—it is triggered only "if" certain information is filed. Moreover, Allergan's hypothetical, where approval is sought only "for a use not claimed by the method [patent]" (Br. 22), does not call for a Paragraph IV certification, because the hypothetical patent does not claim a use "for which the [ANDA] applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii).

"fil[ings] with the Secretary," where there is no case-or-controversy requirement.

Novo's reading would also result in an inexplicable anomaly. Courts could "delete" misleading patent information when brands' patents claim *no* approved use, but not "correct" misleading patent descriptions that block marketing for *a subset of* approved uses. Yet "[a] misleading use code can cause the same practical harm (unjustified delay in a generic drug's entry into the market) as does the listing of a patent that claims *no* approved uses." U.S. Invitation Br. 16.

Even if Congress's "draftsmanship" was less than "elegant," Novo's reading—which enables brands to block generic marketing for concededly non-infringing uses—reflects an "implausible substantive intent." *Eli Lilly*, 496 U.S. at 679. Congress's "silence" in including an unnecessary phrase from Section viii cannot justify an interpretation that "is contrary to all other textual and contextual evidence." *Burns* v. *United States*, 501 U.S. 129, 136 (1991); see also *Field* v. *Mans*, 516 U.S. 59, 75 (1995) (reasoning from a negative pregnant cannot justify "results strangely at odds with other textual pointers").

7. The meaning of "correct"

Citing an *earlier* Congress's decision not to pass a bill specifying what information a counterclaimant might "correct," Novo dismisses "correct" as an "artifact" of "failed bills." Br. 38. But while this Court's "preference for avoiding surplusage constructions is not absolute" (*ibid.*), it would be strange indeed for Congress to leave such "surplusage" in the first of two verbs defining a finely tuned statute's remedies. Cf. *Chickasaw Nation* v. *United States*, 534 U.S. 84, 94 (2001) (treating a "numerical cross-reference" in "a

parenthetical" as surplusage); *Lamie* v. *United States Trustee*, 540 U.S. 526, 536 (2004) (treating one item in a list as surplusage where "the text is plain"); see *Flemming* v. *Fla. Citrus Exch.*, 358 U.S. 153, 166 (1958) (endeavoring "neither to delete nor to distort" FDCA's terms).

Moreover, where this Court has considered congressional rejection of statutory language, the Senate and House were typically considering the same bill in "tandem" during the same Congress. *E.g.*, *Hamdan* v. *Rumsfeld*, 548 U.S. 557, 579 (2006); *Lindh* v. *Murphy*, 521 U.S. 320, 329 (1997). Here, the first bill died in an earlier Congress, and FDA promulgated major reforms in the interim.

Novo is left suggesting that Congress authorized "correcting" patent information so generics could help brands fix their scrivener's errors. Novo admits that "'correc[t]' has little or no independent work to do under [this reading]." Br. 38. The only situation where Novo can imagine "correct" doing "independent work" is if a brand listed "the wrong patent number." *Ibid.*

Setting aside the implausibility of Congress passing a counterclaim to correct typos, brands already have ample incentives and opportunity to file correct patent numbers. Pet. Br. 33 & n.7.[5] If they do not, generics can file Paragraph IV certifications asserting non-infringement of the mistakenly listed patent, and brands can be denied their automatic 30-month stay of generic approval. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Further, mistakenly listed patents must be "deleted."

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[5] 21 C.F.R. § 314.53(f) permits notifying FDA of inaccurate patent information.

Novo suggests (Br. 12) but never explains how an erroneous "expiration date" can be corrected. It cannot. Under Novo's interpretation, the counterclaim is unavailable if the patent claims "*any*" approved use—regardless of an erroneous expiry. Thus, the counterclaim could never "correct" an "expiration date." Only patent numbers could arguably be "corrected," and that use of the statute is trivial. U.S. Br. 23 n.3.

B. The Act's text and regulatory context foreclose Novo's reading of "patent information."

Novo's crabbed reading of "patent information" is equally unconvincing. Novo cannot dispute that a use code "[describes] the patented method of use" (21 C.F.R. § 314.53(c)(2)(ii)(P)(3)), and thus is "information" about the "patent." And, as noted, in *no* circumstance would Novo's reading allow courts to order correction of a patent's "expiration date"—one of only two pieces of "patent information" that Novo says the counterclaim reaches.

Novo also lacks a good answer to our showing that the statute references all "patent information *submitted under*" Sections 505(b) or (c), not just "patent numbers and expiration dates." Novo would have the Court read the statute in a vacuum, ignoring closely related FDA regulations addressing the same topic—the "Submission of patent information." 21 C.F.R. § 314.53. But FDA expressly invoked Sections 505(b) and (c) as authority for those regulations. Pet. Br. 36. Moreover, unlike other Hatch-Waxman provisions, the counterclaim does not reference patent information "described in," "required under," or "prescribed by" those subsections. Pet. Br. 34 & n.8. Novo's contrary arguments are unpersuasive.

1. According to Novo, to read the phrase "submitted under subsection (b) or (c)" to include "patent information submitted under FDA regulations" is "to rewrite the statute." Br. 40. But Novo cannot explain how one "submits" patent information "under" the Act *without* submitting it under FDA regulations.

True, Congress might have cited "regulations" by "chapter and verse." Br. 43. But doing so is unusual, and certainly not required. Hatch-Waxman language referencing the "submission of information *under* a Federal law" most naturally refers to submitting such information "in furtherance of or compliance with a comprehensive scheme of regulation." *Eli Lilly*, 496 U.S. at 666-667. Likewise, "patent information submitted under [Section 505](b) or (c)" most naturally refers to submissions in compliance with regulations implementing that provision.

2. Recognizing this difficulty, Novo says FDA's regulations do *not* implement Section 505(b) or (c). Br. 45. According to Novo, FDA invoked "21 U.S.C. § 371(a)" alone, and "*actually* said" only that "'Section 505(b) and (c) of the act describes the content of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements.'" *Ibid.* (citation omitted).

This argument ignores the immediately preceding sentence of the Final Rule—the first sentence under "Legal Authority"—which states: "Our principal legal authority for the final rule is section 505 of the act, in conjunction with our general rulemaking authority in section 701(a) (21 U.S.C. § 371)." 68 Fed. Reg. at 36697-36698 (reprinted *infra* at 28a). FDA thus invoked 21 U.S.C. § 371(a), as it would for any FDCA rulemaking. But the *substantive* provision that FDA

invoked was Section 505—and especially subsections (b) and (c), which address Hatch-Waxman's "patent submission and patent certification requirements." *Ibid.* All of this is what FDA "*actually* said." Resp. Br. 43.

3. Novo ignores that Section 505's patent information submission requirements for method patents are limited to patents that "claim[] a method of using [the] drug and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G); Pet. Br. 37-38. Novo cannot explain how FDA would ascertain that the requisite numbers and dates were filed without knowing the claimed method of use or that the patent supports an infringement claim—which is what use codes reveal. As FDA noted, "specific information on the approved methods of use protected by a submitted patent" is "essential" to "implement[ing] the [Paragraph IV] certification and section viii statement provisions." 68 Fed. Reg. at 36682-36683.

4. Noting that "'under' * * * must draw its meaning from its context" (Br. 42 n.9), Novo dismisses this Court's explanation in *Ardestani* v. *INS* that, when followed by a statute, "under" most naturally refers to regulatory proceedings conducted "'by reason of the [statute's] authority.'" 502 U.S. 129, 135 (1991). According to Novo, "[t]he context here has nothing to do with FDA regulations." Br. 42 n.9.

Novo is blinking at reality. The statutory text—"patent information submitted under [Section 505](b) or (c)"—parallels the regulatory text—"Submission of patent information * * * under section 505(b) of the act" and "patent information submitted" and "provided in accordance with Section 505(b) and (c)." Pet.

Br. 40. It is not credible to suggest that "Congress did not even hint *in the counterclaim* that it was referring to [FDA's] regulations." Resp. Br. 43.

Indeed, this Court has relied on Congress's *silence* concerning FDA rules, when "amend[ing] the [FDCA] in *other* respects," as evidencing ratification. *United States* v. *Rutherford*, 442 U.S. 544, 554 n.10 (1979) (emphasis added). Congress was anything but silent here. After hearing extensive testimony about FDA's regulations, Congress repeatedly referenced them and authorized a counterclaim using nearly identical language. It is untenable to think Congress rejected FDA's definition of "patent information" in favor of one limited to two items submitted to FDA—half of which (dates) could not be reached by the counterclaim, and half of which (numbers) brands have every reason to state correctly.

5. Nonetheless, citing a 2002 bill that would have required brands to submit information on "the approved use covered by the [patent's] claim," Novo insists that our interpretation "'resurrect[s] [a] scheme rejected by Congress.'" Br. 44 (citation omitted). But this "drafting history" was superseded by FDA's decision to define "patent information" to include a "description of the patented method of use." 21 C.F.R. § 314.53(c)(2)(ii)(P)(3). At that point, (a different) Congress no longer needed to define "patent information" to include use codes; it could simply reference the information submitted to FDA—which is what it did, with support from both sides of the aisle. *E.g.*, 149 Cong. Rec. 16689 (2003) (Sen. Hatch).

What FDA could *not* do, however, was authorize judicial intervention if brands filed inaccurate patent information. 68 Fed. Reg. at 36683. "[L]egislation

would be needed to finish the job." 149 Cong. Rec. at 15516 (Sen. Schumer). The bill actually adopted thus "provide[d] 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 (June 17, 2003).

That is, Congress expressly "enforce[d] the patent listing requirements at the FDA" by allowing generics "to file a counterclaim to have the brand drug company delist the patent or correct the patent information in FDA's Orange Book." 149 Cong. Rec. at 31200. Novo's naked assertion (at 46) that Congress "agreed not to make th[e] same information" required by FDA "subject to the counterclaim" is baseless.

FDA's regulations also illustrate why Congress's Members referred to "patent information," not "use codes." Resp. Br. 36-37. FDA had just defined that term and, to that point, *itself* wrote use codes. *Id.* at 37. But once use codes were written by *brands*, Congress needed a mechanism for judicial "correction." See U.S. Br. 10.

6. Novo also suggests that, if everything brands submitted to FDA were "patent information," then FDA would have to publish it under § 355(c)(2), yet FDA does not do so. Br. 41-42. But unlike Novo's example of information that is not published—"e-mail addresses of agents" (*id.* at 42)—use codes are actually "information" about a "patent," and FDA *does* publish them. JA500-595.

In sum, had Congress desired a "far narrower" provision (Br. 44), it easily could have allowed court

orders to correct "the patent number or expiration date." Instead, acting against the backdrop of FDA regulations defining "patent information" to include brand-submitted use codes, Congress authorized courts to correct "patent information submitted under Section 505 (b) or (c)." Congress's decision must be respected.

III. Novo's patent description requires reinstating the district court's injunction.

Novo also misunderstands the counterclaim's remedial language. According to Novo, its use code is "correct," and in any event Caraco must "satisfy the traditional four-factor test for injunctive relief." Br. 46-47. Novo is twice mistaken.

A. Novo's view that patent descriptions need only track drug labels contravenes the Act and FDA's regulations.

1. Novo ignores our demonstration that the term "correct" describes not a standard for avoiding liability, but the remedy for meeting the statute's requirements. Pet. Br. 48. It follows, however, that because Novo's patent does not claim two of three approved uses of repaglinide, yet FDA rejected Caraco's request to carve out the sole patented use, Novo's use code requires correction.

We know what a proper use code looks like. Novo's first submission ("use of repaglinide in combination with metformin to lower blood glucose" (JA99)) accurately reflected the lone use claimed by Novo's patent. Novo's expanded narrative does not.

2. Novo nonetheless insists that "there is nothing to 'correct.'" Br. 46-47. Quoting a snippet from 21 C.F.R. § 314.53(c)(2)(ii)(P)(1), Novo repeatedly says

FDA lets brands describe "each approved method of use *or* indication." *E.g.*, Br. 48. But that requirement is joined to later requirements by a *conjunctive*, requiring brands to provide both "a description of each approved method of use or indication * * * and * * * the description of the patented method of use." 21 C.F.R. § 314.53(c)(2)(ii)(P)(1)-(3). The notion that use codes may be divorced from patent claims grossly misrepresents FDA's regulations. U.S. Br. 4, 23.[6]

3. Citing an earlier PRANDIN use code, Novo argues that "if this indication-based use code created by FDA was proper," then the use code here "must be proper." Br. 50. But indication-based use codes are incorrect only where (as here) they misrepresent the patented method(s) of use. And since the PRANDIN use code described *a different patent* (the '924 patent), its validity depends on *that patent's* claims.

4. Unable to satisfy FDA's regulations, Novo suggests that describing the patent's scope is the job of "the patent itself—not the use code." Br. 47. In fact, both the patent and the "patent use code" (JA500) describe the patent's scope, but for different purposes and at different levels of detail. By analogy, there are several ways of describing where one lives. To complete a real estate transaction, one needs a deed describing the property's metes and bounds; but to give friends driving directions, a street address suffices.

So too with patents and patent use codes. To review patent applications, the PTO requires a "metes and bounds" description. But "[t]o effectively imple-

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[6] Contrary to Novo's assertion (Br. 51), the Solicitor General represents FDA, which lacks independent litigating authority.

ment the certification and section viii statement provisions" (68 Fed. Reg. at 36682), shorter descriptions suffice. Novo questions FDA's ability to discern method patents' claims from "a 240-character tweet." Br. 48. Yet the descriptions must be "accurate and detailed" (68 Fed. Reg. at 36682), and Novo's initial, 71-character narrative—which all agree is accurate—served its purpose with 169 characters to spare.

5. Novo denies "committing a federal crime." Br. 51. But unlike Hatch-Waxman provisions targeting "untrue," "false or misleading" statements (21 U.S.C. §§ 355(j)(4)(K), (d)(7)), the counterclaim asks whether patent information requires "correcting," given what the patent "does not claim." Pet. Br. 51. Caraco has met this burden, requiring issuance of an order.

B. *eBay*-style balancing is unauthorized, but would warrant relief.

Nor does Caraco's right to an order turn on *eBay*-style balancing. Resp. Br. 53-56. Novo waived this argument by not raising it below. *Stern*, 131 S. Ct. at 2608; Caraco C.A. Br. 59 n.4. But *eBay* applies only where courts have the option of awarding damages—which are unavailable here—and in any case the equities overwhelmingly favor Caraco.

1. *eBay* is doubly inapposite. The Patent Act authorized two remedies—damages and injunctions—and "provide[d] that injunctions 'may' issue 'in accordance with the principles of equity,'" "on such terms as the court deems reasonable." *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388, 392 & n.2 (2006) (citation omitted).

By contrast, the counterclaim authorizes *one* remedy—"an order requiring the [brand] to correct or delete the patent information"—and states that ge-

nerics "shall not be entitled to damages." 21 U.S.C. § 355(j)(5)(C)(iii). Congress gave no indication that this remedy is discretionary, limited by "principles of equity," or subject to "terms [that] the court deems reasonable." *eBay*, 547 U.S. at 392 n.2. Courts have no "mandate" to "strike a balance of equities"; "the balance has been struck." *TVA* v. *Hill*, 437 U.S. 153, 194 (1978).

2. Even if *eBay* applied, Caraco would satisfy it. *First*, an order correcting Novo's use code would thereafter enable petitioners to sell repaglinide through Caraco, Sun, or, if necessary, "a third party." JA645-646, JA661; Pet. Supp. Br. 10-11.[7] And in all events, the order would eliminate a "sufficient cause[]" of Caraco's injury. *Khodara Envt'l, Inc.* v. *Blakey*, 376 F.3d 187, 195 (3d Cir. 2004) (Alito, J.).

Second, damages are unavailable and Caraco cannot successfully sue FDA. Resp. Br. 52. Courts have repeatedly held that "patent law" is "outside" FDA's "expertise and authority." 68 Fed. Reg. at 36683 (collecting decisions). Indeed, "the very enactment of the counterclaim provision assumed that no alternative remedy was available." Pet. 51a (Dyk, J., dissenting).

Third, the balance of harms powerfully favors Caraco, whose products concededly do not infringe. Caraco's lost market share cannot be recouped, whereas Novo cannot articulate any cognizable harm to itself in restoring its original use code—except the absurd notion that the First Amendment protects its right to submit incorrect patent information to FDA. Br. 54.

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[7] Upon request, Caraco will lodge supporting documentation with the Clerk.

Fourth, "the public interest" abhors "conduct which unfairly tends to destroy competition." *Spectrum Sports, Inc.* v. *McQuillan*, 506 U.S. 447, 458 (1993). Novo enjoyed a 17-year monopoly. It should not enjoy "an effective extension of the patent term" (*Eli Lilly*, 496 U.S. at 670) by manipulating FDA into blocking non-infringing low-cost medicines, at the expense of ill patients, let alone under an Act designed to expedite generic competition. U.S. Br. 26-33.

CONCLUSION

The judgment below should be reversed, and the district court's injunction reinstated.

Respectfully submitted.

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NOVEMBER 2011

Shorter Oxford English Dictionary
(5th ed. 2002)

[Page 94]

any /ˈɛni/ *adjective* (in mod. usage also classed as a *determiner*), *pronoun, & adverb.*

[Old English *ǽnigġ* = Old Frisian *ēnich*, Old Saxon *ēnig*, Middle Low German *einich*, Middle Dutch *ēnich* (Dutch *eenig*), Old High German *einag* (German *einig*), Old Norse *einigr*, Gothic *ainaha*, from Germanic: see ONE *adjective, noun & pronoun*, -Y[1].]

►**A** *adjective.* **1** *gen.* As *sing.*, a –, some –, no matter which, or what. As *pl.*, some—no matter which, of what kind, or how many: ‣**a** Used primarily in interrogative, hypothetical, and conditional contexts. OE. ‣**b** With a preceding negative (expressed or implied): none at all of, no—of any kind; not even one. OE. ‣**c** In affirmative senses: every one of (the sort named). ME.

2 With quantitative emphasis: ‣**a** A quantity or number of, however great, or however small. E16. ‣**b** A large or considerable (number, amount, etc.). *colloq.* M19.

3 With qualitative emphasis: of any kind or sort whatever; one or some, however imperfect. M19.

* * *

[Page 73]

an *adjective* (*indef. article*) see A *adjective.*

* * *

[Page 1]

a /ə; *stressed* eɪ/ *adjective* (usu. called the *indefinite article*; in mod. usage also classed as a *determiner*). Before a vowel sound (see below) **an** /ən; *stressed* an/.

[Old English *ān* one, weakened to proclitic form in early Middle English]

▶**I 1** One, some, any, (the oneness, or indefiniteness, being implied rather than asserted). OE. ‣**b** One like. LME.

2 Before quantifiers: some, a matter of, about. *obsolete* exc. *dial.* & in a few, a great many, a good many. OE.

3 A certain, a particular. ME. ‣**b** A single; the same. M16.

🕮 **1** SHAKES. *Wint. T.* I have … said many A prayer upon her grave. KEATS I had a dove and the sweet dove died. C. TOMLINSON As good a student As any in the house. M. LASKI They had passed and repassed each other a dozen times. J. BETJEMAN In Ealing on a Sunday Bell-haunted quiet falls. **b** SHAKES. *Merch. V.* A Daniel come to judgment. TENNYSON Shall I weep if a Poland fall? **2** WILLIAM TURNER Stepe them a fiue or sixe dayes in vineger. **3** *Notes & Queries* It was popularized by a Mr. Trudgen. *once upon a time.* **b** SHAKES. *Haml.* These foils have all a length? E. DICKINSON I'll tell you how the Sun rose—A ribbon at a time.

►**II 4** In, to, for, each. (Orig. the preposition *a*, Old English *an*, *on*, defining time, as in twice *a* day; afterwards identified with the indef. article, and extended from time to space, measure, weight, number: see A *preposition*[1] 3.) OE.

🕮 **4** DEFOE Four pieces of eight a man. YEATS But always went to chapel twice a week. *Oxford Times* Teams of six a side, each member of the one team fighting a duel with the six members of the other. J. STALLWORTHY Roast chestnuts, a shilling / a bag.

¶ *An* is freq. before a consonant to end of 13, before sounded *h* until 18. In standard English *an* is now used before a vowel sound (including *h* mute), as *an egg*, *an honour*; *a* before a consonant (including sounded *h* and *eu-*, *u-* pronounced /ju, ju:/) as *a pen*, *a host*, *a eunuch*, *a unit*. But before an unaccented syll., some retain *an* before sounded *h*, as *an historian*, a smaller number before *eu-*, *u-*, *as an university*.

* * *

UNITED STATES CODE

Title 35—Patents
Part III—Patents and Protection of Patent Rights
Chapter 28—Infringement of Patents

§ 271. Infringement of Patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would

constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act

for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not

earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section

2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) Applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

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[Page 36676]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 02N-0417]

RIN 0910-AC48

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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[**Page 36681**]

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g. Method-of-Use Patents—Must the "Use" Be Approved in the Approved Drug Product? The preamble to the proposed rule mentioned that patents claiming a method of use would be able to be submitted, but did not address such patents except to confirm our position that patents may not be submitted for listing

if they claim methods of use that are not approved for the listed drug or are not the subject of a pending application.

(Comment 7) Comments disagreed as to whether the method-of-use claim in a patent submitted for listing must be a use approved in the NDA. Several comments urged us to list only those patents claiming methods of use approved in the NDA or that required clinical trials. One comment argued that listing only patents for approved uses was the only way to stop NDA holders from claiming broad uses or indications not in the approved labeling. In contrast, other comments argued that the act did not prevent NDA applicants or holders or patent owners from submitting patents for listing that claimed uses not approved by FDA. Some comments stated that patent infringement is not limited to approved uses. Other comments stated that section 505(b)(1) of the act contemplates the listing of patents claiming unapproved uses if a claim of patent infringement could reasonably be asserted, citing *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) (*Purepac*).

(Response) If an NDA applicant or holder or patent owner intends to submit information on a patent that claims a method of use, the patent must claim a use that is described in the NDA. If we have already approved the NDA, the patent must claim a method of use that is in the labeling of the approved NDA. This has been our position since before we issued the final patent information rule in 1994 (see 59 FR 50338, 50363-50364 (Oct. 3, 1994)). The pre-existing requirement can be found at § 314.53(b) and (c)(2).

Sections 505(b) and (c) of the act support our position that only patents claiming approved methods of

use be submitted for listing. Section 505(b)(1) of the act provides that the NDA applicant "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug * * * ." The corresponding language in section 505(c)(2) of the act is nearly identical. Only method-of-use patents "which claim the drug for which the applicant submitted the application" must be listed. "Drug" is an ambiguous term, one which, for many years, we have consistently interpreted in the Hatch-Waxman Amendments to refer to the drug product. One court has said that:

> The meaning of the word "drug" in 21 U.S.C. § 355(b)(1) cannot be determined apart from its context. Neither the FDA nor this court disputes that the definition of drug in § 321(g) covers both drug products and active ingredients. The relevant statutory section in this case, however, modifies the word "drug" by attaching the phrase "for which the applicant submitted the application." In that context the FDA's interpretation of drug as meaning drug product is consistent with and indeed required by the statute.

(See *Pfizer, Inc.* v. *FDA*, 753 F. Supp. 171, 176 (D. Md. 1990).) All of the benefits afforded NDA holders under the Hatch-Waxman Amendments, such as the 30-month stay, derive from obtaining our approval of a particular drug product. Accordingly, only method-of-use patents that claim a use of the drug product in the pending or approved application must be submitted. Method-of-use patents for uses that the NDA holder "has not chosen to make available to the public" (id. at 177) must not be submitted for listing.

This construction of the statute is also supported by the more recent case law. Since we issued the pro-

posed rule, there have been several judicial opinions discussing method-of-use patents. In *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), and in the related case *TorPharm, Inc.* v. *Thompson*, Civ. No. 03-0254 (D.D.C. April 25, 2003) (appeal pending for both Purepac and TorPharm), the district court held that, where a patent did not claim a use approved in the NDA, an ANDA applicant could not be required to certify to that patent, and the agency could properly find that no ANDA applicant was entitled to 180-day exclusivity on that patent. In *Warner-Lambert Co. v. Apotex Corp.,* 316 F.3d 1348 (Fed. Cir. 2003), the Federal Circuit held that an ANDA applicant does not need to certify to a patent claiming a use not covered by the applicable NDA, and there is no cause of action against an ANDA applicant for patent infringement under 35 U.S.C. 271(e)(2)(A) for patents that claim an unapproved use. In *Allergan, Inc.* v. *Alcon Labs., Inc.,* 324 F.3d 1322 (Fed. **[Page 36682]** Cir. 2003), the Federal Circuit issued a per curium opinion that held that a method-of-use patent holder does not have an infringement action against an ANDA applicant when the use claimed in the patent is not FDA approved and the ANDA applicant is not seeking approval of that use. These decisions are consistent with our position that sponsors must not submit method-of-use patents that do not claim an approved use for listing in the Orange Book. They also highlight the need for an improved declaration that will clarify the claimed scope of the method-of-use patents being submitted.

We have modified the required declaration relating to method-of-use patents submitted. Although we agree, as discussed in the response to comment 11 of section II.A of this document, that each individual

claim of a patent does not need to be listed on the declaration forms for drug substance and drug product patents, we do require identification of individual claims for method-of-use patents. The declarant must describe each individual method of use for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use. This information will expedite our review of ANDA and 505(b)(2) applications that do not seek approval for all the approved uses. In determining whether an ANDA applicant can "carve out" the method of use, rather than certify to the listed patent, we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book.

The need for accurate and detailed information related to the approved methods of use claimed in the patent being submitted for listing is underscored by the decision in *Purepac Pharm. Co.* v. *Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002). In that case, the NDA holder submitted information on a patent claiming what was later determined to be an unapproved use of the approved drug product. This submission was accompanied by the required signed declaration from the NDA holder that the patent covered the method of use for the approved product. Accordingly, we listed the patent and the use code information submitted with the patent. Years later, well after litigation over this patent was underway, the NDA holder clarified to FDA that the patent did not, in fact, claim the use for which the NDA was approved.

This submission of inappropriate patent information led to confusion and then to litigation over an

ANDA applicant's obligation to submit either a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the act or a "section viii" statement under section 505(j)(2)(A)(viii) of the act. The section viii statement, which is also applicable to 505(b)(2) applications, permits the ANDA or 505(b)(2) applicant to avoid certifying to a patent by stating that it is not seeking approval for the use claimed in the listed patent. A section viii statement does not carry the requirement for notice to the NDA holder and patent owner, and the related opportunity for a 30-month stay.

We have implemented the section viii provisions of the act by deferring to the NDA holder's or patent owner's assertion that the method-of-use patent claims an approved use of the drug product. When the NDA holder or patent owner submits a method-of-use patent for an approved NDA, we rely upon the requirements in the regulations and the required declaration as the evidence that the patent claims an approved use. Therefore, when an ANDA applicant has sought to duplicate the labeling for which the innovator has submitted the patent, and not to specifically omit, or "carve out" labeling, we require the ANDA applicant to submit a certification to that patent. A section viii statement would not be appropriate because the ANDA applicant is seeking approval for exactly the same labeling as that in the NDA for which the patent was submitted.

Our position has been that, for an ANDA applicant to file a section viii statement, it must "carve out" from the proposed ANDA labeling, the labeling protected by the listed patent. Unless the ANDA applicant can show that it is carving out certain me-

thod-of-use labeling, a section viii statement is not a correct submission for the listed patent. In *Purepac*, the court rejected our reliance on the regulations and the general declaration as a reasonable basis for this approach to implementation. The court specifically pointed to the patent submissions in the case, and noted that the NDA holder had not complied with the requirement that NDA holders submit only those patents claiming an approved use for the drug. Although the court noted that the facts in *Purepac* were unique (the NDA holder later admitted that it made its submission "without regard" to FDA's regulations), there may be other cases in which NDA holders have submitted patents claiming unapproved uses of approved drug products.

Following the *Purepac* decision, we have two options for implementing the section viii statement provisions under sections 505(b)(2)(B) and 505(j)(2)(A)(viii) of the act that intersect with the patent submission considerations described in the proposed rule. One approach would be to permit each ANDA and 505(b)(2) 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, and then to submit a paragraph IV certification or section viii statement as the applicant sees fit. The second approach would be to require the NDA applicant or holder to identify specifically the approved uses claimed by the method-of-use patent, with reference to the approved labeling, and declare under penalty of perjury that the patent claims an approved use. This would permit ANDA and 505(b)(2) applicants, and us, to assess whether the ANDA or 505(b)(2) applicant is seeking approval for a use the sponsor states is claimed in the listed patent, and

thus determine whether the applicant must submit a patent certification or may submit a section viii statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the act.

In the absence of explicit statutory language, we believe an approach that requires the NDA applicant or holder or patent owner to identify the approved methods of use protected by the patent is most consistent with the general balance adopted in Hatch-Waxman. This approach permits the NDA applicant or holder to determine which patents claim its approved drug product and then, when appropriate, to resolve disputes over infringement of those patents through patent litigation. If ANDA and 505(b)(2) applicants could always avoid the possibility of a 30-month stay 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—despite the NDA holder's assertion to the contrary—there would be little reason for any applicant to submit a paragraph IV certification for a method-of-use patent. This approach would essentially eliminate the certification, notice, and litigation process as to any listed method-of-use patent, producing an outcome that is inconsistent with the act.

To effectively implement the certification and section viii statement provisions set out in the statute, we must have adequate information concerning method-of-use patents. Since 1994, we have requested, but not required, that NDA applicants submit to FDA information on the approved use claimed by the patent. Since the **[Page 36683]** *Purepac* case and other instances have raised questions about what aspects of the approved drug are claimed by a listed use patent,

we believe that 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 the ANDA and 505(b)(2) applicants referencing the approved drug.

We further note that we list methods of use for approved products in the Orange Book in the section on use codes. Due to the limitations of our database system and software constraints, we are limited to using 240 total characters for the use code description in the Orange Book. Traditionally, we have created the use code description for the Orange Book from the information submitted by the NDA applicant or holder. After considering the comments, and in light of the previously described litigation, we have determined that it is more efficient and accurate to ask the NDA holder to give us the exact use code description to be published in the Orange Book. Use codes are intended to alert ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling. We understand that in some cases 240 characters may not fully describe the use as claimed in the patent. The declaration, which includes the complete description of the method-of-use claim and the corresponding language in the labeling of the approved drug, will be publicly available after NDA approval.

h. Miscellaneous Patent Listing Comments. i. Should We Create an Administrative Process to Challenge Patent Listings or to De-List Patents or to Review the Listability of Patents? The proposed rule did not propose an administrative process for challenging

patent listings or for seeking removal of a patent from the Orange Book, nor did we propose a new process to internally review the patents for listability.

(Comment 8) Several comments stated that parties, such as generic drug companies and even third parties, need a method for challenging patent listings or for de-listing patents in the Orange Book. Some comments explained that the lack of an administrative procedure for challenging patent listings either encouraged NDA applicants to submit inappropriate patent information, or did not deter the practice, to delay generic competition. A number of comments maintained that FDA has more than a ministerial role and should review patents to determine if they meet the requirements for listing. Several comments contend that we have the authority to determine the attributes of the approved drug and thus to determine the appropriate patent listings. Various administrative mechanisms were suggested through which FDA could conduct a review of patents. These suggestions ranged from hiring patent lawyers to review submitted patents to development of a full administrative hearing process.

One comment stated that patent owners need an administrative process to enforce the listing of their patents because an NDA holder might "fail" to list eligible patents.

(Response) 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. The courts have the experience, expertise, and authority to address complex and important issues of patent law. This final rule supports that assumption in two

ways. First, the final rule clarifies what patents must and must not be submitted for listing. This will make it easier for NDA applicants and holders and patent owners to avoid inadvertently submitting patents that do not meet the statutory and regulatory requirements. The clarification will reduce the pressure on us to intercede in patent listing disputes and will allow the courts and parties to focus on the ultimate issue of patent invalidity or non-infringement. Second, the final rule requires NDA applicants or holders or patent owners to submit detailed information and to certify to its correctness. This should further ensure that only patents meeting the statutory requirements will be submitted for listing.

We decline to create an additional administrative process for challenging patent listings beyond that already established in § 314.53(f). We also decline to create a new process for de-listing patents or for internal FDA review of patents beyond the limited review of the patent declaration described in this final rule. Section 505(b)(1) of the act directs NDA applicants to submit certain patent information. It requires that "[u]pon approval of the application, the Secretary shall publish" the patent information (emphasis added). In section 505(j)(7)(A)(ii) and (iii) the statute mandates that we publish revisions to this information every 30 days. These short time frames do not contemplate a substantive agency review of the scope of the patent and its application to the approved drug product. Indeed, the requirement of prompt publication ("upon submission"), combined with the 30-day timeframe for updating the Orange Book, are strong evidence that Congress did not intend us to undertake anything other than a ministerial action.

In addition to the absence of any statutory basis for a substantive agency review of patents, we have long observed that we lack expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority. Although we will continue to relay questions about the accuracy of a patent submission to the NDA holder (see § 314.53(f)), our patent listing role remains ministerial. Courts have upheld our determination that our role with respect to patent listing is ministerial. (See *aai Pharma* v. *Thompson*, 296 F.3d 227, 242-43 (4th Cir. 2002), *cert. denied*, 123 S. Ct. 1582 (2003); *American Biosci., Inc.* v. *Thompson, 269 F.3d 1077, 1084 (D.C. Cir. 2001)*; *In re Buspirone Patent Litigation,* 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002); *Watson Pharm., Inc.* v. *Henney,* 194 F. Supp. 2d 442, 445-446 (D. Md. 2001); *Mylan Pharm., Inc.* v. *Thompson,* 139 F. Supp. 2d 1, 10-11 (D.D.C.)*, rev'd on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001).) We recognize that one court has held that parties have no private right of action to seek de-listing of patents (see *Mylan Pharmaceuticals, Inc.* v. *Thompson*, 268 F.3d 1323 (Fed. Cir. 2001)). Nevertheless, it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings or permitting third parties to submit patents for listing. We lack both the resources and the expertise to resolve such matters.

Furthermore, even if we were to establish an administrative process for patent review, our decisions on these patent listing matters would inevitably lead to disputes and increased litigation against us. This litigation could question whether such an administra-

tive process was within our legal authority. Even if the courts were to decide that we may review submitted patents, there would be repeated litigation over individual patent listing decisions. Given the uncertainty of the listing status of the challenged patent during the litigation, there is no assurance that, if we reviewed submitted patents, ANDAs or 505(b)(2) applications would be approved sooner and generic drugs would enter the market any more rapidly. **[Page 36684]**

We agree that there have been a few cases in which legitimate concerns have been raised about whether specific submitted patents meet the statutory requirements for submission and listing. We believe that these concerns will be adequately and efficiently addressed by the clarification of the types of patents that must and must not be submitted and by improvements to the patent information required. We further believe that even if legally permissible, it is not necessary for us to develop a patent review mechanism. The final rule permits us to allocate our limited resources to public health activities, while leaving questions of patent law to the courts, which are better able to handle such questions. This division of responsibility is fully consistent with the process established in the Hatch-Waxman Amendments.

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[Page 36697]

III. Description of the Final Rule

A. Section 314.53(b)—What Patents Must Be Submitted?

1. Which Patents Would the Final Rule Require To Be Submitted?

Section 314.53(b) describes the patents for which information must be submitted. The final rule states, in relevant part, that information must be submitted on the required declaration forms for each patent that claims the drug or a method of using the drug that is the subject of the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. The patents include patents that claim:

- The drug substance (active ingredient),
- The drug product (formulation and composition), and
- A method of use.

Those patents that claim a different polymorphic form of the drug substance that is the active ingredient described in the NDA must be submitted if the applicant has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA. The drug product (formulation and composition) patents submitted must claim the specific drug product described in the pending or approved NDA. For patents that claim a method of use, the NDA applicant or holder must submit only those patents that claim indications or other conditions of use that are the subject of a pending or approved application. Each pending or approved method of use and related patent claim must be described.

2. What Patents Must Not Be Submitted?

Section 314.53(b), as finalized, states that information on patents claiming packaging, patents claim-

ing metabolites, and patents claiming intermediates must not be submitted. Process patents also must not be submitted. The final rule clarifies that the prohibition on submission of packaging patents does not apply to patents that claim the drug product as defined in § 314.3. If a patent claims the finished dosage form of the drug product, it must be submitted for listing.

B. Section 314.53(c)—What Does the Patent Declaration Say?

Section 314.53(c)(1) describes the general requirements for submission of patent information and the conditions for acceptance of the patent information. Section 314.53(c)(2)(i) requires a person submitting an NDA, an amendment, or a supplement, to submit an original signed declaration form as part of its submission of patent information. The appropriate declaration form must be used for submitting patent information. The information required to be submitted is described. Each form seeks specific patent information and requires a signed attestation from the NDA applicant or holder or patent owner that the information is accurate and complies with the requirements of the regulations.

Section 314.53(c)(2)(ii) requires that the NDA holder submit a declaration form with information relating to the approved NDA and additional information on use codes within 30 days of NDA approval. The information required to be submitted is described. Each form includes specific patent information and requires a signed attestation from the NDA holder or patent owner that the information is accurate and complies with the requirements of the regulations. This section also requires submission of information on patents submitted for listing after NDA

approval. This declaration form is the only declaration form that we will rely on to determine whether a patent is eligible for listing based on the patent information submitted.

C. Section 314.53(c)(3)—What Is Required to Be Filed If There Are No Relevant Patents?

The final rule modifies the statement used to describe the fact that the NDA applicant or holder believes there are no relevant patents to be submitted. The language is changed to conform to the descriptions used for drug substance (active ingredient), drug product (formulation and composition) and method of use to those used in the other regulatory provisions.

D. Sections 314.95(a) and 314.52(a)—When Are Notice and Certification Required?

The final rule modifies §§ 314.95(a) and 314.52(a) to state that, if an ANDA or 505(b)(2) application is amended to include a paragraph IV certification, notice must be provided to the NDA holder and patent owner only if the application did not already contain a paragraph IV certification or there was not a full opportunity for a 30-month stay. If an ANDA or 505(b)(2) applicant changes its paragraph IV certification before the 45-day period after notice to the NDA holder and patent owner has expired, and the NDA holder or patent owner has not initiated patent litigation, such paragraph IV certification and related notice are not considered to have satisfied the requirement of providing one notice of a paragraph IV certification and a full opportunity for a 30-month stay.

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V. Legal Authority

Our principal legal authority for the final rule is section 505 of the act, in **[Page 36698]** conjunction with our general rulemaking authority in section 701(a) (21 U.S.C. 371) of the act. Section 505(b) and (c) of the act describes the contents of an NDA and 505(b)(2) application, including the patent submission and patent certification requirements. Section 505(j) of the act describes the contents of an ANDA, including patent certification requirements. Sections 505(b)(2)(A) and 505(j)(2)(A)(vii) of the act, respectively, require patent certifications, while sections 505(b)(3) and 505(j)(2)(B) of the act require those applicants who have made a paragraph IV certification to provide notice to the NDA holder and patent owner.

The final rule clarifies the types of patents which NDA applicants and NDA holders must and must not submit to FDA for listing in the Orange Book. It also requires a more detailed patent declaration from NDA applicants and NDA holders or patent owners using declaration forms. The specific legal authority for each provision is set forth in the preamble discussion accompanying it.

For ANDA and 505(b)(2) applicants, the final rule reduces the number of notifications sent to patent owners and NDA holders. The specific legal authority for this action is set forth in the preamble discussion of our changed interpretation.

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