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 Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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

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

INTEREST OF *AMICUS CURIAE*[1]

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 manufacturers to block generic entry through the submission of erroneous patent information to the Food and Drug Administration (FDA). GPhA respectfully submits

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[1] No counsel for a party authored 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 received timely notice of *amicus*'s intent to file this brief and have consented to its filing; their written consents have been submitted to the Clerk.

this *amicus curiae* brief to address the adverse ramifications of the court of appeals' decision and the urgent need for this Court's review.

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 demonstrates that its 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 expedite 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 also be submitted with the NDA. 21 C.F.R. § 314.53(c)(1)-(2). Once an NDA is approved, the drug is listed along with its associated patent information 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).

An ANDA must contain a response to each patent listed in the Orange Book for the brand-name drug that the ANDA references. With respect to each such patent, the applicant generally must make one of four certifications: (I) the required patent information has not been filed with FDA; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

2. Some patents—known as "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. And some approved methods of using the drug—for example, combining that same Drug X with Drugs A and B to treat a different disease—may not be patented.

The rules are slightly different with respect to such patents. If a method-of-use patent claims at least one but fewer than all of the approved methods, then the ANDA applicant, instead of making one of the certifications described above, may also choose to "carve out" the patented uses of the drug with a "section viii" statement. A section viii statement means that the generic applicant does not seek FDA approval for the patented uses. In that case, the ANDA must contain 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).

3. 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 by the brand-name manufacturer in the Orange Book, the two options have very different implications for the timing of FDA approval. A paragraph IV certification will significantly delay approval in many cases. The filing of a paragraph IV certification is an act of patent infringement, see 35 U.S.C. § 271(e)(2)(A), subjecting the ANDA applicant to suit by the brand-

name manufacturer. If the brand-name manufacturer files a patent infringement suit within 45 days after receiving notice of the ANDA applicant's 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). A section viii statement, by contrast, does not delay FDA approval, 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.[2]

4. This case arises from petitioners' application to the FDA for approval to market a generic version of repaglinide, a diabetes drug manufactured by respondents under the brand name PRANDIN. The application sought to market 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 a label that would omit reference to the patented method for using repaglinide, thereby disabling petitioners from

[2] Paragraph I and paragraph II certifications likewise do not delay approval of the ANDA because they are premised on the non-existence of an applicable patent. See 21 U.S.C. § 355(j)(5)(B)(i). A paragraph III certification delays final FDA approval until the patent's expiration date. See 21 U.S.C. § 355(j)(5)(B)(ii).

arguing that the generic version they sought to distribute would not infringe respondents' patent.

Respondents brought this patent infringement action against petitioners for proposing to market a generic version of repaglinide. Petitioners filed a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii)(I), which authorizes defendants in an infringement action 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). A sharply divided panel of the Federal Circuit held that such a counterclaim is available only when the patent at issue does not claim *any* approved method of using the drug. That is, so long as the brand-name manufacturer's method-of-use patent covers at least one approved use, a generic manufacturer cannot file a counterclaim to dispute an erroneous description that blocks the generic's application.

SUMMARY OF ARGUMENT

The Federal Circuit's decision in this case incorrectly resolves an important issue of federal law and will have serious adverse consequences for generic drug manufacturers, the FDA, and American consumers. This Court's immediate review is warranted.

A. As a general matter, 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 market share. 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, which will in many cases induce the generic manufacturer to file a paragraph IV certification and permit the brand-name manufacturer to obtain a 30-month stay of FDA approval. The FDA can do little to address this problem, because it lacks the authority and expertise to engage in substantive review of brand-name manufacturers' patent submissions.

B. The decision below enables—and thus encourages—brand-name manufacturers to engage in abusive manipulation of the statutory scheme. When 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, a generic manufacturer will often file a section viii statement that seeks approval to market a generic version for only the unpatented uses. See 21 U.S.C. § 355(j)(2)(A)(viii). In order to avoid infringing the brand-name manufacturer's patent, the generic manufacturer will then seek FDA approval for labeling that "carves out" the patented uses of the drug, a departure from the otherwise-applicable requirement that the generic drug bear the same label as the brand-name version.

In deciding whether to approve the carve-out label, however, the FDA defers entirely to the description of the brand-name manufacturer's patent filed with the NDA. If, as in this case, the brand-name manufacturer submits an overbroad description that covers both patented and unpatented uses, the FDA will reject the proposed labeling. The generic manufacturer will thus be required to abandon its product or go to market with a label that references the patented use and therefore infringes the brand-name manufacturer's patent.

Congress enacted a solution to this problem in Section 355(j)(5)(C)(ii)(I). That provision allows a generic manufacturer to file a counterclaim in an infringement action seeking an order requiring "correct[ion]" of the patent information submitted by a brand-name manufacturer when there is "an approved method of using the drug" that the "patent does not claim." 21 U.S.C. § 355(j)(5)(C)(ii)(I). The panel majority's erroneous conclusion that the counterclaim is available only when the patent at issue does not claim *any* approved use of the drug removes any check on the submission of overbroad patent descriptions to the FDA. Emboldened by the knowledge that their patent descriptions will not be rejected by the FDA and are not subject to judicial review, brand-name manufacturers can be expected to submit ever broader patent descriptions that bear little resemblance to the specific methods of use actually claimed by their patents. Indeed, in a recent report directed to investors in the brand-name drug industry, a major investment services firm

enthusiastically predicted that brand-name manufacturers will successfully use this strategy to block generic competition and prolong their monopoly profits.

C. The decision below also frustrates the FDA's administration of the Hatch-Waxman Act. The panel majority construed the phrase "patent information" in Section 355(j)(5)(C)(ii)(I) to mean only the number and expiration date of a patent listed by the brand-name manufacturer with the FDA. That conclusion gives no deference to 21 C.F.R. § 314.53, the FDA regulation requiring brand-name manufacturers to submit a considerably more exhaustive set of "patent information." Even though the FDA was not a party to this proceeding, the decision below still poses grave practical problems for the FDA. Because the FDA lacks the authority and expertise to evaluate the substance of brand-name manufacturers' patent listings, judicial review provides the only real check on their submission of erroneous patent information. By removing that check, the decision below converts the FDA's patent listing process into a conduit for misinformation.

D. The result of all this is to deny consumers the benefits of safe, effective, and affordable generic pharmaceuticals. Each year, generic drugs save American consumers more than $120 billion, and the cost to consumers of just a single year's delay in generic entry for a widely prescribed drug can approach $1 billion. The decision below provides brand-name manufacturers with a roadmap for blocking generic competition, and thus threatens to impose staggering costs on consumers.

ARGUMENT

A sharply divided panel of the Federal Circuit held in this case that 21 U.S.C. § 355(j)(5)(C)(ii)(I) does not permit correction of the description of a patent submitted to the FDA by a brand-name manufacturer unless the patent at issue does not claim *any* approved use of the drug. That erroneous conclusion 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. As a result, the decision below will lead to serious adverse consequences for generic drug manufacturers, the FDA, and American consumers. This Court's immediate review is warranted.

A. Brand-Name Manufacturers Have Strong Incentives And Ready Means To Delay Generic Competition

As explained above, see pp. 3-4, *supra*, a generic manufacturer seeking FDA approval for a generic version of a drug must respond, patent by patent, to the listings of patents the brand-name manufacturer has previously furnished to the FDA for listing in the Orange Book. The generic manufacturer's responses govern the timing of FDA approval for its proposed generic version. If the generic manufacturer must submit a paragraph IV certification that the brand-name manufacturer's patent is invalid or will not be infringed by the generic version, then the brand-name manufacturer may initiate patent infringement litigation and obtain an automatic 30-month stay of FDA approval. See 35 U.S.C.

§ 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii). But if the generic manufacturer is able to respond that the patents as described in the Orange Book do not purport to cover its proposed generic version—either because the relevant patents have expired or because the generic manufacturer has filed a section viii statement and seeks to market the drug for only unpatented uses—then there is no delay of FDA approval. See 21 U.S.C. § 355(j)(5)(B)(i)-(iii).

Brand-name manufacturers therefore have powerful incentives to claim that a patent *does* cover a particular use of a drug. By overstating the scope of their patents or by filing patents of dubious validity or applicability, brand-name manufacturers can force ANDA applicants to make paragraph IV certifications that will stall their applications during the 30-month stay period. See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 715 (2009) (observing that brand-name manufacturers have "exploit[ed] the product-approval process" and "convert[ed] it into a tool for suppressing competition").

The potential gains to brand-name manufacturers from such manipulative conduct are dramatic. Once generic manufacturers obtain FDA approval to sell a given drug, generic products can be expected to "quickly gain a large share of the market." Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (1998).[3] Indeed, a study prepared by the Congressional Budget Office

[3] Available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

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.* These figures confirm the common-sense fact that generic entry results in an immediate and dramatic decrease in sales for the incumbent brand-name manufacturer. Brand-name manufacturers therefore have every incentive to delay generic entry for as long as possible—time is money.

Meanwhile, the FDA can do little to stem the problem, because it does not 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). As the FDA 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); see also *Teva Pharm., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (acknowledging FDA's "purely ministerial role" with respect to "the patent information supplied by NDA holders"). Consequently, in the absence of effective judicial review, brand-name manufacturers are free to submit overstated patent information to the FDA in order to block entry by generic competitors.

B. The Decision Below Threatens To Stifle Generic Competition By Enabling—And Thus Encouraging—Brand-Name Manufacturers To Block Generic Drugs That Do Not Infringe Any Of Their Patents

1. This case involves a particularly pernicious form of manipulative conduct that a brand-name manufacturer may engage in when it holds a patent that covers at least one but fewer than all of the methods for using a particular drug. As explained above, the Hatch-Waxman Act allows an ANDA applicant in this scenario to file a section viii statement indicating that the brand-name manufacturer's patent "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). Doing so permits the generic applicant to take advantage of an exception to the usual rule that the generic drug's label must be identical to that of its brand-name counterpart. See 21 U.S.C. § 355(j)(2)(A)(v) and (4)(G); see also U.S. Invitation Br. at 3-5, *PLIVA, Inc.* v. *Mensing*, No. 09-993 (cert. granted Dec. 10, 2010). A generic applicant that has filed a section viii statement may submit a proposed label to the FDA that omits reference to—*i.e.*, carves out—the patented methods of using the drug. See Pet. App. 5a. By omitting reference to the patented use, the generic manufacturer avoids infringement, which in turn allows it to avoid the filing of a paragraph IV certification that could delay approval of the ANDA.

To facilitate the processing of section viii statements, FDA regulations require brand-name manufacturers to include in the patent information sub-

mitted with an NDA a "description of the patented method of use." 21 C.F.R. § 314.53(c)(2)(ii)(P)(3). This description, known as a "use code narrative" or "use code," is then employed by the FDA in determining whether to approve a generic manufacturer's proposed carve-out label. Reflecting the broader principle that the FDA's role in listing patents is ministerial, the FDA defers entirely to the brand-name manufacturer's description of the scope of its patent. If there is any overlap between the proposed carve-out label and the use code submitted by the brand-name manufacturer, the FDA will not approve the section viii statement. Pet. App. 6a.

There is significant potential for mischief in this process, and this case illustrates that all too well. After the FDA had preliminarily accepted petitioners' section viii statement, respondents amended the use code associated with their unexpired patent to cover the uses for which petitioners sought approval. Although there is no question that respondents' use code is overbroad—and respondents in fact *concede that the uses for which petitioners sought approval would not infringe their patent*—respondents' erroneous use code led the FDA to reverse course and reject petitioners' section viii statement.

Congress has provided a method for generic manufacturers to deal with such gamesmanship. Section 355(j)(5)(C)(ii)(I) of Title 21 authorizes a generic manufacturer defending a patent-infringement suit to file 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." By its terms, the statute authorizes a counterclaim seeking "correct[ion]" of patent information contained in the Orange Book whenever there is "an approved method of using the drug" that "the patent does not claim." The court of appeals nonetheless held that a generic manufacturer may assert a counterclaim only when the patent at issue does not claim *any* approved method of using the drug. See Pet. App. 12a.

That is wrong. As the dissent from the denial of rehearing en banc explained, the panel majority's conclusion effectively "eviscerates" section viii in many cases. Pet. App. 62a. 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 any generic competitors from carving out unpatented uses for the drug. *Ibid.* Secure in the knowledge that overbroad descriptions will not be rejected (or even reviewed) by the FDA and cannot be challenged in court, brand-name manufacturers can be expected to submit ever broader patent descriptions.

Our prediction is not idiosyncratic. A recent report directed at investors in the brand-name drug industry greeted the decision below with 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.").[4]

This Court's immediate review is required to prevent brand-name manufacturers from exploiting the vacuum in oversight created by the decision below. As the petition explained (at 22), in recent years brand-name manufacturers have increasingly turned to filing method-of-use patents in an effort to extend their monopoly power as their patents on drug compounds expire. See Kurt R. Karst, *Analysis Shows Patent Use Codes Have Doubled Since August 2003* (July 8, 2010).[5] Thus, many brand-name manufacturers will be well placed and eager to employ the same manipulative tactics that respondents used here.

2. The panel majority floated two arguments in hopes of deflating the significance of its decision. Neither one withstands scrutiny.

First, there is no merit to the suggestion that paragraph IV litigation will provide an adequate substitute for a counterclaim seeking correction of

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[4] Available at http://www.fdalawblog.net/files/morgan-stanley-rpt---puc-decision.pdf.

[5] 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-httpwwwhpmcomvattorneycfmrid22.html.

overbroad patent information. See Pet. App. 14a, 16a. First of all, that suggestion overlooks the fact that infringement litigation (which is frequently spawned by a paragraph IV certification) carries with it an automatic 30-month stay of FDA approval of the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The whole point of a section viii statement is that a generic manufacturer should be able to sell a drug *immediately* when it is marketed for an unpatented use. The prospect that the generic manufacturer may *ultimately* prevail, after long and costly infringement litigation, is cold comfort.

Moreover, the unavailability of a counterclaim to correct overbroad patent descriptions may well make it impossible for the generic manufacturer to prevail in many cases where, as here, the brand-name manufacturer has indisputably erred in describing what the patent actually covers. As explained above, if the FDA concludes that the section viii applicant's proposed labeling overlaps with a use code submitted by the brand-name manufacturer, the FDA will reject the section viii statement and the carve-out in the proposed labeling. The generic manufacturer will then be forced to market the drug with the same label used by the brand-name counterpart, which is by definition infringing with respect to the patented use. Thus, a generic manufacturer's only recourse is to abandon competition or try to demonstrate that the brand-name company's patent is invalid, even if the uses for which the generic manufacturer seeks FDA approval would in no way infringe the patent.

It is likewise impossible to explain away the significance of the court of appeals' decision by

asserting that the FDA somehow "gummed up the works." Pet. App. 20a (Clevenger, J., concurring); see also Pet. App. 14a (majority opinion) (suggesting that "Caraco's real complaint should lie with the FDA"). As the dissenting opinion explained, the FDA required respondents to modify their label for repaglinide to include a single, broad indication. See Pet. App. 47a. But the FDA never required respondents to amend the use code submitted with their NDA, which was the decisive factor in the FDA's decision not to approve petitioners' ANDA. See *id.* at 47a-48a.

Even if the FDA had introduced some complication, that would not diminish the adverse impact of the decision below. Nothing in the panel majority's opinion turned on the FDA's supposed role in respondents' amendment to the use code. Instead, the panel majority held broadly that 21 U.S.C. § 355(j)(5)(C)(ii)(I) never authorizes a counterclaim if the patent at issue claims at least one of the drug's approved uses—a conclusion that will apply no matter how badly the brand-name manufacturer misrepresents the scope of its patent, and no matter the reason it gives for having done so.

C. The Decision Below Effectively Invalidates A Crucial FDA Regulation And Undermines The FDA's Implementation Of The Hatch-Waxman Act

Certiorari is also warranted because the decision below threatens to disrupt the FDA's orderly implementation of the Hatch-Waxman Act. As noted above, an FDA regulation titled "Submission of

patent information" requires brand-name manufacturers to submit with an NDA a detailed list of "patent information." 21 C.F.R. § 314.53(c)(1)-(2). With respect to patents claiming a method of using the drug, the NDA applicant must submit not only the use code discussed above, but also an "[i]dentification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted." 21 C.F.R. § 314.53(c)(2)(ii)(P)(2). The FDA has explained that this "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). 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." *Ibid.*

In the course of holding that petitioners could not assert a counterclaim under Section 355(j)(5)(C)(ii)(I), the panel majority reasoned that the statutory phrase "patent information" means only "the patent number and the expiration date" submitted by the NDA applicant. Pet. App. 15a (citing 21 U.S.C. § 355(b)(1)). The panel majority afforded no deference to the FDA's construction of the phrase "patent information" embodied in 21 C.F.R. § 314.53, even though that regulation was promulgated mere months before Congress passed the amendments that added Section

355(j)(5)(C)(ii)(I)'s counterclaim provision to the Hatch-Waxman Act. See Pet. App. 16a; Pet. App. 33a-38a (Dyk, J., dissenting). By construing the phrase patent information so narrowly, the panel majority's decision effectively invalidates the FDA's broader interpretation of that term in 21 C.F.R. § 314.53.

The practical implications of that erroneous conclusion will hamstring the FDA. 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. At the very least, the Court should not permit the decision below to stand without calling for the views of the FDA on the important issues implicated by this case.

D. The Decision Below Threatens To Impose Staggering Costs On American Consumers

The significance of the decision below extends beyond its immediate impact on the generic industry. It also threatens to deprive consumers of the important benefits of generic competition—namely, affordable prices for safe and effective generic drugs.

Prices of generic drugs are dramatically lower than the prices of their brand-name counterparts. According to FDA estimates, the entry of just two generic manufacturers into the market for a given drug "reduces the average generic price to nearly half the brand name price." FDA, *Generic Competition and Drug Prices* (Mar. 1, 2010).[6] "For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." *Ibid.*

The lower prices of generic drugs translate into massive aggregate benefits for American consumers. Today, 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 Pharmaceutical Ass'n, *Facts at a Glance*.[7] A recent study reported that 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 Pharmaceutical Ass'n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009*, at 1 (July 2010).[8]

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[6] Available at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.

[7] Available at http://www.gphaonline.org/about-gpha/about-generics/facts.

[8] Available at http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf.

Of course, the flip side of the dramatic benefits associated with generic entry is that any *delay* in generic entry imposes enormous costs. Indeed, one commentator has estimated that, for a set of 21 widely prescribed prescription drugs, a 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). By providing a roadmap for brand-name manufacturers seeking to block generic entry, the decision below threatens to impose these staggering costs on American consumers.

* * * *

Before the Hatch-Waxman Act's passage, generic drugs accounted for only about 12% of all prescriptions filled in the United States. See FDA, *Greater Access to Generic Drugs* (Jan. 2006).[9] Today, that figure is approximately 75%. The decision below, however, creates a serious roadblock to maintaining or furthering this success. This Court should grant review now to resolve this highly important question and to clear the way for generic manufacturers to continue to bring safe, effective, and affordable drugs to American consumers.

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[9] Available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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