No. 10-844

In the Supreme Court of the United States

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

v.

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

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

BRIEF OF REP. HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

CARLOS T. ANGULO*
ZUCKERMAN SPAEDER LLP
1800 M STREET, N.W.,
SUITE 100
WASHINGTON, DC 20038
(202) 778-1800
cangulo@zuckerman.com

**Counsel of Record*

Counsel for Amicus Curiae Rep. Henry A. Waxman

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Pages

CASES

STATUTES

LEGISLATIVE MATERIALS

REGULATORY MATERIALS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[1]

Amicus Curiae Rep. Henry A. Waxman is a Member of Congress with an important interest in this case. Rep. Waxman is the Ranking Member of the House Energy and Commerce Committee, the House Committee with jurisdiction over matters relating to the Food and Drug Administration ("FDA") and generic drugs. Rep. Waxman has long championed increased consumer access to safe and effective, lower-cost generic drugs and has a strong interest in the proper judicial construction of the laws effectuating this legislative goal – in particular, the legislation known as the Hatch-Waxman Act ("Hatch-Waxman"), of which Rep. Waxman was a principal architect.[2]

This case presents a question of congressional intent – namely, the meaning of, and purpose behind, the counterclaim provisions added by Congress in 2003 to Hatch-Waxman. Rep. Waxman is particularly well-suited to address this issue and believes that the Federal Circuit's narrow interpretation of the counterclaim provisions conflicts with Congress' intent in enacting them – i.e., to strengthen the generic drug approval process against brand company abuses by providing generic companies with a judicial remedy for correcting

---

[1] The parties have consented to the filing of this brief. No party, counsel for a party, or person other than *amici* or their counsel authored this brief in whole or in part or made a monetary contribution to fund its preparation or submission.

[2] The formal name of Hatch-Waxman is the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

inaccurate patent information submitted by the brand to FDA. Indeed, the Federal Circuit's construction of the statute, far from strengthening the Hatch-Waxman system, eviscerates certain of its key aspects – in particular, the process for expedited FDA approval of generic drug applications for unpatented uses under the statute's "section viii" – and, if adopted by this Court, would enable brand companies to improperly delay generic competition for years, costing consumers and the health care system dearly.

STATEMENT

The counterclaim provisions are part of a comprehensive Hatch-Waxman framework aimed at "mak[ing] available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. See also *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (goal of Hatch-Waxman is "to get generic drugs into the hands of patients at reasonable prices – fast.") Hatch-Waxman has been a great success. In 1984, when the statute was originally enacted, only 19 percent of the drugs prescribed in the United States were generic.[3] Today, that number stands at 70 percent.[4] Generic drugs typically cost 80-85% less than their brand name counterparts. Increased access to generic drugs has saved consumers billions

---

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* viii (July 1998) ("CBO Report").

[4] Susan Okie, *Multinational Medicines-Ensuring Drug Quality in an Era of Global Manufacturing*, 361 New Eng. J. Med. 737, 738 (2009).

of dollars[5] and helped hold down national health care costs.

Critical to the Hatch-Waxman framework is the process established by the statute and implemented by FDA to identify and resolve patent issues between generic and brand drug manufacturers.

A company seeking FDA approval for a generic version of an approved brand drug (the "reference listed drug" or "RLD") must submit an Abbreviated New Drug Application ("ANDA") in which, among other things, it must account for each patent related to the RLD. 21 U.S.C. 355(j). Some patents do not claim the composition of the approved drug product, but rather a method of using the drug product (for example, to treat a particular medical condition or to be administered with a second drug). Hatch-Waxman provides two options for ANDA applicants seeking FDA approval in spite of any unexpired "method of use" patents claiming an approved use of an RLD.

First, if the ANDA applicant seeks approval for a patented use of the RLD, it must submit a "Paragraph IV" certification stating that the patent claiming the use is invalid, unenforceable, or uninfringed by the proposed generic product. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Upon receiving the required notice of the certification from the ANDA applicant, the holder of the RLD may within 45 days bring patent litigation ("Paragraph IV litigation") against the generic. 21 U.S.C. 355(j)(5)(B)(iii).

---

[5] CBO Report at viii.

Commencement of this litigation automatically stays FDA approval of the ANDA for 30 months. *Id.*

However, in cases where a brand company method of use patent does not cover all approved uses of the RLD, the ANDA applicant may instead seek immediate FDA approval for *unpatented* uses by submitting a "section viii" statement. 21 U.S.C. 355(j)(2)(A)(viii). While FDA generally cannot approve an ANDA unless the proposed generic label matches the RLD's label (21 U.S.C. 355(j)(2)(A)(v)), a section viii approval allows the generic to "carve out" labeling referring to the patented use(s) of the RLD and include only labeling for unpatented uses. 21 C.F.R. 314.94(a)(8)(iv). Thus, whereas Congress expected that a Paragraph IV filing would lead to patent litigation between the generic and the brand and would delay FDA approval of the generic ANDA for at least 30 months, it envisioned that a section viii statement, if approved, would allow a generic to obtain immediate approval of its ANDA for uses outside the scope of patent coverage. See *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) ("[A] section viii statement indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent.")

In order for an ANDA applicant to properly address brand company patents, it must of course know which patents cover the RLD. Under the Hatch-Waxman system, the burden of providing this information falls on the holder of the RLD, which must submit to FDA certain patent information that the agency publishes in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the "Orange Book."

The Hatch-Waxman statute itself requires that a brand company seeking FDA approval of a new drug include in its New Drug Application ("NDA") the patent number and the expiration date of any patent which claims the drug or a use of the drug, and that could reasonably form the basis of a patent infringement suit. 21 U.S.C. 355(b)(1).[6] In June 2003, FDA issued regulations requiring the holder of an approved NDA to submit to the Orange Book, under penalty of perjury, additional specific information for each method of use patent claiming the approved drug, including,

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

21 C.F.R. 314.53(C)(2)(ii)(P). This information is known as a "use code."

---

[6] If the relevant patent is issued after the submission of the NDA, the applicant must amend its application to include the required patent information. 21 U.S.C. 355(b)(1).

In the preamble to its 2003 regulations, FDA emphasized that requiring NDA holders to submit specific use codes was "essential" to the Agency's, and the ANDA applicant's, ability to identify unpatented uses for the RLD that could serve as the basis for an immediate section viii approval. *Applications for FDA Approval to Market A New Drug*, 68 Fed. Reg. 36676, 36685 (June 18, 2003). The Agency explained that

> requir[ing] the NDA applicant or holder to identify specifically the approved uses claimed by the method of use patent . . . would permit ANDA . . . applicants, and us, to assess whether the ANDA . . . 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 . . . .

Id. at 36682. Previously, FDA had required only an unsworn certification from the NDA holder that its listed patents covered the approved method(s) of use for the RLD. But the agency realized that NDA holders were submitting "inappropriate patent information" that misleadingly described the scope of their method of use patents and "led to confusion and then to litigation over an ANDA applicant's obligation to submit either a paragraph IV certification . . . or a 'section viii' statement." *Ibid.* Hence, the use code requirement.

However, FDA does not review the substance of method of use patents (e.g., to determine if a particular listed patent in fact covers a claimed

method of use). Hatch-Waxman does not require FDA to review substantively patent information submitted by NDA holders, and FDA's longstanding position has been that it lacks the resources and patent expertise to do so, and that patent issues should be resolved by private litigants in the courts. As FDA's Chief Counsel explained to Congress,

> as we understand the statute, it requires us to publish patent information on approval of the NDA, thus making the agency's role ministerial, and courts have so held. I think that one of the signal features of Hatch-Waxman is that generic and innovator firms are supposed to resolve their disputes about patent listings and about patents in general in private litigation in the courts, where the expertise really resides with respect to patent questions.

Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before S. Comm. on the Judiciary, 108th Cong. 6-7 (2003) ("*Barriers to Entry Hearing*") (statement of Daniel Troy, FDA Chief Counsel). FDA adhered to this approach in the 2003 regulations, rejecting calls that it review the substance of the newly-required use codes and reemphasizing that "[t]he courts have the experience, expertise, and authority to address complex and important issues of patent law." 68 Fed. Reg. at 36683.

At the same time FDA was considering and eventually issuing its 2003 regulations, Congress

was considering legislation to address a wide range of Hatch-Waxman issues, including NDA holders' submission of misleading patent information for the Orange Book. Committees in both Houses of Congress (including the Subcommittee on Health of Rep. Waxman's House Energy and Commerce Committee) held hearings on Hatch-Waxman reform, in which FDA actively participated, presenting its views on proposed legislation and/or explaining the reasons for and content of its regulations, first as proposed and later as issued.[7] FDA made Congress aware of the agency's new requirements that NDA holders submit specific method of use information. E.g., *Barriers to Entry Hearing* at 7 (statement of D. Troy, FDA Chief Counsel) ("As I mentioned, we have tightened the requirements and increased the information required for drug patent submission and listings . . . . The required submissions include patent information on . . . approved uses of the drug"). FDA also made clear its view that substantive issues relating to the patent listing requirements should be resolved in litigation between the brand and the generic, not by the agency. *Id.* at 6-7.

---

[7] E.g., *Barriers to Entry Hearing*, at 5-8 (statement of D. Troy, FDA Chief Counsel); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before S. Comm. on the Judiciary*, 108th Cong. 7-10 (2003) ("*Greater Access Hearing*") (statement of D. Troy, FDA Chief Counsel); *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration: Hr'g Before Health Subcomm. of the H. Comm. on Energy and Commerce*, 107th Cong. 27-29 (2002) (statement of Lester Crawford, FDA Acting Commissioner).

Against this backdrop, and with the "invaluable help" of FDA (*Greater Access Hearing* at 119 (statement of Sen. Schumer)), Congress enacted the counterclaim provisions at issue here (among other amendments to Hatch-Waxman) in late 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[8] These provisions allow an ANDA applicant to file a counterclaim against the brand company RLD holder in patent litigation

> seeking an order requiring [the brand company] to correct or delete the patent information submitted by the holder under [21 U.S.C. 355(b) or (c)] on the ground that the patent does not claim either –
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. 355(j)(5)(C)(ii)(I). As described by their main legislative architect, the counterclaim provisions were intended to "enforce the patent listing requirements at the FDA by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand company delist the patent or correct the patent information in FDA's Orange Book." 149 Cong. Rec. 31,200 (2003) (statement of Sen. Schumer).

In this case, petitioner Caraco filed an ANDA for a generic version of the diabetes drug

---

[8] Pub. L. 108-173, 117 Stat. 2452.

repaglinide, for which the RLD was the respondent Novo's approved brand product Prandin®. J.A. 100-19. Caraco initially filed a Paragraph IV certification relating to an Orange Book-listed Novo patent (the "'358 patent"), J.A. 124-36, which led Novo to bring an infringement suit against Caraco and to a 30-month stay of FDA approval of Caraco's ANDA. J.A. 137-43. Based on FDA's recommendation, Caraco then amended its ANDA to include a section viii statement with regard to the patent's method claim (Claim 4) on the grounds that according to Novo's use code (J.A. 97-99), the '358 patent claimed only the use of repaglinide in combination with another drug, metformin, and not either of the other two approved uses. J.A. 166-76. FDA indicated that Caraco's section viii request was appropriate. Pet. App. 8a. Approval of this request would have allowed Caraco to carve out from its generic labeling information on the patented combination use and to receive immediate approval for generic repaglinide's approved unpatented uses.

Subsequently, however, Novo amended its use code description to state that the patent claimed "[a] method for improving glycemic control in adults with type 2 diabetes" – a description broad enough to encompass both the combination use of repaglinide claimed by the '358 patent and the unpatented uses. J.A. 371. FDA could not tell from Novo's use code whether the '358 patent claimed a use for which Caraco was seeking approval. Thus, FDA determined that it could not grant the section viii request. Caraco then filed a counterclaim in the Paragraph IV case seeking an order requiring Novo to amend the use code for the '358 patent to again make clear that this patent claimed only use of

Prandin® in combination with Metformin. J.A. 342-68.

The district court denied Novo's motion to dismiss the counterclaim and granted summary judgment for Caraco, ordering Novo to amend its use code for the '358 patent. Pet. App. 65a-103a.[9] A divided panel of the Federal Circuit reversed. Pet. App. 1a-52a.[10] The court of appeals held that the statute did not permit a counterclaim if, as here, the method of use patent covered *any* approved use of the RLD, even if it failed to cover other approved uses. Pet. App. 11a-13a. The Federal Circuit also held that use codes were not "patent information submitted by the holder under [21 U.S.C. 355(b) or (c)]" and therefore could not be the subject of an order requiring the brand company to correct or delete such information. Pet. App. 14a-17a. The Federal Circuit also denied rehearing *en banc*, over the dissent of Judge Gajarsa, who was joined by Judge Dyk, the dissenter from the panel opinion. Pet. App. 53a-64a.[11]

SUMMARY OF THE ARGUMENT

This Court faces two issues of statutory construction regarding the Hatch-Waxman counterclaim provisions. The first concerns the meaning of the words, "on the ground that the

---

[9] See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 649 F. Supp. 2d 661 (E.D. Mich. 2009) and *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F. Supp. 2d 729 (E.D. Mich. 2009).

[10] See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010).

[11] See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 615 F.3d 1374 (Fed. Cir. 2010)

patent does not claim . . . an approved method of using the drug," and whether they preclude counterclaims if, as here, an Orange Book-listed patent claims at least one approved use of the RLD. The second concerns whether the words "patent information submitted under . . . [21 U.S.C. 355(b) or (c)]" include information submitted pursuant to FDA regulations, or only information specifically identified in the statute. The Federal Circuit interpreted each of these passages to invalidate Caraco's counterclaim seeking an order forcing Novo to amend its overbroad use code.

The Federal Circuit's narrow construction of the counterclaim provisions is inconsistent with the statutory text and structure and cannot be squared with Congress' intent in enacting the counterclaim provisions – to enable private litigants to seek through the courts the correction of inaccurate patent information submitted by brand companies to FDA and thereby to strengthen, among other aspects of the Hatch-Waxman system, the section viii process. The section viii process is a key feature of the Hatch-Waxman generic approval framework, designed to enable ANDA applicants, in cases where an approved use of the RLD is not covered by a brand company patent, to obtain immediate FDA approval for that unpatented use and to circumvent costly, prolonged Paragraph IV litigation that would delay generic competition for years. FDA's 2003 use code requirements sought to bolster the section viii process against brand company efforts to claim overbroad coverage for their patents, and the counterclaim provisions enacted only six months later were expressly intended to afford ANDA applicants a means of correcting inaccurate

(including overbroad) Orange Book listings in the courts – the forum FDA and Congress agreed should address substantive patent issues. The Federal Circuit mistakenly concluded that Congress was only trying to overrule the decision in *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), and thus limited the counterclaim provision to the facts of that case, failing to recognize that Congress and FDA had much broader objectives in mind.

Under the Federal Circuit's reading of the counterclaim provisions, an NDA holder, through an overbroad use code, can block its generic competitors' access to the section viii immediate approval pathway, leaving generics with the sole recourse of costly, prolonged Paragraph IV litigation that delays generic entry, *even when the use for which the ANDA applicant seeks approval is not covered by a patent at all – the precise situation for which section viii is intended*. In these circumstances, moreover, the generic would be unable to prove non-infringement of the brand patent (because it would be unable to remove the patent information from its labeling) and, unless it could meet the high hurdle of showing that the patent was invalid or unenforceable, would be forced to delay marketing until expiration of the brand company patent – a patent that under the section viii process is completely irrelevant. Thus, the Federal Circuit's reading of the counterclaim provisions, far from strengthening the section viii process, effectively guts it. This is not the result that Congress intended.

ARGUMENT

I. The Federal Circuit's interpretation of "on the ground that the patent does not claim . . . an approved method of using the drug" is inconsistent with Congress' intent.

The Federal Circuit interpreted "on the ground that the patent does not claim . . . an approved method of using the drug" to preclude counterclaims unless the listed patent claimed no approved use of the RLD. Pet. App. 11a-13a. This reading is completely inconsistent with the text and context of the counterclaim provisions. Congress intended these provisions to cover the situation presented here in which Novo's patent did not cover all approved uses of the product and its overbroad use code improperly extended the scope of its valid patent protection.

1. The plain language of the statute states that a counterclaim may be asserted by a defendant in patent litigation if there is "an approved method of using the drug" that "the patent does not claim" – precisely the case here. Interpreting the statute to mean something different from what it says, the Federal Circuit read "*an* approved method of using the drug" (emphasis added) to mean *any* approved method of using the drug. Congress' decision not to use the word that would have unequivocally signaled the intent ascribed to it by the Federal Circuit shows that Congress intended a different meaning – especially given that the plain language of the statute conveys that different meaning.

Congress was mindful of the precise words it used when it enacted the counterclaim provisions.

In general, Congress "has a special duty to choose its words carefully when it is drafting technical and complex laws[.]" *St. Martin Evangelical Lutheran Church v. South Dakota*, 451 U.S. 772, 791 (1981) (Stevens, J., concurring) (citation omitted). And nowhere is this truer than in the Hatch-Waxman context. Senator Schumer aptly noted that as Congress attempted to close "loopholes" used by brand companies to exploit the Hatch-Waxman process to delay generic competition, "the devil is in the details . . . there is perhaps no other statute for which this phrasing is more true. Change an 'an' to a 'the' and you go from huge savings to huge costs." *Greater Access Hearing* at 119 (statement of Sen. Schumer). Thus, the counterclaim provisions were "extremely carefully crafted." *Ibid.*

Congress' decision to use "an" in the counterclaim provisions instead of "any" was not unconscious or neutral. It demonstrated Congress' clear, careful intent to allow a counterclaim where the Orange Book-listed patent did not claim a particular – "an" – approved use, not just when the patent failed to claim "any" approved use at all. If Congress had wanted the statute to have a narrow application and to preclude counterclaims when the NDA holder filed a use code that claimed both patented and unpatented uses, it knew exactly what word to use – "any." But it chose not to use that word here. See *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 176-77 (1994) ("If . . . Congress intended to impose aiding and abetting liability [in section 10(b) of the Securities Exchange Act of 1934], we presume it would have used the words 'aid' and 'abet' in the statutory text. But it did not.") (citations omitted).

2. Congress' use of "any" elsewhere in the counterclaim provisions confirms that Congress understood the meaning and effect of that word, but opted for a different, broader approach in setting forth the grounds on which a counterclaim could be brought. *Lopez v. Gonzalez*, 594 U.S. 47, 55 (2006) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation marks omitted). 21 U.S.C. 355(j)(5)(C)(ii)(II) states that "[s]ubclause I [i.e., the counterclaim provision] does not authorize the assertion of a claim described in subclause (I) in *any* civil action or proceeding other than a counterclaim described in subclause (I)." (emphasis added). There, Congress used "any" to state absolutely that a claim based on the grounds set forth in the counterclaim provision could *never* be asserted except as a counterclaim under that provision. If Congress had meant to assert, in the same section, the similarly absolute proposition that a counterclaim could *never* be asserted if the Orange Book-listed patent claimed at least one approved use of the RLD, it would have used "any" in the counterclaim provisions as well. *Central Bank*, 511 U.S. at 176 ("Congress knew how to impose aiding and abetting liability when it chose to do so.") (citations omitted).

3. "[O]n the ground that the patent does not claim . . . an approved method of using the drug" also complements the wording of the section viii provisions, which indisputably apply when an Orange Book-listed patent fails to claim at least one approved use of the RLD. Specifically, section viii

applies when the listed patent is "a method of use patent which *does not claim a use for which the applicant is seeking approval under this subsection*." 21 U.S.C. 355(j)(2)(A)(viii) (emphasis added). No one suggests that Congress intended a section viii approval to require that the NDA's holder's patent claim *no* approved method of use – merely that there be a single, particular approved use not claimed by the patent. If Congress had intended to limit counterclaims to cases in which the patent claimed no approved use, it would not have used language that complements the section viii language (compare "does not claim . . . an approved method of using the drug" to "does not claim a use for which the applicant is seeking approval.") See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669, 673 (1990) (noting "complementary" Hatch-Waxman provisions and interpreting statutory language in light of "the structure of the Act . . . taken as a whole").

4. The Federal Circuit's limitation of counterclaims to situations where the listed patent claimed no approved use renders superfluous the statute's language allowing the counterclaimant to seek an order "correct[ing]" the submitted information. *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) ("[O]f course we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof.") (citation omitted). The counterclaim language provides that a counterclaimant may seek an order "requiring the holder to correct *or* delete the patent information…." 21 U.S.C. 355(j)(5)(C)(ii)(I) (emphasis added). If the counterclaim provisions were only intended to cover instances where the patent claimed no approved use, Congress would only have needed to provide for an

order that the NDA holder delist the patent and "delete" the information relating to the patent from the Orange Book. For "correct" to have any meaning in the statute separate and independent from "delete," Congress would also had to have contemplated, and did contemplate, a situation like this one – when the patent covered at least one approved use, but did not cover other approved uses, and where the patent information therefore needed to be amended ("correct[ed]"), as opposed to deleted outright, to reflect only the patented use. A reading that restricts the counterclaim provisions to situations in which deletion of the information is the only appropriate remedy fails to give full effect to the language Congress carefully chose.

That Congress included "correct[ion]" or "delet[ion]" of patent information as alternative remedies under the counterclaim provisions disposes of the Federal Circuit's suggestion that these provisions were intended as a limited response to *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). In *Mylan*, the NDA holder submitted for listing in the Orange Book information on a patent that claimed no approved use of the RLD. The ANDA applicant sought to have the patent delisted, but the Federal Circuit held that it had no private right of action to contest the NDA holder's submission. 268 F.3d at 1332. The Federal Circuit in this case concluded that the counterclaim provisions legislatively overruled *Mylan* and should be limited to its facts – i.e., situations in which the patent claimed no approved product and did not belong in the Orange Book at all. Pet. App. 12a-13a. However, the statutory language allowing a counterclaimant to seek an order requiring the NDA

holder to "correct" *or* "delete" Orange Book information makes clear that Congress intended to address brand company patent listing activities to which the appropriate response was *either* "delet[ion]" of patent information, as the ANDA holder sought in *Mylan*, *or* "correct[ion]" of that information, as Caraco sought here. If Congress had only wanted to address the *Mylan* situation, it would not have needed to provide for "correct[ion]" of patent information.

Despite the Federal Circuit's reliance on *Mylan* to explain its view of Congress' intent, nothing in the legislative history suggests that the counterclaim provisions were a direct response to that decision, Moreover, the holding in *Mylan* was that Hatch-Waxman did not provide ANDA applicants with *any* new rights of action that it could assert against the brand. 268 F.3d at 1332. This holding applied no less to Caraco's claim here that the brand company improperly extended the scope of its patents by submitting a use code that purports to cover both patented and unpatented uses than to Mylan's claim that the NDA holder improperly listed a patent that covers no patented use at all. There is nothing in the legislative history to suggest that even if Congress' goal in enacting the counterclaim provisions was to overrule the *holding* in *Mylan*, it intended only to address the *fact situation* in *Mylan*.

5. The reading of the statute that makes the most sense given its text and structure is also the *only* reading of the statute that makes sense given the context in which, and purposes for which, Congress enacted the counterclaim provisions. *Deal v. United States*, 508 U.S. 129, 132 (1993) (noting the "fundamental principle of statutory construction

(and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used.") (citations omitted).

As discussed, *supra*, at 7-9, Congress was clearly aware of, and legislated in the immediate wake of, the 2003 FDA regulations requiring NDA holders to submit specific information on each approved use claimed by the patent. FDA made crystal clear in its preamble to the regulations that a key objective of the new requirements was to enable the agency and ANDA applicants to determine whether there were unpatented uses for the RLD that could serve as the basis for a section viii approval. The agency emphasized that

> [t]he specific method-of-use claims are *essential* to our review because [section viii] allow[s] ANDA . . . applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval. . . . Thus, the claim-by-claim listing of method-of-use patents will permit ANDA . . . applicants to assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement.

68 Fed. Reg. at 36682 (emphasis added). See also *id.* ("To effectively implement the certification and section viii provisions set out in the statute, we must have adequate information concerning method-of-use patents.").

Against this backdrop, and with FDA's "invaluable help" (*Greater Access Hearing* at 90 (statement of Sen. Schumer)) Congress enacted the counterclaim provisions to "enforce the patent listing requirements at the FDA." 149 Cong. Rec. 31,200 (2003) (floor statement of Sen. Schumer). See also *Barriers to Entry Hearing* at 90 (written statement of Sen. Schumer) (noting that the legislation "includes a strong enforcement mechanism . . . which will give teeth to the FDA's new listing provisions."). It is inconceivable that Congress manifested its intent to "give teeth to the FDA's new listing requirements" by disallowing a counterclaim where the NDA holder (1) failed to provide FDA with precisely the information that the agency's regulations required (i.e., specific information regarding methods of use claimed by the patents) and (2) used an overbroad use code to thwart the section viii process that the regulations were expressly designed to strengthen.

The Federal Circuit's reading is particularly unwarranted because it denies ANDA holders the judicial forum that Congress and FDA agreed was best equipped to address the patent listing issues implicated by the FDA regulations. FDA's longstanding view, with which Congress agreed, was that the agency lacked the expertise to substantively review patent information submitted by NDA applicants/holders and that disputes regarding the substance of that information (such as whether a particular patent claimed a particular approved use) should be resolved in litigation between private parties. The counterclaim provisions acknowledged and respected FDA's limited role in the patent review process and were designed to "go[] farther

than the rule is capable of in ensuring that consumers will see real savings from closing these loopholes." *Ibid.* See also 149 Cong. Rec. 15,516 (2003) (statement of Sen. Schumer) ("In fact, when the FDA actually talked about closing these loopholes, it was made clear that legislation would be needed to finish the job"). The Federal Circuit's reading of the counterclaim provisions thoroughly undermines Congress' intention to vest authority for the correction of misleading Orange Book listings in the courts.

Congress did not intend to ignore the problem of overbroad use codes and to focus only on the listing of patents that claim no approved use at all. There is no meaningful distinction in this context between the listing of a patent that claims no approved use of the RLD and the submission of a use code narrative that fails to distinguish between patented and unpatented uses. Both tactics involve the submission of misleading Orange Book information. Both manipulate the patent listing process to claim patent protection where none exists and to delay generic competition by leaving an ANDA applicant that is eligible for immediate approval with the sole (and, as discussed infra at 24-26, likely unhelpful) recourse of costly paragraph IV litigation that might delay generic competition for years. And both are addressed directly by FDA's requirement that the NDA holder "identify specifically," under penalty of perjury, "the approved uses claimed by the method of use patent." 68 Fed. Reg. at 36682.

Congress, too, sought to address both tactics by providing for a counterclaim through which ANDA applicants can seek to have their applications

restored to an immediate approval track. There is no evidence whatsoever and it would defy logic to suggest that in creating a judicial mechanism to enforce the FDA regulations, Congress sought or had any reason to address these two situations differently. Pet. App. 63a (Gajarsa, J., dissenting from denial of rehearing *en banc*) (noting that the majority's reading of the counterclaim provisions produces "an untenable and absurd result" that "contravenes the intent of Congress.") If, as this Court noted in *Arlington Cent. Sch. Dist. Bd. Of Educ. v. Murphy*, 548 U.S. 291, 296 (2006), the plain meaning rule of statutory construction does not apply "where the disposition required by the text is . . . absurd," it is certainly true that the Court should reject an "absurd" reading of the counterclaim provisions that is *not* supported by the statutory text or context.

Indeed, the Federal Circuit's reading of the counterclaim provisions, far from advancing FDA's and Congress' goal of increasing access to generic drugs, would eviscerate the section viii process that FDA's regulations and the counterclaim provisions were designed to protect. The section viii process provides for immediate approval of an ANDA when there is no issue of patent infringement, validity, or enforceability that needs to be addressed through the Paragraph IV litigation process (because the ANDA seeks approval for a use not covered by a patent). The Federal Circuit's decision, however, allows a brand company, through an overbroad use code, to deny the ANDA applicant access to that process. Under the Federal Circuit's reading, an ANDA holder otherwise entitled to immediate approval under section viii must instead look to the

Paragraph IV litigation process and challenge the listed patent on grounds of non-infringement, invalidity, and/or unenforceability – the very process that the section viii alternative was designed to avoid, and that Congress recognized would delay generic competition for years.

Even if the NDA holder is ultimately unsuccessful in the Paragraph IV litigation, the important point is that because of the automatic stay, it has been able to delay generic competition for at least 30 months while the litigation is ongoing. It is clear that generics "quickly gain a large share of the market" upon their approval by FDA. CBO Report at 28. The Congressional Budget Office found that for each of seven of the most prescribed drugs, generic companies gained 65% or more of the market within two years of entry. *Id.* Thus, it is a victory in and of itself for a brand company to lock a generic company into Paragraph IV litigation that will maintain the stay and delay the onset of generic competition, regardless of the eventual outcome of the litigation. That is what overbroad use codes, no less than the listing of a patent that claims no approved use, are designed to achieve,.

To make matters worse, moreover, as Judge Dyk's dissent, Judge Clevenger's concurrence, and Judge Gajarsa's dissent from the denial of rehearing *en banc* all recognized, an ANDA applicant that sought a section viii approval but was involuntarily forced into Paragraph IV litigation because of an overbroad use code would not be able to prove non-infringement because it would have no basis for distinguishing its label from the brand's. *See* Pet. App. 20a (Clevenger, J., concurring) (noting that as a result of the court's decision, "Caraco can no longer

assert that its proposed labeling does not infringe the '358 patent");[12] Pet. App. 50a (Dyk, J., dissenting) ("Novo's adoption of a broad use code for PRANDIN likely prevents Caraco from being able to disprove infringement in the paragraph IV lawsuit, because Caraco is now compelled to include information regarding the patented combination therapy in its label.*");* Pet. App. 63a (Gajarsa, J., dissenting from denial of rehearing *en banc*) ("Caraco . . . cannot disprove infringement . . . because the FDA requires it to use Novo's original label, which includes information regarding the patented combination therapy.")[13] Failure in the

---

[12] Judge Clevenger determined that this result was FDA's fault because it had revised the labeling requirements for Prandin® and Novo's revision of its use code description was merely an effort to track the revised labeling. *Ibid*. But as Judge Dyk pointed out, the labeling changes in no way required Novo to change its original use code description, and the revised description clearly violated FDA regulations. Pet. App. 20a. The actual "fault" here lies in the assumption that the use code must track exactly the revised labeling even when it differs significantly from the scope of the listed patent.

[13] A Paragraph IV defendant may also prevail if it shows that the patent to which it certified was either invalid or unenforceable (for example, because the patentholder engaged in inequitable conduct before the U.S. Patent and Trademark Office). That is a high burden. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011) (patents are presumed valid, and invalidity must be proven by clear and convincing evidence); *Therasense Inc. v. Becton Dickinson & Co.*, Nos. 2008-1511, -1512, -1513, -1514, -1595, 2011 WL 2028255 (Fed. Cir. May 25, 2011) (en banc) (inequitable conduct requires clear and convincing evidence of "but-for" materiality and specific intent to deceive).

Paragraph IV litigation would, in turn, delay the generic from going to market until the expiration of the patent that is the subject of the Paragraph IV litigation – *a patent that would be completely irrelevant if the generic company had been able to pursue a section viii carve-out*. Congress could not possibly have intended, and did not intend, the counterclaim provisions to have this effect.

II. The Federal Circuit's interpretation of "patent information submitted . . . under [21 U.S.C. 355(b) or (c)]" is inconsistent with Congress' intent.

The Federal Circuit also held Caraco's counterclaim invalid on the grounds that the information Caraco sought to correct – the use code for the '358 patent − was not "patent information submitted by the [NDA] holder . . . under [21 U.S.C. 355(b) or (c)]," and therefore could not be ordered by a court to be "correct[ed]" or "delete[d]" under the statute. Pet. App. 14a-17a. The court of appeals held that such "patent information" included only the patent number and expiration date required to be submitted for Orange Book publication by the statute itself, and did not include the use code and other information required to be submitted under FDA regulations. *Ibid*. This narrow reading of "patent information," like the federal circuit's narrow reading of "on the ground that the patent does not claim . . . an approved method of using the drug," is directly contrary to the text, structure, and context of the statute. Congress clearly intended "patent information submitted . . . under section [21 U.S.C. 355(b) or (c)]" to include the use codes required under FDA regulations.

1. The plain language of the statute leaves no room to suggest that use codes are not "patent information submitted . . . under [21 U.S.C. 355(b) or (c)]." A use code is clearly "information" about a "patent." And use code narratives are certainly "submitted . . . under [21 U.S.C. 355(b) or (c)]" because they are submitted pursuant to FDA regulations implementing the NDA approval and post-approval requirements set forth in those sections. *Greater Access Hearing*, *supra*, at 129 (written statement of D. Troy, FDA Chief Counsel) ("FDA has implemented the statutory patent listing provisions by informing interested parties of what patent information is to be submitted, who must submit the information, and when and where to submit the information."). In this context, therefore, "submitted . . . under [21 U.S.C. 355(b) or (c)]" naturally means "submitted as part of the NDA process 'subject to' or 'governed by' 21 U.S.C. 355(b) or (c)." See *Ardestani v. INS*, 502 U.S. 129, 135 (1991) (defining "under" in an analogous context to mean "subject to" or "governed by"). There is no question that the use codes fall within that definition.

If Congress had wanted to limit the counterclaim language to provide only for the correction or deletion of the "patent information" expressly required by statute, it instead could easily have referenced patent information "required by" or "referenced in" or "defined in" 21 U.S.C. 355(b) or (c). Again, Congress' choice of words in the Hatch-Waxman context has particular importance. *Supra*, at 15. Congress had at its disposal language that would have conveyed the narrow intent ascribed to it by the Federal Circuit. The fact that Congress chose

language that is naturally read not to have that narrowing effect shows that Congress did not intend that effect.

2. Congress did not draft the "patent information" language on a blank slate. The statutory language mirrors the verbiage used by FDA in its regulations and in discussing the regulation with Congress, to which the agency provided "invaluable help" (*Greater Access Hearing* at 119 (statement of Sen. Schumer)) in the process of drafting the statute. E.g., 21 C.F.R. 314.53 (entitled "*Submission* of *patent information*") (emphasis added); 21 C.F.R. 314.53(C)(2)(ii)(P) (requiring "*[i]nformation* on each method of use patent including the following[.]") (emphasis added); 68 Fed. Reg. at 36683 ("[W]e believe that it is necessary than an NDA holder *submit* more specific *information* on the approved methods of use protected by a submitted patent") (emphasis added); *Barriers to Entry Hearing* at 7 (testimony of D. Troy, FDA Chief Counsel) ("[W]e have tightened the requirements and increased the *information* required for drug patent *submission* and listings) (emphasis added).

FDA understood use codes to fall within the definition of "patent information submitted . . . under [21 U.S.C. 355(b) or (c)]," and Congress, in repeating FDA's language and working closely with the agency in drafting the counterclaim provisions, sought to ratify the agency's understanding. Pet. App. 37a (Dyk, J., dissenting) ("[I]t is well established that where, as here, Congress was specifically aware of the agency's interpretation of a statutory term at the time the statute was enacted, this is compelling evidence of legislative adoption of the agency's interpretation") (citing cases). At the

very least, Congress' decision to use the same language as FDA shows that its intent was to afford this language a broad scope: If Congress, in full awareness of the FDA's interpretation, had intended to adopt a different, more narrow interpretation than FDA's, it would not have used the same words FDA used. See *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not . . . hide elephants in mouseholes.") (citations omitted).

3. The Federal Circuit suggested that because the original Hatch-Waxman statute contained an "express statutory definition" limiting "patent information" to the patent number and expiration date, this definition also applies to "patent information" as it appears in the counterclaim. Pet. App. 15a. The court of appeals' underlying premise, however, is incorrect. As Judge Dyk noted in his dissent, Hatch-Waxman does not define "patent information." Pet. App. 27a. And although the only patent information *required* to be submitted by Hatch-Waxman is the patent number and expiration date, the statute clearly envisions, and in fact cannot be implemented effectively without, specific information relating to patents and the particular methods of uses they cover.[14] Indeed, both the Paragraph IV and section viii provisions in Hatch-Waxman *depend on* the availability to ANDA

[14] The Federal Circuit did not question FDA's authority to promulgate the use code regulations. Nor has Novo suggested at any point in this litigation that FDA lacked such authority.

applicants and FDA of information that will relate the brand company patents covering particular methods of use to the methods of use approved by FDA for the RLD's. Pet. App. 30a (Dyk, J., dissenting) (reviewing the statute and concluding that Hatch-Waxman "plainly contemplates that 'patent information' will include information that describes the scope of the patent and that relates the patent to the drug or method of use."). This information cannot be gleaned merely from a listing of a patent number and expiration date. FDA itself recognized that more specific information than what was required in the statute was "necessary" for it "[t]o effectively implement the [Paragraph IV] and section viii statement provisions." 68 Fed. Reg. at 36682-83. And the counterclaim provisions were Congress' way of enforcing these important requirements.

That Congress and FDA both recognized the need for the submission of patent information other than patent number and expiration date undermines the court of appeals' view that in enacting the counterclaim provisions, Congress was adhering to an earlier fixed and narrow "definition" of "patent information." Congress did not have such a limited perspective and fully expected that FDA needed to, and in fact would, develop additional patent listing requirements, as it did in 2003 when it enacted the use code regulations. There is no basis on which to distinguish between the "patent information" that Congress initially required in the statute and the "patent information" that Congress authorized and fully expected FDA to require in order to implement the statute effectively.

4. The Federal Circuit's reading of "patent information submitted . . . under [21 U.S.C. 355(b) or (c)]," like its reading of "an approved method of using the drug," is irreconcilable with Congress' clear intent to provide a judicial mechanism for the correction of inappropriate patent listings. The use codes that the Federal Circuit deemed to be outside the scope of the counterclaim provisions were the very information that FDA required in its regulations and that the agency deemed critical to its efforts to administer the section viii process that allows for expedited generic competition. In fact, without correct method of use information, FDA cannot determine whether ANDA applicants have filed appropriate section viii certifications to the method of use patent, as required by statute. As discussed, *supra*, at 7-9. Congress intended the counterclaim provisions to provide a means of correcting inaccurate Orange Book information in the forum that FDA and Congress had consistently agreed was best equipped to address patent listing issues – the courts. It makes no sense to suggest that Congress did not intend the counterclaim provisions to apply to patent information that FDA specifically required in the regulations – especially given that, as discussed *supra*, the submission of incorrect use codes claiming both approved and unapproved uses has the same purpose and effect as the improper listing of a patent that claims no approved use at all.

Again, the Federal Circuit's narrow reading of the counterclaim provisions would fatally undercut the section viii framework. If an ANDA applicant cannot file a counterclaim to require the NDA holder to amend overbroad use code narratives, there is

nothing to stop the manipulation of the patent listing process to prevent ANDA applicants and FDA from identifying unpatented uses that are suitable for expedited section viii treatment. That an ANDA applicant otherwise eligible for section viii treatment could still seek recourse through prolonged Paragraph IV litigation that the section viii process was intended to avoid and that the ANDA applicant has little chance of winning (*supra*, at 24-26) is cold comfort and plainly inconsistent with Congress' intent to provide ANDA holders with the choice of the Paragraph IV and section viii pathways.

CONCLUSION

The decision below should be reversed.

Respectfully submitted.

CARLOS T. ANGULO*
Zuckerman Spaeder LLP
1800 M Street, N.W.
Suite 1000
Washington, DC 20036
(202) 778-1800
cangulo@zuckerman.com

**Counsel of Record*

Counsel for Amicus Curiae Rep. Henry A. Waxman

SEPTEMBER 2011