

No. 10-844

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**In the Supreme Court of the United States**

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CARACO PHARMACEUTICAL LABORATORIES, LTD. AND  
SUN PHARMACEUTICAL INDUSTRIES, LTD.,  
*Petitioners,*

v.

NOVO NORDISK A/S AND NOVO NORDISK, INC.,  
*Respondents.*

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

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**BRIEF OF THE GENERIC PHARMACEUTICAL  
ASSOCIATION AS *AMICUS CURIAE* IN  
SUPPORT OF PETITIONERS**

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**BRIEF OF THE GENERIC PHARMACEUTICAL  
ASSOCIATION AS *AMICUS CURIAE* IN  
SUPPORT OF PETITIONERS**

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**INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>**

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing more than 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with safe, effective, and affordable generic drugs. Their products account for nearly 75% of all prescriptions dispensed in the United States, and they save consumers more than \$120 billion each year.

GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. The decision below undermines that goal by enabling brand-name drug manufacturers to block generic drug market entry through the submission of erroneous patent information to

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<sup>1</sup> No counsel for a party wrote this brief, in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amicus curiae* or its counsel made a monetary contribution to this brief's preparation or submission. Petitioners and respondents have consented to the filing; their written consents have been submitted to the Clerk.

the Food and Drug Administration (FDA). Indeed, the decision below eviscerates one of the core mechanisms provided by Congress to generic drug manufacturers, skewing the carefully calibrated statutory scheme heavily in favor of brand-name manufacturers and imposing staggering unintended costs on consumers. The decision also severely disrupts the existing drug approval system by converting the FDA's patent listing process into a conduit for misinformation.

GPhA respectfully submits this *amicus curiae* brief to highlight those adverse ramifications of the court of appeals' decision. Because the many benefits of generic drug availability would be substantially diminished if the Federal Circuit's decision is not reversed, GPhA's members have a significant interest in this case.

### STATEMENT

1. Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, with the primary objective of "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. The Act furthers that objective through two principal mechanisms that allow generic versions of brand-name drugs to be "marketed more cheaply and quickly." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

First, the Act permits a generic manufacturer to forgo the filing of a full-fledged new drug application

(NDA), see 21 U.S.C. § 355(b), and instead to file an abbreviated new drug application (ANDA), see 21 U.S.C. § 355(j). If the generic applicant's ANDA demonstrates that the generic version is bioequivalent to the brand-name drug, the ANDA may rely on the clinical safety and efficacy data submitted by the brand-name manufacturer with its NDA, thus eliminating costly and time-consuming duplication of clinical studies. See *Eli Lilly*, 496 U.S. at 676; *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 n.1 (2005) (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv), and (8)(B)).

Second, the Act seeks to facilitate the resolution of disputes over the validity and scope of patents that the brand-name manufacturer claims protect its product. The Act does so by requiring an NDA applicant to

file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). FDA regulations in turn specify a more exhaustive list of “patent information” that must be submitted with the NDA. See 21 C.F.R. § 314.53(c)(1)-(2). This case concerns “method-of use patents,” *i.e.*, patents that “claim[] a method of

using” the drug.<sup>2</sup> For such patents, FDA regulations require brand-name manufacturers to include in the patent information submitted with an NDA a “description of the patented method of use.” 21 C.F.R. § 314.53(c)(2)(ii)(P)(3). This description is known as a “use-code narrative” or “use code.”

Once an NDA is approved, the drug and its associated patent information are listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. See 21 U.S.C. § 355(j)(7)(A)(i)(I) and (ii). ANDA applicants rely on the patent information in the Orange Book in deciding whether to seek FDA approval for a generic version of a brand-name drug and, if so, for which uses and by which administrative mechanism. The FDA likewise relies on the Orange Book when determining the scope of the brand-name manufacturer’s patent; FDA does not have the authority or expertise to evaluate substantively the accuracy of patent information submitted with an NDA.

2. An ANDA must contain a response to each patent listed in the Orange Book for the brand-name drug that the ANDA references. See 21 U.S.C. § 355(j)(2)(A)(vii). With respect to each such patent,

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<sup>2</sup> Method-of-use patents apply not to the drug itself but to the manner in which the FDA has authorized the drug to be used. For example, a brand-name manufacturer may hold a patent on using Drug X, in combination with Drugs Y and Z, to treat a particular disease. However, other approved methods of using the drug—such as combining that same Drug X with Drugs A and B to treat a different disease—may not be patented.

the applicant generally must certify that: (I) the required patent information has not been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

The lattermost option is known as a “paragraph IV” certification. An ANDA applicant filing a paragraph IV certification must provide the brand-name manufacturer with a detailed basis for its belief that the patent is invalid and/or not infringed. See 21 U.S.C. § 355(j)(2)(B)(i). The submission of a paragraph IV certification is, by statute, a technical act of patent infringement. 35 U.S.C. § 271(e)(2)(A). If the brand-name manufacturer files a patent infringement suit within 45 days after receiving notice of the paragraph IV certification, the FDA’s approval of the ANDA is automatically stayed for 30 months, unless a court determines before that time that the patent is invalid or would not be infringed by the marketing of the generic drug. 21 U.S.C. § 355(j)(5)(B)(iii). The court entertaining the infringement lawsuit has discretion to extend the stay beyond 30 months. *Ibid.*

3. In some instances, the patent on the listed drug itself will have expired, but a brand-name manufacturer will possess an unexpired method-of-use patent covering a particular approved use for the drug. If such a patent claims at least one—but fewer

than all—approved uses, an ANDA applicant may seek approval solely for the unpatented uses.

In such cases, rather than submitting a paragraph IV certification, the ANDA applicant may submit to the FDA a statement that the relevant patent “does not claim a use for which the applicant is seeking approval.” 21 U.S.C. § 355(j)(2)(A)(viii). That type of submission is known as a “section viii” statement. The ANDA applicant making a section viii statement must also remove or “carve out” any mention of the patented method of use from its proposed labeling for the generic drug. 21 C.F.R. § 314.92(a)(1). The FDA will approve the section viii statement only if there is no overlap between the proposed carve-out labeling and the use code(s) listed by the brand-name manufacturer in the Orange Book. Pet. App. 6a.

Although both a paragraph IV certification and a section viii statement may permit an ANDA applicant to obtain FDA approval before expiration of a patent listed in the Orange Book, the two options have very different implications for the timing of such approval and thus for the entry of generic drugs into the marketplace. A paragraph IV certification will significantly delay FDA approval in many cases, because the brand-name manufacturer can trigger the 30-month automatic stay simply by filing an infringement suit. The filing of a section viii statement, by contrast, does not itself delay approval of an ANDA, see 21 U.S.C. § 355(j)(5)(B)(i)-(iii), because it asserts that the patent as described in the Orange

Book does not even claim to cover the use in question.

4. Brand-name manufacturers have long sought to block or delay generic competition through manipulation of the Hatch-Waxman Act's patent-listing procedures. Because generic drugs are so much less expensive than their brand-name counterparts, generic entry almost immediately results in a large decrease in the brand-name incumbent's sales price and market share. See Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (July 1998).<sup>3</sup> A study prepared by the Congressional Budget Office determined that, within a year of entering a market, generic drugs accounted for an average of 44% of prescriptions dispensed through pharmacies. *Ibid.* For seven of the drugs examined in the study, the generic manufacturers' share of the market was 65% or more within two years. *Ibid.*

That swing in market share is typically accompanied by fierce price competition. "For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." FDA, *Generic Competition and Drug Prices* (Mar. 1, 2010).<sup>4</sup> Those savings redound directly to consumers' (and taxpayers') benefit. A recent study reported that

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<sup>3</sup> Available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

<sup>4</sup> Available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>.



generic drugs “saved the nation’s health care system more than \$824 billion dollars” over the last ten years, with savings of \$139.6 billion in 2009 alone. IMS Health & Generic Pharm. Ass’n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009*, at 1 (July 2010).<sup>5</sup>

Brand-name manufacturers therefore have powerful incentives to delay generic entry for as long as possible. They can accomplish that goal by overstating the scope of their patents or by filing patents of dubious validity or applicability. A generic manufacturer may then file a paragraph IV certification denying the validity of the patent, but the brand-name manufacturer can then obtain an automatic 30-month stay of the generic’s FDA approval simply by filing an infringement suit within 45 days. See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 715 (2009) (noting that brand-name manufacturers have “exploit[ed] the product-approval process” and “convert[ed] it into a tool for suppressing competition”).

Recognizing that brand-name manufacturers could effectively frustrate generic competition by listing inaccurate or overbroad patent information in the Orange Book, Congress amended the Act in 2003 to provide a method for generic manufacturers to address such gamesmanship regarding method-of-use patents. Specifically, Congress authorized defen-

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<sup>5</sup> Available at [http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010\\_0.pdf](http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf).

dants in a paragraph IV infringement action (*i.e.*, generic manufacturers) to bring a “counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information submitted by the holder \* \* \* on the ground that the patent does not claim \* \* \* an approved method of using the drug.” 21 U.S.C. § 355(j)(5)(C)(ii)(I). The availability of such a counterclaim forms the basis of the dispute here.

5. This case arises from petitioners’ application to the FDA for approval to sell a generic version of repaglinide, a diabetes drug manufactured by respondents under the brand name PRANDIN. Petitioners sought approval of generic repaglinide for two uses that respondents concede did not violate their patents on the drug. Nevertheless, respondents sought to block petitioners’ application by amending the description of a patent on file with the FDA to claim (erroneously) that the patent in fact covers petitioners’ proposed use. As a result, the FDA rejected petitioners’ request for approval of labeling that would omit reference to the patented method for using repaglinide, thereby disabling petitioners from arguing that the generic version they sought to distribute would not infringe respondents’ patent.

Respondents brought this patent infringement action against petitioners for filing an ANDA for a generic version of repaglinide. Petitioners filed a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii)(I), seeking an order requiring respondents to correct the description of their patent listed in the Orange Book. The district court entered an order directing respon-

dents to replace their overbroad use code with the previously submitted, correct listing.

A sharply divided panel of the Federal Circuit reversed. The majority held that the Act's counterclaim provision was unavailable to petitioners for two reasons.

First, the majority interpreted the statutory phrase "an approved method of using the drug" as foreclosing the bringing of a counterclaim any time the listed patent claims *any* approved method of using the drug—even if it is not the use for which the generic manufacturer seeks approval. Pet. App. 12a. That is, even if the use code listed in the Orange Book indisputably encompasses unpatented uses, the generic manufacturer cannot counterclaim to challenge that description, so long as the description is broad enough to cover at least one patented use.

Second, the majority construed the term "patent information" in the provision as referring *only* to the patent's number and expiration date. Pet. App. 15a. Under that reading, a generic manufacturer may not file a counterclaim to "correct or delete" the use code information submitted by the NDA applicant to the FDA. The majority interpreted this limitation as further proof that the Act "does not allow generic manufacturers to counterclaim unless the listed patent bears no relation to the listed drug." Pet. App. 14a.

This Court requested the views of the Acting Solicitor General. The Acting Solicitor General

advised this Court that the decision below is incorrect. This Court granted certiorari.

### SUMMARY OF ARGUMENT

The question presented is whether a generic drug manufacturer seeking to market an approved drug for *unpatented* uses may file a counterclaim against the brand-name manufacturer in a patent infringement action to require the brand-name manufacturer to correct the inaccurate method-of-use patent information submitted to the FDA. The statute's text, structure, and purpose clearly answer that question in the affirmative. This brief focuses on two serious errors the Federal Circuit committed in concluding otherwise.

A. First, as Judge Gajarsa correctly observed in dissent below, the Federal Circuit's decision "eviscerates" the important section viii process. Pet. App. 62a. Because ANDA applicants will now be unable to challenge overbroad method-of-use patent descriptions via a counterclaim, such descriptions will proliferate in the Orange Book, leading the FDA to reject otherwise proper section viii carve-out statements by generic manufacturers. As a result, generic manufacturers will be forced to proceed by the time-consuming and costly paragraph IV certification process (read: patent infringement litigation), or to withhold their product from the market altogether until the patent expires.

Forcing generic manufacturers to choose either intolerable option is entirely inconsistent with the statutory scheme, given Congress's clear intent to

afford the streamlined section viii process when generic drug approval is sought for non-infringing uses only. The section viii mechanism has been vitally important to the success of many generic drugs, and its unavailability will impose serious, adverse consequences on generic manufacturers and the American public alike.

B. Second, the Federal Circuit's decision renders meaningless the statutory language authorizing generic manufacturers to request that brand-name manufacturers "correct or delete" improper patent information submitted to the FDA. The decision below also disregards other language in the Act and the FDA's reasonable regulations. Furthermore, it runs contrary to the purposes for which patent information is maintained in the Orange Book. As explained below, these failures will further encourage brand-name manufacturers to submit overbroad patent descriptions to the FDA, fundamentally undermining the effectiveness of the patent-listing process.

### **ARGUMENT**

The court of appeals' erroneous decision provides brand-name manufacturers with a roadmap for blocking FDA approval of generic drugs that would not infringe any patent held by the brand-name manufacturer. If left standing, it will lead to severe, unintended consequences for generic manufacturers, the FDA's regulatory regime, and American consumers.

### **A. The Decision Below Eviscerates The Important Section viii Statement Process**

The Act's counterclaim provision is the backstop that ensures proper functioning of the section viii process. By eliminating the availability of a counterclaim in cases such as this, the decision below removes a crucial check on the submission of misleadingly broad patent use code descriptions by brand-name manufacturers, and renders the important section viii mechanism for generic drug approval a "dead letter." Pet. App. 62a. The decision thus disrupts the entire regulatory scheme.

1. As explained above, the Federal Circuit held that a defendant in a paragraph IV infringement lawsuit may assert a counterclaim *only* if the patent at issue does not claim *any* approved method of using the drug. That rule forecloses the bringing of a counterclaim if the manufacturer of a brand-name drug holds a patent that covers at least one (but fewer than all) of the approved methods for using that drug, that manufacturer files an admittedly overbroad use code description with the FDA, and the generic manufacturer seeks approval to market a generic version of the drug for only unpatented uses.

The unavailability of a counterclaim in such circumstances will further motivate brand-name manufacturers to submit overbroad use codes to frustrate generic competition. The proliferation of overbroad use codes in the Orange Book creates serious problems for generic manufacturers who would otherwise seek FDA approval via the more stream-

lined section viii process. Because an overbroad use code will erroneously claim both patented *and* unpatented uses of the relevant drug, a generic manufacturer will be unable to “carve out” the patented use, and the FDA will not accept the generic manufacturer’s section viii statement.

2. If the section viii carve-out process is unavailable, ANDA applicants seeking to bring generic drugs to market for unpatented uses face limited choices. The FDA can do little to stem the problem of overbroad use codes, because it does not substantively review or analyze the patent information submitted to it, and will not correct information in the Orange Book unless the brand-name manufacturer withdraws or amends its listing. See 21 C.F.R. § 314.53(f). The FDA’s involvement in the patent-listing process is, by design, “purely ministerial.” *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008). As the agency has explained, there is no “statutory basis for a substantive agency review of patents,” and the FDA “lack[s] expertise in patent matters” in any event. 68 Fed. Reg. 36,683 (2003).

Nor is the paragraph IV certification process an adequate substitute for submitting a section viii statement. Because filing a paragraph IV certification is a technical act of patent infringement, the ANDA applicant is subject to immediate suit by the brand-name manufacturer. Such a lawsuit imposes significant burdens not associated with the filing of a section viii carve-out statement.

First, in defending a paragraph IV infringement suit, the ANDA applicant must clear a far more onerous hurdle than the showing required under section viii. The ANDA applicant-turned-defendant must prove in court that the brand-name manufacturer's patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Where (as here) the brand-name manufacturer has overstated what the patent actually covers, however, the unavailability of a counterclaim to correct the improper patent description may well make it *impossible* for the generic manufacturer to prove non-infringement. That is because the generic manufacturer will be forced to market the drug with the same label as its brand-name counterpart, which is *by definition* infringing with respect to the patented use. See 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 also cannot disprove infringement in the infringement lawsuit because the FDA requires it to use Novo's original label, which includes information regarding the patented combination therapy.").

In such circumstances, the generic manufacturer's only recourse will be to attempt to prove that the brand-name company's entire method-of-use



patent is invalid. Alternatively, the generic manufacturer may choose to abandon its approval efforts altogether and wait until the very last relevant method-of-use patent held by the brand-name manufacturer expires. Obviously, neither option is attractive to an applicant seeking agency approval for uses that in no way infringe the patent.

It is this added imposition of being required to prove *invalidity* of the entire patent—as opposed to *non-infringement* of a particular use—that the panel majority failed to appreciate when it concluded that its interpretation of the Act “facilitates efficient resolution of disputes concerning potential overlapping of protected and unprotected uses.” Pet. App. 14a. Where, as here, a generic manufacturer seeks approval of a drug for unpatented uses only, the lower court’s decision does not “strike a balance of the pioneering and generic manufacturers’ interests,” *ibid.*; rather, it awards a windfall to strategic brand-name manufacturers that have (even intentionally) submitted overbroad patent descriptions to block generic competition.<sup>6</sup>

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<sup>6</sup> While acknowledging that Novo’s broad use code “threatens to impair Caraco’s ability to disprove infringement” in paragraph IV litigation, the concurrence below incorrectly attributed that result to the FDA’s actions in this particular case. Pet. App. 20a; Pet. App. 47a-48a. But the problem is *not* limited to situations in which the FDA initiates a request for a labeling change. When a brand-name manufacturer submits an overbroad use code in the first instance, it is equally foreseeable that the generic manufacturer will be unfairly forced to proceed via a paragraph IV certification and make a showing of patent invalidity.

Moreover, even if a generic manufacturer is ultimately successful in a paragraph IV infringement suit, it will have suffered significant unwarranted delay in market entry because of the automatic 30-month stay. See 21 U.S.C. § 355(j)(5)(B)(iii). Such delay imposes enormous costs on consumers: One commentator has estimated that, for a set of 21 widely prescribed prescription drugs, a mere one-year delay in the entry of generic competition “represents, under conservative assumptions, a transfer from consumers to producers of about \$14 billion.” C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009). Add to that the additional costs and uncertainty inherent in *all* federal litigation—particularly complex patent litigation. Cf. *Teva Pharm., USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (filing paragraph IV certification introduces “hazard of sparking costly litigation”).

The section viii process, by contrast, avoids litigation altogether. Indeed, the whole point of a section viii statement is to permit a generic manufacturer to sell a drug *immediately* when it is approved for only an unpatented use. See, e.g., *Purepac Pharm. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002) (immediate approval offered by section viii makes it “an attractive route for generic manufacturers”), *aff’d*, 354 F.3d 877 (D.C. Cir. 2004). The prospect that the generic manufacturer *may* ultimately prevail in proving invalidity, after long and costly litigation, is cold comfort.

3. Evisceration of the section viii process is particularly inappropriate, given the mechanism’s crucial function in the larger regulatory scheme. Limiting the availability of the process is inconsistent with the statute, the legislative history, and the case law.

First, the section viii carve-out process derives from clear statutory language. Section viii specifically addresses how ANDA applicants should address method-of-use patents, and it explicitly authorizes the ANDA applicant to declare “that the method of use patent does not claim” the use for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(viii). There is no limiting language—in section viii or elsewhere in the statute—requiring more.

Second, the Act’s legislative history demonstrates that Congress anticipated that there could be brand-name drugs approved for multiple uses, where only some of those uses were patented, and that there should be no barrier to entry for generic drugs seeking approval for unpatented uses. See Pet. App. 38a. The report accompanying the House version of the Act noted that the Act “permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2654; see also *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (citing this statement as “unusually strong support” for the notion that the Act does not prevent a generic manufacturer from obtaining approval for fewer indications than the FDA has approved for the brand-name manufacturer).

Indeed, the report discusses an example in which a listed drug has been approved for two indications, but only one of those indications is protected by a method-of-use patent. It recognizes that, in such circumstances, “the applicant could seek approval for only the [unpatented] indication.” H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. at 2654; see also *id.* at 2655. By “requir[ing] patent owners to submit information to FDA regarding \* \* \* use patents that cover approved drugs,” the Act allows “generic copies of these drugs [to] be approved when the patents expire,” which furthers Congress’s goal of “mak[ing] available more low cost generic drugs.” *Id.* at 2647-2648.

Finally, courts also have recognized the crucial importance of section viii as an available option for qualifying ANDA applicants. For example, in *Purepac Pharmaceuticals*, a brand-name manufacturer had improperly listed in the Orange Book a patent claiming an unapproved use for a drug. When a generic manufacturer submitted a section viii statement seeking approval of that drug for the actual approved use (not covered by patent), the FDA rejected the statement, reasoning that only approved method-of-use patents *should* be included in the Orange Book, and therefore the listed patent *must have* claimed the actual approved use. The FDA insisted that the parties were required to litigate their dispute in a paragraph IV infringement suit.

The district court directed the FDA to accept the ANDA applicant’s section viii statement. The court acknowledged that the paragraph IV “mechanism

slows the process of bringing generic drugs to market, thus assuring the brand manufacturer of a continued monopolistic position in the market.” 238 F. Supp. 2d at 207. It observed that, “[i]f used in circumstances not intended by Congress, paragraph IV thus could upset the careful balancing of the rights of NDA holders and the interests of generic manufacturers (and the drug-buying public) that lies at the core of the Hatch-Waxman Amendments.” *Ibid.* Thus, where there was no evidence of “any convergence between the scope of [the] method of use patent and the use for which the generic manufacturer seeks to market its drug product,” to require a paragraph IV certification “would result [in] a substantial windfall to the NDA holder that cannot be squared with congressional intent.” *Ibid.* So too here.

4. Last, but certainly not least, the evisceration of section viii will have dire consequences for American consumers. The decision below effectively extends the term of the brand-name manufacturer’s expired drug patent. A generic manufacturer obviously may not sell a brand-name drug for patented uses, but the Federal Circuit’s rule renders the generic manufacturer unable to sell the drug for *unpatented* uses covered by the overbroad use code. Thus, it must wait until *all* method-of-use patents held by the brand-name manufacturer expire. Again, this delay in generic entry imposes steep costs to drug purchasers.

Indeed, the section viii process has been historically important to the success of many generic

drugs. For example, FDA's approval of generic ramipril, a popular ACE inhibitor drug for treating hypertension, followed section viii statements filed by several ANDA applicants that carved out patented uses relating to reducing the risk of heart attack and heart failure. See Aaron F. Barkoff, *FDA Denies King Pharma's Citizen Petition Concerning Altace, Approves Ramipril ANDAs* (June 25, 2008).<sup>7</sup> The introduction of generic ramipril in mid-2008 immediately diminished the brand-name manufacturer's market share, resulting in large cost savings for consumers. See King Pharmaceuticals Press Release (Feb. 26, 2009) (company's nearly \$200 million revenue loss in Q4 2008 as compared to Q4 2007 was "primarily due to the market entry of generic substitutes for" brand-name ramipril).<sup>8</sup> Another major drug for treating high blood pressure, carvedilol, was approved by FDA in 2007, after generic manufacturers were able to carve out patent-protected uses relating to treatment for congestive heart failure. See FDA, *First-Time Generics – September 2007* (Apr. 30, 2009).<sup>9</sup> Before generic approval, the brand-name drug had annual sales of

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<sup>7</sup> Available at <http://www.orangebookblog.com/2008/06/fda-denies-king-pharmas-citizen-petition-concerning-altace-approves-ramipril-andas.html>.

<sup>8</sup> Available at <http://www.sec.gov/Archives/edgar/data/1047699/000095014409001638/g17835exv99w1.htm>.

<sup>9</sup> Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm062071.htm>.

approximately \$1.6 billion. See Glenmark Pharmaceuticals Ltd. Press Release (Sept. 10, 2007).<sup>10</sup> Predictably, the entry of generic competition led to lower prices and corresponding benefits to consumers.

As the United States noted in urging this Court to grant certiorari (U.S. Inv. Br. 19), in FY 2010 alone the FDA approved 11 ANDAs with carve-out labeling. Over the years, the FDA has rejected the overwhelming majority of petitions filed by brand-name manufacturers seeking to block agency approval of proposed section viii carve-out labels. See Kurt R. Karst, *The Itch Is Scratched – FDA Denies XYZAL Carve-Out Petition; Another Precedent Added to the Generic Drug Labeling Carve-Out Citizen Petition Scorecard* (Feb. 24, 2011).<sup>11</sup> Generic drugs approved via the section viii statement process save consumers billions of dollars each year.

The section viii process looks to be even more critical in the near future. A large number of brand-name drug patents are nearing expiration, and generic manufacturers are well positioned to carve out patented uses of those drugs when seeking FDA approval. See Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS

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<sup>10</sup> Available at [http://www.glenmarkpharma.com/GLN\\_NWS/pdf/Release\\_CarvedilolApproval\\_september\\_062007.pdf](http://www.glenmarkpharma.com/GLN_NWS/pdf/Release_CarvedilolApproval_september_062007.pdf).

<sup>11</sup> Available at [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2011/02/the-itch-is-scratched-fda-denies-xyzal-carve-out-petition-another-precedent-added-to-the-generic-dru.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/the-itch-is-scratched-fda-denies-xyzal-carve-out-petition-another-precedent-added-to-the-generic-dru.html).

HEALTH L. 311, 338 (2010) (“By 2016, pharmaceutical companies are expected to lose \$140 billion in annual sales due to patent expiration and the entry of generics.”). As a result, brand-name manufacturers have increasingly turned to filing method-of-use patents in an effort to extend their monopoly power. See Kurt R. Karst, *Analysis Shows Patent Use Codes Have Doubled Since August 2003* (July 8, 2010).<sup>12</sup> Should the decision below stand, brand-name manufacturers will have even stronger incentives—and ready means—to leverage patentable, incremental use improvements into a categorical prohibition on generic competition for the duration of the brand’s method-of-use patent. Such manipulative tactics will come at the expense of the development of truly new and different advancements, and American consumers will pay the price.

**B. The Decision Below Undermines The Purpose Of NDA Submissions To The Orange Book**

The Federal Circuit also erred in holding that the Act’s counterclaim provision does not authorize an order compelling the patent holder to revise the use-code narrative listed in the Orange Book. The court’s unduly narrow interpretation of the term “patent information” undermines the purposes behind NDA

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<sup>12</sup> Available at [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2010/07/analysis-shows-patent-use-codes-have-doubled-since-august-2003--by-kurt-r-karst-httpwwwwhpmcomvattorneycfmrid22.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/07/analysis-shows-patent-use-codes-have-doubled-since-august-2003--by-kurt-r-karst-httpwwwwhpmcomvattorneycfmrid22.html).



submissions to the FDA, and further frustrates the regulatory scheme.

1. For starters, the Federal Circuit’s construction renders superfluous the statutory language authorizing “correct[ion]” of “patent information” as a remedy for inclusion of an improper use code. Although “patent information” is not explicitly defined in the Act, FDA regulations spell out a detailed list of “patent information”—including a use-code narrative—that must be submitted with an NDA. See 21 C.F.R. § 314.53(c)(2)(ii)(P)(3). Those regulations were promulgated mere months before Congress passed the amendments that added the counterclaim provision, and they provide the context for the Act’s use of the term. See Pet. App. 16a; Pet. App. 33a-38a (Dyk, J., dissenting).

Nevertheless, the court of appeals held that “patent information” means only “the patent number and the expiration date” submitted by the NDA applicant. Pet. App. 15a. Thus, according to the court, a counterclaim may *not* be brought to remedy an improper use-code narrative. That holding, combined with the court’s conclusion that a counterclaim is unavailable whenever the patent claims at least one approved use, means that a defendant in paragraph IV litigation may file a counterclaim *only* when the patent submitted by the NDA applicant claims neither the relevant drug nor any approved use for that drug. In such circumstances, however, the patent should not have been listed in the Orange

Book in the first place, and the proper remedy would be to “delete” it, not “correct” it.<sup>13</sup>

Accordingly, the Federal Circuit’s decision does not sanction “correct[ing]” patent information that misrepresents the scope of the patent. Indeed, under the court’s construction, there are *no* circumstances in which “correct[ion]” of “patent information” will ever be required. The court’s interpretation, therefore, does not give meaning to the full statutory provision, and should be rejected. See, *e.g.*, *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) (“In construing a statute we are obliged to give effect, if possible, to every word Congress used.”); see also *ibid.* (“Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings”).

Furthermore, although it is generally agreed that Congress enacted the counterclaim provision in part to respond to the Federal Circuit’s decision in *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (2001), see Pet. App. 13a, that case cannot dictate the full scope of the statutory provision. See Pet. App. 32a (Dyk, J., dissenting) (“viewing the overruling of *Mylan* as limited to complete delisting would be inconsistent with the explicit statutory language”). Courts are obligated to give meaning to the actual words used

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<sup>13</sup> *Mylan* itself suggests that deletion is the proper remedy in such a case. See, *e.g.*, *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1330 (Fed. Cir. 2001) (“*Mylan* and the FDA concede that there is no cause of action to *delist* a patent from the Orange Book.”) (emphasis added).

by Congress, even when it legislates more broadly than the originating concern. “[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.” *Penn. Dep’t of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (internal quotation marks omitted) (quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985)). This Court should respect Congress’s actual response to *Mylan* and give effect to the statute’s unambiguous text.

2. By authorizing a remedy to “correct or delete” erroneous “patent information,” the Act presumes that patent information listed in the Orange Book *should be* correct. If that statutorily prescribed remedy is to have any force at all, it *must* dictate that the NDA applicant tailor its use code to correspond to the legitimate scope of the patent, not to whatever use the brand-name manufacturer chooses to claim.

Requiring NDA applicants to submit a use code that accurately reflects the uses covered by the patent is consistent with the common understanding of the verb “to correct.” The Act does not define that term, and therefore the Court should construe it in accordance with its ordinary or natural meaning. See *Chapman v. United States*, 500 U.S. 453, 461-462 (1991). To “correct” information is to “make or set right” such information or “rectify” its errors. See Webster’s New Int’l Dictionary 597 (2d ed. 1957); see also Webster’s Third New Int’l Dictionary 511 (1986) (similar); Webster’s Ninth New Collegiate Dictionary 293 (1983) (similar). Certainly, “patent information”

describing uses outside of the listed patent's scope contains errors that courts have the authority to order the NDA applicant to "make or set right" or "rectify."

The Federal Circuit effectively held, however, that there is nothing "to correct" in the Orange Book so long as the brand-name manufacturer's use code description encompasses at least one approved method of using the listed drug—regardless of whether it adheres to the actual scope of the patent. Yet one can imagine a variety of circumstances in which there is great potential to mislead by offering deliberately overbroad information. Suppose, for example, that an individual has moved and is trying to avoid bill collectors. Suppose further that his credit-card agreement requires him "to correct" his address upon moving. Potential disclosures include: "123 Maple Street," "Arlington," "Virginia," "United States," or even "planet Earth." Under the court of appeals' reasoning, any one of these responses would suffice. Similar mischief here can be prevented only if the brand-name manufacturer is required to "make or set right" or "rectify" his submission with reference to the proper scope of the patent itself.

Second, permitting ANDA applicants to require the correction of overbroad use codes harmonizes the counterclaim provision with the statutory language governing the NDA application process. Specifically, the Act requires NDA applicants to submit "the patent number and expiration date of any patent which claims \* \* \* a method of using such drug *and with respect to which a claim of patent infringement*

*could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.*” 21 U.S.C. § 355(b)(1) (emphasis added). This last phrase necessarily establishes an accuracy constraint on the language used to describe a patent in the Orange Book. That is, a patent holder could not “reasonably” “assert[]” “a claim of patent infringement” if the patent’s method of use was indefinite or overbroad, and thus the patent information submitted to the FDA likewise may not be so. As the dissent below observed, the final phrase in Section 355(b)(1) “contemplates that the scope of the patent must be accurately described and that the patent must be related to the drug or method of use for which the NDA application is submitted.” Pet. App. 27a-28a. (Dyk, J., dissenting). See also 21 U.S.C. § 355(c)(2) (same language in requirements for submission of patent information after submission of NDA).

Finally, because the FDA does not substantively evaluate the patent information submitted by the brand-name manufacturer—and because any disputes as to the correctness of that information must be resolved by the courts—it is especially important that there be a readily administrable standard as to what the “correct[ion]” remedy requires. Cf. *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 560 (Fed. Cir. 1994) (“The patent system as a whole benefits from clear, unambiguous rules.”). Such a clear rule can be supplied only by reference to the patent itself. For that reason as well, use-code

narratives should be required to hew closely to the language of the patents.

3. The Federal Circuit's overly restrictive interpretation of the term "patent information" is also wrong because it renders the counterclaim provision unacceptably ministerial, and is inconsistent with the purposes served by the Orange Book.

The patent information submitted with an NDA is not simply received and catalogued by the FDA for posterity. It is relied on by both the agency and the public in understanding the applicability and scope of relevant patent rights, and it is "essential to the operation of the statute." Pet App. 29a. As the FDA has explained, the "claim-by-claim listing of method-of-use patents" is necessary to permit ANDA applicants "to assess whether they are seeking approval for a use claimed in the listed patent," and thus to "determine whether to submit a patent certification or a section viii statement." 68 Fed. Reg. 36,685 (2003); see also *Purepac Pharm.*, 354 F.3d at 880 ("In order to determine what patents cover existing brand-name drugs and hence whether any paragraph IV certifications or section viii statements are needed, applicants look in the 'Orange Book.'). It is also necessary so that the FDA "can verify that the certification or statement is correct, and that only the appropriate methods of use are included in the proposed labeling for the ANDA." 68 Fed. Reg. 36,685.

In addition, even before an ANDA is submitted, generic drug manufacturers look to the patent

information maintained in the Orange Book in deciding whether to attempt to commercialize particular drugs for particular uses. Inaccuracy in the listed information therefore disrupts ongoing innovation efforts, and imposes significant costs on generic manufacturers in the form of wasted research and development expenses.

The decision below seriously undermines those basic purposes of the Orange Book by providing a remedy only where a patent number or expiration date has been submitted in error with an NDA. But errors of that sort are merely clerical, and the “correct[ion]” of such discrepancies cannot possibly be the purpose behind the litigation remedy explicitly afforded to generic manufacturers by the statute—Congress did not authorize this cause of action to fix mere scrivener’s errors.

The Federal Circuit’s decision also undermines the regulatory scheme by treating similarly situated NDAs differently. Under that court’s reading, an NDA applicant may be required to “delete” the submitted patent information if it does not appropriately relate to the listed *drug*, but may not be required to “delete” it if it does not relate to the patented *method of use*. As the dissent below observed, however, “[t]here is no basis in the statutory language or statutory purpose for distinguishing between drug information and method of use information. Either both must be ‘patent information,’ or neither must be patent information.” Pet. App. 33a (Dyk, J., dissenting). Clearly, “all Orange Book information is ‘patent information.’” *Ibid.*

Similarly, an NDA applicant could be required to “delete” patent information if the use code claims *one* unpatented use, whereas that same applicant would not be required to “delete” patent information if that same unpatented use were listed *in combination with* at least one patented use. This difference in treatment is illogical—in either case, the applicant has submitted inaccurate information. Yet only in the latter case may the brand-name manufacturer manipulate the system to block non-infringing uses by a generic competitor.

4. The Federal Circuit’s misguided construction of the counterclaim provision will only further encourage brand-name manufacturers to submit overbroad patent descriptions to the FDA. So long as a brand-name manufacturer has a patent covering at least one approved method of using a drug, the manufacturer can “follow [respondents] lead and draft exceedingly broad use codes” that will prevent all generic competitors from carving out unpatented uses for the drug. Pet. App. 62a. Secure in the knowledge that overbroad descriptions will not be rejected by the FDA and cannot be challenged in court, brand-name manufacturers can be expected to submit ever-broader patent descriptions.

That prediction is not idiosyncratic. A recent report directed at investors in the brand-name drug industry greeted the decision below with great enthusiasm and predicted that brand-name manufacturers will deliberately and successfully pursue this strategy to extend their lucrative monopolies on certain drugs. See Morgan Stanley Research



Europe, *Pharmaceuticals: Potential Selective Upside for Industry post Prandin Ruling 2* (Sept. 1, 2010) (“We anticipate that several companies will extract significant [earnings per share] and [net present value] upside from utilization of PUC (Patent Use Code) narrative strategies.”); see also *ibid.* (“[W]e anticipate increasing listing of ‘use’ patents in the Orange Book as the [brand-name] industry seeks to maximize any commercial gains.”).<sup>14</sup> In practical terms, such “upside” for brand-name manufacturers is pure “downside” for consumers.

The implications of the lower court’s decision will impair the FDA’s regulatory function. As the FDA has explained, “[a] fundamental assumption of the Hatch-Waxman [Act] is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents.” 68 Fed. Reg. 36,683 (2003). But the panel majority’s conclusion means that there will be no judicial forum available to resolve disputes over the scope of a brand-name manufacturer’s use-code narrative. By thus removing the only effective check on the submission of misleading patent descriptions for publication in the Orange Book, the decision below renders the FDA’s patent listing process a conduit for misinformation.

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<sup>14</sup> Available at <http://www.fdalawblog.net/files/morgan-stanley-rpt---puc-decision.pdf>.

Before the Hatch-Waxman Act's passage, generic drugs accounted for about 12% of all prescriptions filled in the United States. See FDA, *Greater Access to Generic Drugs* (Jan. 2006).<sup>15</sup> Today, by contrast, roughly 75% of all U.S. prescriptions are filled with generic drugs, and domestic sales of generic drugs average more than \$50 billion per year. See Jonathan D. Rockoff, *Prescription-Drug Sales Rise 5.1%*, Wall St. J., Apr. 2, 2010; Generic Pharm. Ass'n, *Facts at a Glance*.<sup>16</sup> The successful proliferation of generic drugs—and the massive savings that consumers enjoy as a result—is due in no small part to Congress's enactment and the courts' faithful enforcement of the Act's provisions. The Federal Circuit's decision erects a serious roadblock to maintaining or furthering these savings. This Court should restore the path for generic manufacturers to deliver safe, effective, and affordable drugs to American consumers.

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<sup>15</sup> Available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm>.

<sup>16</sup> Available at <http://www.gphaonline.org/about-gpha/about-generics/facts>.

**CONCLUSION**

The judgment of the Federal Circuit should be reversed.

Respectfully submitted.

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