No. 10-844

IN THE
Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD., *et al.*,
Petitioners,
v.
NOVO NORDISK A/S, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Federal Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Found.
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

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QUESTIONS PRESENTED

Amicus curiae addresses the following issue only:

Whether the counterclaim set forth in 21 U.S.C. § 355(j)(5)(C)(ii) is available to the defendant in a patent infringement action, where the patent that the plaintiff seeks to enforce claims an FDA-approved method of use for the drug for which the defendant seeks marketing approval.

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011). In particular, WLF has appeared in cases before this Court and the U.S. Court of Appeals for the Federal Circuit in a number of cases related to the proper resolution of drug patent disputes between "pioneer" drug manufacturers and generic drug manufacturers. *See, e.g., Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.), *cert. denied*, 540 U.S. 1048 (2003).

WLF believes that both pioneer and generic manufacturers play an important role in providing quality health care to the American public. If advances in health care are to continue, it is vital that innovator companies that develop new drugs and medical devices, or new methods of using those products, be afforded periods of patent protection, during which potential

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[1] Pursuant to Supreme Court Rule 37.6, WLF state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to this filing; letters of consent have been lodged with the Court.

competitors are not permitted to market the same product. Patents provide an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new therapies will be able to realize a return on their investment when their research and development expenditures bear fruit. On the other hand, once an appropriate period of patent exclusivity has expired, consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

WLF believes that Congress struck an appropriate balance between those competing interests when it adopted the Hatch-Waxman Act.[2] WLF believes it imperative that federal courts refereeing patent disputes between pioneer and generic drug manufacturers strictly apply the procedural rules set forth in the Hatch-Waxman Act. Otherwise, courts will not be giving effect to the careful balance struck by Congress between those two groups of manufacturers. WLF is concerned that Petitioners, by seeking to expand the circumstances under which generic manufacturers are permitted to file legal challenges to the exclusive marketing rights of pioneer manufacturers, are engaged in a short-sighted exercise that could, if successful, undermine the long-term interests of the American

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

health care system.

WLF agrees with Novo that Caraco's withdrawal of its Paragraph IV certification deprived the federal courts of jurisdiction to hear Caraco's counterclaim. This brief does not address that issue, however, but rather focuses solely on whether, in light of Caraco's concession that the patent-at-issue claims an approved method of using repaglinide, Caraco is entitled to avail itself of the counterclaim authorized by 21 U.S.C. § 355(j)(5)(C)(ii)(I).

STATEMENT OF THE CASE

Respondents Novo Nordisk A/S and Novo Nordisk, Inc. (collectively, "Novo") market and distribute the drug repaglinide under the brand name PRANDIN. Novo (as the holder of an approved NDA) is the only drug company authorized by the Food and Drug Administration (FDA) to sell repaglinide. PRANDIN is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. FDA has approved PRANDIN for three uses: (1) repaglinide by itself (*i.e.*, monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidnediones ("TZDs").

Novo's patent for the chemical composition of repaglinide expired in 2009. However, it holds a method-of-use patent for use of repaglinide in combination with metformin (the " '358 patent") that does not expire until 2018. Accordingly, drug manufacturers wishing to obtain permission from FDA pursuant to an Abbreviated New Drug Application

(ANDA) to market a generic version of repaglinide must demonstrate that they are capable of doing so without infringing the '358 patent.

In 2005, Petitioner Caraco Pharmaceutical Laboratories, Ltd. filed an ANDA with FDA, seeking permission to market repaglinide. The ANDA included a "Paragraph IV" certification with respect to the '358 patent – an assertion that a patent covering the FDA-approved drug (and listed in FDA's "Orange Book") is either invalid or will not be infringed by the sale or use of the generic drug.[3] A provision of the Hatch-Waxman Act (35 U.S.C. § 271(e)(2)) deems the filing of a Paragraph IV certification to constitute an act of patent infringement. Accordingly, Novo responded to Caraco's ANDA by filing a patent infringement suit in June 2005 against Caraco in federal district court in Michigan.

Ordinarily, an ANDA applicant must agree to use the same product labeling previously approved by FDA for use with the brand-name drug to which the proposed generic drug will be compared (known as the "reference listed drug" or "RLD"). If (as here) the FDA-approved labeling includes reference to an approved use that is covered by a method-of-use patent, a generic manufacturer would be unable to avoid infringing the patent if it simply replicated that labeling. The Hatch-Waxman offers a potential remedy for that problem – use of a "Section viii" statement. Section viii, 21 U.S.C. § 355(j)(2)(A)(viii), allows the ANDA applicant to submit to FDA a proposed label that carves out the from the RLD labeling the patented method of using the listed

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[3] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

drug. FDA will approve the revised labeling, however, only if it determines that the drug so labeled will remain safe and effective for the remaining non-patented methods of use.

In April 2008, Caraco amended its ANDA to replace its Paragraph IV certification with a Section viii statement. The latter sought to carve out from the RLD labeling any reference to the method of use covered by the '358 patent. FDA ultimately rejected Caraco's requested "carve out" on the basis of the "use code narrative" that Novo had submitted for inclusion in the Orange Book.[4] Novo's "use code narrative" for the '358 patent (as amended by Novo in 2009) included (per FDA's regulations) a description of its approved indication: "A method for improving glycemic control in adults with type 2 diabetes mellitus." In rejecting Caraco's "carve out" request, FDA declined to undertake its own analysis of the '358 patent. The United States later explained that Caraco "could not carve out the single approved indication that corresponded to [Novo's] new use code because that would leave [Caraco's] labeling without any approved indication, rendering its drug not safe and effective." U.S. Br. 12. FDA rejected Caraco's challenge to Novo's 2009 revision of the use code narrative. Caraco did not

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[4] FDA's Orange Book lists the patent number and expiration date of every patent that claims a drug that is the subject of an approved NDA or that claims a method of using the drug. By regulation, FDA also requires the NDA holder to submit, for each listed method-of-use patent, a "use code narrative" of up to 240 characters; FDA describes the narrative as a "description of the approved indication or method of use" for the approved drug. Pet. App. 212.

seek judicial review under the Administrative Procedure Act from that decision, nor did it seek APA review of the rejection of its Section viii "carve out" request.

Instead, Caraco in June 2009 filed a counterclaim in the Michigan patent infringement litigation. The counterclaim sought an order, under 21 U.S.C. § 355(j)(5)(C)(ii), requiring Novo to "correct" the use code information regarding the '358 patent that it had submitted to FDA for inclusion in the Orange Book. Rejecting Novo's assertion that § 355(j)(5)(C)(ii) did not authorize such a counterclaim, the district court granted summary judgment to Caraco on the counterclaim. Pet. App. 67a-72a. It ordered Novo to submit a new use code narrative stating that the '358 patent covered "the use of repaglinide in combination with metformin to lower blood glucose." *Id.* at 65a-66a.

The Federal Circuit reversed the grant of summary judgment and vacated the injunction requiring Novo to amend its use code narrative. *Id.* at 1a-18a. The court explained that the counterclaim provision was limited to situations in which the patent listed in the Orange Book claimed neither "the drug for which the application was approved" nor "an approved method of using the drug." *Id.* at 11a-12a. Because all parties agreed that the '358 patent did, in fact, claim "an approved method of using" repaglinide, the appeals court held that Congress had not authorized Caraco to file a counterclaim. *Id.* The court said that if Caraco seeks to expedite approval of its ANDA through a Section viii statement, "its real complaint should lie with the FDA, not with Novo," noting that it was FDA that approved Novo's amended use code narrative and

denied Caraco's Section viii "carve out." *Id.* at 14a.

The appeals court also stated that if a generic manufacturer seeks through litigation to contest an infringement claim, it should do so in connection with its defense of litigation filed by the pioneer manufacturer in response to a Paragraph IV certification:

> This court recognizes that a broad use code covering all uses of a pharmaceutical could require generic manufacturers to prove specifically that their use will not overlap with and infringe the patented use. This proof, under Hatch-Waxman procedures, will take the form of a Paragraph IV lawsuit. In that context, the generic may provide proof that their use will not cause infringement of the patented use. This court perceives that the Hatch-Waxman Act will thus ensure that a generic drug for non-patented purposes will not be used for patented purposes via a simple section viii certification. Instead, the generic manufacturer will need to alleviate the risk of infringement or induced infringement in a proceeding that fully tests for infringement and its implications, including potential health and safety risks.

Id.

The Federal Circuit also provided an alternative basis for reversing the district court's injunction: "the counterclaim provision only authorizes suits to correct or delete an erroneous patent number or expiration

date. The authorization does not extend to use code narratives." *Id.* at 15a-16a. The appeals court held that Caraco's counterclaim was improper because it sought to "correct or delete" Novo's use code narrative, not merely the patent number or expiration date. *Id.* WLF does not address this alternative holding.

SUMMARY OF ARGUMENT

Novo's brief spells out multiple reasons why Caraco is not entitled to an injunction requiring Novo to amend its use code narrative. WLF focuses this brief on one of those reasons: the counterclaim provision adopted by Congress in 2003 is unavailable when, as here, the patent listed in the Orange Book claims "an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii). Caraco struggles mightily to avoid the plain meaning of the quoted language, but that meaning is fully supported by common sense, standard grammar, and by the overall purposes of the 2003 statute (the "2003 Amendments") that added the counterclaim provision to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

The counterclaim provision is available to Caraco only if it can show that the '358 patent "does not claim either . . . the drug for which the application was approved . . . or an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I)(aa) and (bb). Caraco argues that this language means that it need only show that there is at least one "approved method of using" repaglinide that is *not* claimed by the '358 patent. The utter implausibility of Caraco's interpretation is most readily apparent if one examines the structure of the

counterclaim provision. Under that structure, two propositions ("Proposition A" and "Proposition B") are parallel to one another, and the generic company must demonstrate both in order to assert a counterclaim. As Caraco reads the statute, Proposition B should be interpreted to mean, "There exists at least one FDA-approved method of use that the patent-at-issue does not claim." But if that interpretation is ascribed to Proposition B, there is no interpretation that can be given to Proposition A that would maintain the parallel structure between the two propositions. Proposition A unquestionably requires a showing that the listed patent does *not* cover the RLD. There is no way to express that meaning in a manner that parallels the meaning ascribed to Proposition B by Caraco (*i.e.*, that requires the generic company to demonstrate existence instead of nonexistence). That lack of parallelism is eliminated if one adopts Novo's interpretation: the counterclaim provision requires a generic company to demonstrate that the patent at issue claims neither: (a) the underlying drug; nor (b) any approved method of using the drug.

The 2003 Amendments were adopted to correct a specific problem identified by Congress in connection with the Federal Circuit's 2001 *Mylan* decision: pioneer drug companies listing in the Orange Book patents that claimed neither the RLD nor a method of using the drug. By doing so, a pioneer company could delay approval of an ANDA by forcing a generic company to file a Paragraph IV certification; once the certification was filed, the pioneer company could then file a patent infringement suit, thereby triggering the Hatch-Waxman Act's 30-month stay of approval of the ANDA.

Mylan held that Congress had not authorized generic companies to file suit to force pioneer companies to remove improperly listed patents from the Orange Book. *Mylan*, 268 F.3d 1323. The 2003 Amendments were designed to correct the precise problem illustrated by *Mylan*. No party contests the Federal Circuit's conclusion that the 2003 Amendment, as interpreted by the court of appeals, fully accomplished that purpose. Pet. App. 13a. Indeed, the 2003 Amendments "used exact language from *Mylan* in the new counterclaim provision." *Id.* Accordingly, there is no reason to attribute to Congress a desire to correct the distinct set of "abuses" alleged by Caraco (the writing of overly broad use code narratives), particularly given that FDA did not direct manufacturers to begin writing use code narratives until several months *after* Congress adopted the 2003 Amendments.

There is no merit to Caraco's assertion that the Federal Circuit's decision leaves it without an effective remedy. As the Federal Circuit noted, a Paragraph IV lawsuit permits "efficient resolution" of all infringement/invalidity issues in an environment that "fully tests for infringement and its implications." *Id.* at 14a. One serious issue that arises in an suit involving method-of-use patents is "induced infringement." *Id*. If generic versions of repaglinide are approved while the '358 patent is still in force, there is a serious danger that doctors and medical insurers will infringe the patent by prescribing repaglinide for use in combination with metformin. Novo is entitled to seek to block approval of Caraco's ANDA to the extent that it can demonstrate that if Caraco wins approval, it will induce others to infringe the '358 patent.

Moreover, the structure and the legislative history of the 2003 Amendments make clear that Congress sought to avoid upsetting the balance created by the Hatch-Waxman Act. It sought to ensure that the interests of both pioneer and generic drug companies were respected. In particular, it placed strict limits on the litigating rights of generic companies. Congress recognized that forcing patent holders to face too broad an array of legal challenges to their patents could seriously undermine the value of those patents. Any such diminishment in value has the potential to undermine continued advances in health care. Steps designed to ease the entry of generic drugs into the marketplace may lead to short-term price reductions for consumers, but – as Congress recognized – consumers are best served if a balance is maintained between short-term cost concerns and the longer-term need to encourage the level of research-and-development funding necessary to ensure continued medical advances.

ARGUMENT

I. CARACO'S CLAIM DOES NOT FALL WITHIN THE NARROW COUNTERCLAIM AUTHORIZED BY THE 2003 AMENDMENTS

The FDCA does not create a private right of action to enforce or restrain violations of its provisions and accompanying regulations. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001). *See* 21 U.S.C. § 337(a) ("All such proceedings for the enforcement, or to restrain violations, of [the

FDCA] shall be by and in the name of the United States."). Accordingly, the Federal Circuit held in *Mylan* that Congress has not authorized generic companies to sue to enforce the FDCA provision that prohibits pioneer drug companies from listing in the Orange Book a patent that claims neither the RLD (that is, the FDA-approved drug to which the proposed generic drug will be compared) nor a method of using the RLD. *Mylan*, 268 F.3d at 1330. The court dismissed for failure to state a cause of action a lawsuit filed by a generic company that objected to an Orange Book listing of a patent that covered a metabolite of the RLD rather than the RLD itself. *Id.* at 1332.

In response, some Members of Congress sought to overturn the result in *Mylan* by adopting legislation that would have created explicitly the private right of action that *Mylan* had rejected. *See* Respondents Br. 6-8, 44-45. That legislation failed following "a firestorm of criticism from Republican legislators" and a statement by President Bush that the it "would unnecessarily encourage litigation around the initial approval of new drugs and would complicate the process of filing and protecting patents on new drugs." *Id.* at 7-8. The result is that *Mylan* continues as an accurate statement of current federal law: a generic company does not possess a free-standing right of action against a pioneer drug company to correct allegedly improper Orange Book listings, even if the improper listing is interfering with the generic company's ability obtain approval of an ANDA.

Instead, Congress adopted the 2003 Amendments as a compromise between those who sought to overturn

Mylan and those who sought to avoid increased litigation between pioneer and generic companies. In particular, the 2003 Amendments added the counterclaim provision at issue in this lawsuit; it provides in full:

> (ii) Counterclaim to infringement action.
>
> (I) In general. If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant [for an ANDA], the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either –
>
> (aa) the drug for which the application was application was approved; or
>
> (bb) an approved method of using the drug.
>
> (II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

21 U.S.C. § 355(j)(5)(C)(ii).

The parties dispute the meaning of the phrase, "does not claim . . . an approved method of using the

drug." Caraco asserts that the phrase ought to be interpreted to mean, "There exists at least one FDA-approved method of use that the patent at issue does not claim." *See* Petitioners Br. 23. Petitioners assert that they meet the conditions for asserting the counterclaim, because they have demonstrated that there are *two* (out of three) FDA-approved methods of using repaglinide that are not claimed by the '358 patent: (1) repaglinide administered alone; or (2) repaglinide combined with TZDs. *Id.*

That interpretation of the phrase is not plausible. The most natural reading of the words in that phrase is that Congress intended to require a counterclaimant to demonstrate that the patent-at-issue does not claim any approved methods of using the drug. Caraco's interpretation inverts the order of the words as actually written. Had Congress really intended the meaning suggested by Caraco, it much more likely would have written the statute as paraphrased above, rather than (as it actually did) phrasing the language in the negative. Novo has cited to numerous grammatical sources that support their interpretation – that "not . . . an" means the same as "not even one." Respondents Br. 29. Caraco cites no contrary authority. There is no reason for ascribing to the disputed language anything other than its most natural meaning. *See United States v. LaBonte*, 520 U.S. 751, 757 (1997) ("[W]e assume that in drafting this legislation, Congress meant what it said.").

Moreover, the interpretation supported by Caraco leads to a number of statutory anomalies. First, under Caraco's interpretation, the counterclaim would *always*

be available whenever (as here) the patent holder is basing its infringement action on a method-of-use patent. Suppose, for example, that Novo held three method-of-use patents for repaglinide, one for each of the three FDA-approved methods of using repaglinide. Suppose further that Novo's lawsuit alleged that Caraco's ANDA infringed the method-of-use patent covering use of repaglinide in combination with TZDs. Under Caraco's interpretation of the counterclaim provision, Caraco would still be permitted to proceed with its counterclaim seeking to "correct or delete" the Orange Book listing for the TZDs method-of-use patent. That is so, because there would be two "approved method[s] of using" repaglinide that the TZDs patent "does not claim" – namely, use of repaglinide by itself and use of use of repaglinide in combination with metformin. Under Caraco's interpretation, the counterclaim to "correct or delete" the TZDs patent could proceed, even though the NDA holder owns separate method-of-use patents covering the FDA-approved uses not claimed by the TZDs patent. Given Congress's evident concern that strict limits be imposed on the scope of the right of action granted to generic drug companies to challenge Orange Book listings, it is highly improbable that Congress would have wanted to permit a counterclaim whenever the patent holder is basing its infringement action on a method-of-use patent and FDA has approved more than one method of using the RLD.

Second, Caraco's proposed interpretation is inconsistent with the parallel structure created by subclauses (aa) and (bb). As structured, the counterclaim provision requires the generic company

seeking to assert an Orange Book counterclaim to make two parallel showings. It must show that the listed patent "does not claim" either "(aa) the drug for which the application was approved" or "(bb) an approved method of using the drug." Under Novo's interpretation, the two showings remain in parallel – the counterclaimant must show that the patent-at-issue asserts neither of two sorts of claims: (1) a claim for the RLD itself; or (2) a claim for an FDA-approved method of using the RLD.

Under Caraco's interpretation, the parallelism between (aa) and (bb) is lost. Caraco interprets (bb) as conveying the following requirement: a showing that there *exists* "at least one FDA-approved method of use that the patent-at-issue does not claim." Once that interpretation of (bb) is adopted, there is no way to express the meaning of (aa) in a parallel manner. The requirement imposed by (aa) can only be expressed in terms of a negative showing: the counterclaimant must demonstrate that the listed patent does *not* assert a claim for the RLD. There is no way to express that required *negative* showing in a manner that parallels the *affirmative* showing required under the meaning ascribed to (bb) by Caraco (*i.e.*, in a manner that requires the generic company to demonstrate existence instead of nonexistence). Had Congress not intended the parallel structure posited by WLF, it would have been unlikely to structure the counterclaim provision such that both (aa) and (bb) are listed as items that the counterclaimant must demonstrate that the listed patent "does not claim." The absence of parallelism created by Caraco's interpretation of the counterclaim provision is an additional reason to reject that

interpretation.

Moreover, as the Federal Circuit noted, Congress adopted the "exact language from *Mylan*" in crafting the counterclaim provision, Pet. App. 13a – thereby suggesting that it intended to address the precise situation encountered in *Mylan* rather than to grant generic companies to raise broad challenges to any and all "abuses" they perceived in Orange Book listings. In *Mylan*, the pioneer company, on the eve of approval of an ANDA for a generic form of BuSpar®, listed in the Orange Book a new patent that supposedly was BuSpar-related. The generic manufacturer filed suit, claiming that the patent "did not claim BuSpar or an approved method of using BuSpar." 268 F.3d at 1331. The appeals court dismissed the suit, holding that regardless whether the listing was improper, federal law did not grant ANDA filers a private right of actions to challenge the improper listing of patents in the Orange Book. *Id.* Because the 2003 Amendment adopted language that mirrored the precise claim in raised in *Mylan*, the court below concluded that Congress intended to limit the counterclaim provision to *Mylan*-type case in which the counterclaiming alleges that the listed patent "did not claim [the RLD] or an approved method of using [the RLD]." Pet. App. 13a (quoting *Mylan*, 268 F.3d at 1331). The court explained:

> The 2003 amendment used exact language from *Mylan* in the new counterclaim provision. This choice of legislative language suggests that the 2003 Amendment sought to correct the specific issue raised in *Mylan*, i.e., to deter pioneer manufacturers from listing patents that were not

> related at all to the patented product or method. Thus, the language selected for this Amendment supports this court's interpretation that "an approved method" means "any approved method." A patent listing that covers one amongst several approved methods of using a formulation protects that patented method and thus bears a direct relation to the purpose of the Orange Book listings. This court does not detect a situation such as the one [that] occurred in *Mylan*.

Pet. App. 13a.

Moreover, it is anachronistic to suggest that when Congress adopted the 2003 Amendments in June 2003, it did so in order to allow ANDA applicants to file counterclaims challenging overly broad Orange Book use code narratives – allegedly written by pioneer drug companies in an effort to delay generic competition. Use code narratives did not even exist until 2002; and until August 2003, they were written exclusively by FDA itself, not by pioneer drug companies. *See* 68 Fed. Reg. at 36, 683.

Caraco relies for its interpretation of the counterclaim provision almost exclusively on Congress's use of the phrase "correct or delete." Caraco asserts that the word "correct" would be rendered superfluous if the counterclaim were interpreted as suggested by Novo. To the contrary, Novo has suggested scenarios under its interpretation, under which the courts could be called upon to "correct" information included in the Orange Book (e.g., correction of an inaccurate patent

number). Respondents Br. at 38. But even if the Court concludes that Novo's interpretation would render the word "correct" superfluous, that alone would not be sufficient grounds to adopt Caraco's fanciful interpretation of "does not claim . . . an approved method of using the drug." Adopting Caraco's interpretation would require distorting the language and legislative history of the entire counterclaim provision – a far less appealing interpretive solution than simply concluding that a single word in the statute is surplusage.

II. THE DECISION BELOW PROMOTES "EFFICIENT RESOLUTION" OF ALL INVALIDITY/INFRINGEMENT ISSUES BY STEERING THEM TOWARD PARAGRAPH IV LAWSUITS

There is no merit to Caraco's assertion that the Federal Circuit's decision leaves it without an effective remedy. To the contrary, to the extent that Caraco disputes Novo's infringement claims, it can assert its position in connection with its defense of a patent infringement action. To the extent that Caraco is unhappy with the manner in which FDA has administered the Orange Book (*e.g.*, FDA's decision to permit Novo to amend its use code narrative or to deny Caraco's requested Section viii "carve out"), it can seek judicial review of FDA's actions under the Administrative Procedure Act. There is no reason to expand the scope of the limited counterclaim created by the 2003 Amendments simply because Caraco is concerned that approval of its ANDA might be delayed

if it is required to seek relief by other means.[5]

Indeed, there are particularly strong reasons to require Caraco to proceed under existing avenues of relief rather than grant it an expanded counterclaim right. As the Federal Circuit noted, a Paragraph IV lawsuit permits "efficient resolution" of all infringement/invalidity issues in an environment that "fully tests for infringement and its implications." *Id.* at 14a. If generic versions of repaglinide are approved while the '358 patent is still in force, there is a serious danger that doctors and medical insurers will infringe the patent by prescribing repaglinide for use in combination with metformin. Novo is entitled to seek to block approval of Caraco's ANDA to the extent that it can demonstrate that if Caraco wins approval, it intends to induce others to infringe the '358 patent.

The issue of induced infringement is well illustrated by the Federal Circuit's recent decision in *Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010). In that case, a generic company obtained an ANDA for a generic version of a budesonide drug through use of a Section viii statement (which asserted that the company would not infringe existing method-of-use patents for administering a budesonide inhalation suspension to treat respiratory diseases).

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[5] For example, a federal district court might ultimately determine that Caraco has not infringed, or induced infringement of, the '358 patent, except that the current labeling (*i.e.*, the labeling without a carve out) is infringing. If the district court went on to determine the terms of an acceptable carve out, it is difficult to believe that FDA would not abide by that determination.

The Federal Circuit ultimately upheld a preliminary injunction against the generic company, finding that the product labeling – while not specifically recommending that the product be used in an infringing manner – was likely to induce third parties to infringe the patent. After a lengthy evidentiary hearing, the district court determined (and the Federal Circuit affirmed) that the patent holder had presented sufficient evidence to establish that the generic company intended to induce others to infringe the method-of-use patent. 633 F.3d at 1059-61. Such induced infringement issues could never be resolved in connection with a counterclaim to correct allegedly improper use code narratives. Rather, disputes such as those between Novo and Caraco will likely require a detailed examination of Caraco's actions to determine whether it intends to seek profits by inducing others to breach of the '358 patent. Such an examination will require courts to look at more than just Caraco's proposed labeling. Accordingly, it makes little sense to stretch the meaning of the counterclaim provision in order to permit Caraco to sue Novo over the use code narrative, when doing so is highly unlikely to resolve all issues between the parties.

Permitting patent holders to be subject to multiple rounds of litigation lessens the value of patents and reduces the incentives to invest in new, life-saving pharmaceuticals. *See* Jenny Mamey, *A Myriad of Misunderstanding Standing: Decoding Judicial Review for Gene Patents*, 113 W.V. L. REV. 1033 (2011) ("These incentives and benefits will be diminished if the availability of patent challenges continues to increase because patent holders will not want the hassles and costs of litigation or risk of patent invalidation to

interfere with their investment.").

The structure and the legislative history of the 2003 Amendments make clear that Congress sought to avoid upsetting the balance created by the Hatch-Waxman Act. It sought to ensure that the interests of both pioneer and generic drug companies were respected. In particular, it placed strict limits on the litigating rights of generic companies. *See*, *e.g.*, 21 U.S.C. § 355(j)(5)(C)(ii)(II) (stating that Subclause (I) does *not* create an independent cause of action by ANDA applicants but rather only permits Subclause (I) claims to be raised as a counterclaim to an infringement suit filed by a patent holder in response to a Paragraph IV certification). Congress recognized that forcing patent holders to face too broad an array of legal challenges to their patents could seriously undermine the value of those patents. Any such diminishment in value has the potential to undermine continued advances in health care. Steps designed to ease the entry of generic drugs into the marketplace may lead to short-term price reductions for consumers, but – as Congress recognized – consumers are best served if a balance is maintained between short-term cost concerns and the longer-term need to encourage the level of research-and-development funding necessary ensure continued medical advances.

Indeed, evidence indicates that, at least partly as a result of decreased protections for patents, annual pharmaceutical research and development in this country decreased in constant dollars in recent years, from $47 billion in 2007 to $44 billion in 2010. Gardiner Harris, "Federal Research Center Will Help

Develop Medicines," *New York Times* (Jan. 23, 2011). As Prof. Richard Epstein has warned:

> The very uncertainty about the underlying choice [between short-term cost savings through use of generic drugs and long-term health benefits from increased research and development brought about by increased rewards to patent owners] is reason enough to be cautious about any fresh efforts to advantage the generic drugs at the expense of their branded rivals. And the ultimate irony may well be this: the next generation of generic drugs is the current generation of patented drugs. Let the spigot shut too tightly and both sides of the market could suffer.

Richard A. Epstein, *Branded Versus Generic Competition? A Kind Word for the Branded Drugs*, 3 HASTINGS SCI. & TECH. L.J. 459 (2011).

CONCLUSION

Amicus curiae Washington Legal Foundation requests that the Court affirm the the judgment below.

Respectfully submitted,

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

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