No. 10–844

In the Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD., and SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Petitioners,

v.

NOVO NORDISK A/S and NOVO NORDISK, INC.,
Respondents.

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

BRIEF OF *AMICUS CURIAE* MYLAN PHARMACEUTICALS INC. IN SUPPORT OF PETITIONERS

Dan L. Bagatell
Counsel of Record
PERKINS COIE LLP
2901 N. Central Avenue,
Suite 2000
Phoenix, Arizona 85012
(602) 351–8000
DBagatell@perkinscoie.com

Shannon M. Bloodworth
PERKINS COIE LLP
700 13th Street, N.W.
Washington, D.C. 20005
(202) 654–6200
SBloodworth@perkinscoie.com

David J. Harth
Sarah C. Walkenhorst
PERKINS COIE LLP
1 East Main Street
Madison, Wisconsin 53703
(608) 663–7460
DHarth@perkinscoie.com
SWalkenhorst@perkinscoie.com

Counsel for *Amicus Curiae*

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STATEMENT OF INTEREST*

Mylan is a manufacturer of generic drugs and frequently files Abbreviated New Drug Applications (ANDAs) under the Hatch-Waxman Act seeking approval of the Food and Drug Administration (FDA) to market drugs for particular uses. Mylan often relies on "section viii" statements that the methods of use it is proposing are not patented. *See* 21 U.S.C. § 355(j)(2)(A)(viii). The FDA, however, will not grant approval to launch if a proposed use falls within the description of a patented method of use that is listed in the FDA's "Orange Book." The accuracy of Orange Book patent information is thus critical.

Regrettably, branded manufacturers often overstate the scope of their patents, and the FDA does not police the accuracy of Orange Book information. In *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (2001), the Federal Circuit held that generic drug manufacturers had no right to sue to correct Orange Book listings. In 2003, however, at the behest of the Federal Trade Commission (FTC) and others, Congress expressly authorized ANDA applicants to file counterclaims to correct or delete erroneous Orange Book patent information. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). The availability of such counterclaims serves as a much-needed check on

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* Pursuant to Rule 37.6, Mylan certifies that no counsel for a party authored this brief in whole or in part and that no person or entity, other than *amicus* or its counsel, has made any monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief. A letter acknowledging consent by petitioners accompanies this brief, and respondents have filed a letter with the Clerk of the Court providing blanket consent to the filing of *amicus* briefs.

branded drug manufacturers and deters them from supplying misinformation to the FDA.

In this case, however, the Federal Circuit has read the counterclaim provision extremely narrowly, holding that correctable "patent information" is limited to patent numbers and expiration dates and that counterclaims are available only in cases when no approved uses whatsoever have been patented. The decision effectively eviscerates the counterclaim provision and permits branded manufacturers to block legitimate section viii applications with false Orange Book listings.

Mylan urges the Court to reverse the Federal Circuit's decision because the result, if upheld, will be devastating to the generic drug industry and consumers—and costly to taxpayers as well. Although the counterclaim provision seems obscure at first blush, it is in fact critical to ensuring effective operation of the Hatch-Waxman Act.

SUMMARY OF ARGUMENT

Congress authorized ANDA applicants that have been sued for patent infringement to counterclaim to "correct" Orange Book "patent information" that overstates patent coverage, not just to "delete" listings where none of the approved uses is patented. The majority below incorrectly assumed that Congress merely intended to reverse the outcome on the particular facts of *Mylan v. Thompson*, which involved a lawsuit to "delist" a patent from the Orange Book. In fact, Congress acted not only in response to *Mylan v. Thompson*, but against the backdrop of an FTC study that documented a variety of problems that were delaying generic entry and new regula-

tions adopted by the FDA governing Orange Book patent information. The legislative history of the 2003 amendments confirms that Congress sought a general solution to the problem of incorrect information in Orange Book listings. The statutory language authorizing corrections as well as deletions of incorrect patent information confirms that Congress intended to fill the loophole in the statute, not to create a new loophole as the majority below supposed.

The majority below also erred in holding that correctable "patent information" is limited to patent numbers and expiration dates and excludes information about their substantive scope. The term "patent information" should be read in light of Congress's purpose to have patentees identify which drugs and methods remain patented so that ANDA applicants can avoid infringement. The courts should also defer to the FDA's longstanding construction of "patent information," which covers use code narratives and other patent-related information, not just patent numbers and expiration dates.

The Federal Circuit's artificially narrow construction should also be rejected because it would upset the careful balance of the Hatch-Waxman Act. Not only would it gut the counterclaim provision, but it would vitiate section viii as well. If the decision below stands, brand-name drug manufacturers will continue to abuse the Orange Book listing system with impunity because the FDA does not review the accuracy of those listings. With no agency oversight and no judicial review, branded drug companies can effectively block generic competitors from filing section viii certifications. Instead, generic competitors would have to file "paragraph IV" certifications of

patent invalidity, which inevitably lead to expensive, time-consuming litigation and automatic 30-month injunctions against FDA approval. The result would be to delay generic entry just where Congress sought to expedite it. As in *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661 (1990), such an interpretation is implausible in light of the structure and purpose of the amendments and must be rejected.

Finally, the Court should bear in mind the significant practical consequences were it to affirm the Federal Circuit's ruling. Patents on the chemical compositions of many leading drugs have expired, and branded drug companies have responded by seeking additional patents on uses of those drugs. If counterclaims to correct Orange Book patent information are limited as in the decision below, branded drug companies will be able to delay generic competition for nonpatented uses, effectively extending expired patents on the basic compositions and greatly and unnecessarily increasing costs to consumers and taxpayers.

The judgment below should be reversed.

ARGUMENT

A. The 2003 Amendments to the Hatch-Waxman Act Were Not Limited to Changing the Result on the Particular Facts of *Mylan v. Thompson*

Congress's 2003 amendments to the Hatch-Waxman Act authorized ANDA applicants to assert counterclaims 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)(bb). Naturally read, the statute authorizes relief when one or more of the approved uses is not claimed in a patent, despite its inclusion in the Orange Book. The Federal Circuit, however, has read the statute to apply only when *none* of the approved uses is patented. Although the latter reading may be linguistically possible, it is strained and makes no sense when the language is read in context and in light of the underlying object and policy of the statute.

The majority below assumed that Congress merely intended to reverse the result on the particular facts of *Mylan v. Thompson*. Pet. App. 13a, 21a. But while *Mylan v. Thompson* was a notorious example of the problem of branded drug manufacturers overstating patent scope, the 2003 amendments were not limited to that fact scenario or to the particular remedy sought in that case. Congress adopted a more general solution to a broader problem.

In *Mylan v. Thompson*, Mylan filed an ANDA to sell a generic version of the anxiety drug buspirone. Just as Bristol-Myers's patent on buspirone itself expired, Bristol-Myers obtained a new patent on a method of ameliorating anxiety using a metabolite of buspirone. Mylan then filed a section viii statement that the new patent did not claim use of buspirone itself to treat anxiety. The FDA, however, suspended approval of Mylan's ANDA based on Bristol-Myers's assertion that the new patent did cover a method of using buspirone itself. 268 F.3d at 1327–28.

At the time (2001), the FDA allowed ANDA applicants a limited means to dispute the accuracy of patent information listed in the Orange Book. A party could write the FDA to question the accuracy

of the patent information submitted, and the FDA would request that the branded manufacturer confirm the information. By regulation, however, the FDA would not change the patent information in the Orange Book unless the branded manufacturer withdrew or amended its patent information in response to FDA's request. In that case, an ANDA applicant had to provide certifications despite its disagreement with the listing. *Id.* at 1327.

Mylan wrote to the FDA to challenge Bristol-Myers's Orange Book listing on grounds that the new patent was limited to use of a metabolite of buspirone. The FDA sought clarification from Bristol-Myers, which responded that the new patent also covered a method of using buspirone itself. *Id.* at 1328. The FDA accepted Bristol-Myers's word, and the patent remained listed in the Orange Book. *Id.* With no administrative remedy, Mylan sued to force Bristol-Myers to delete the erroneous listing and to require the FDA grant approval of the ANDA. *Id.*

Although the district court granted a preliminary injunction, the Federal Circuit reversed, holding that the Hatch-Waxman Act did not authorize a private cause of action for delisting. *Id.* at 1332. According to the Federal Circuit, Mylan's claim was "analogous to those barred in the long line of cases precluding private rights of action" under the statute. *Id.* Orange Book listings were effectively uncorrectable.

Fortunately, the FTC recognized that this result was unacceptable and lobbied to change it. Earlier in 2001, the FTC had begun a study of a variety of dubious strategies that branded drug manufacturers were using to delay generic entry. The study issued in July 2002, about nine months after *Mylan v.*

Thompson. *See* FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Among other things, the FTC noted the FDA's lack of substantive review of Orange Book listings, called on the FDA to clarify its listing requirements, and encouraged Congress to consider allowing generic applicants to counterclaim to challenge the correctness of Orange Book listings when sued for infringement by branded manufacturers. *Id.* at v; *see also id.* at 44–45 & n.13 (specifically discussing *Mylan v. Thompson*).

In 2003, Congress responded to the FTC study and intervening regulatory work by the FDA by adopting the amendments at issue here. The legislative history makes plain that Congress broadly intended to stop abuses that had allowed branded drug manufacturers to delay legitimate generic competition, not simply to make available the particular delisting remedy sought in *Mylan v. Thompson*.[1]

Co-sponsoring Senator McCain observed that the amendments were broadly designed to "close[] loopholes in the current food and drug laws that allow brand pharmaceutical companies to protect themselves from generic competition by unfairly extending drug patent life, maximizing company profits on the backs of American consumers." 149 CONG. REC. 15,490, 15,513 (Jun. 19, 2003).

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[1] For a summary of the background and legislative history of the 2003 amendments, see generally Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Regime on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA: THE J. OF L. & TECH. 165 (2005). *See also* Pet. App. 85a–92a (discussion in the district court's decision).

Co-sponsoring Senator Schumer similarly emphasized the broad reach of the amendments, noting that "[t]he provisions close loopholes in the law and end the abusive practices in the pharmaceutical industry which have kept lower-priced generics off the market and cost consumers billions of dollars." 149 CONG. REC. 31,121, 31,200 (Nov. 24, 2003). Those abuses were many and varied:

> [H]ere is what has happened over the last several years. … A lot of blockbuster drugs were on the market. Their patents were about to expire. The drug industry, accustomed to the high rate of return they have had, came to the conclusion that they had to do everything they could, they had to pull out all the stops to extend their monopolies. They came up with wild and crazy schemes to do it, such as patenting the substance the body makes when the drug is ingested; developing computer programs and listing the patents on the drug; and, in one case, absurdly, a new patent was asked for because the color of the bottle was changed.

149 CONG. REC. 15,490, 15,515 (Jun. 19, 2003) (also noting that "the pharmaceutical industry, instead of spending all its time developing new drugs, was developing new patents … [and] car[ing] more about hiring good lawyers than good chemists, scientists, and doctors").

In later debates, Senator Schumer commented specifically on the counterclaim provision, observing

that "the provisions enforce the patent listing requirements at the FDA by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand drug company delist the patent *or correct the patent information* in the FDA's Orange Book." 149 CONG. REC. 31,121, 31,200 (Nov. 24, 2003) (emphasis added). Senator Schumer thus made explicit the drafters' intent not only to authorize complete delisting of inaccurate Orange Book entries, as Mylan had sought in *Mylan v. Thompson*, but also to authorize *correction* of inaccurate Orange Book information where that more nuanced remedy was warranted.

The statutory language reflects Congress's intent to give courts flexibility to correct incorrect Orange Book information in the way that makes most sense in each case. ANDA applicants may counterclaim 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)(bb) (emphasis added). If Congress had intended to limit counterclaims to extreme cases in which a listed patent is wholly inapplicable, it would have limited the remedy to delisting. Instead, recognizing that branded drug manufacturers could abuse the system in a variety of ways, Congress authorized correction as well as deletion of erroneous patent information. In so doing, it ensured that the counterclaim provision covered cases such as this one in which an Orange Book listing recites both patented and unpatented uses. There is no reason to think that Congress intended to open a new loophole when closing the old one.

B. The Court Should Defer to the FDA's Determination That "Patent Information" Includes Information About Patent Scope, Not Just Patent Numbers and Expiration Dates

As just discussed, Congress authorized counterclaims to ensure that generic drug makers have judicial recourse to correct or delete misinformation about patent coverage that branded drug makers have submitted to the FDA. In holding that correctable "patent information" is limited to patent numbers and expiration dates and excludes uses that the patents purportedly cover, the Federal Circuit has defied both the statutory language and the FDA's longstanding interpretation of "patent information."

The Hatch-Waxman Act requires NDA applicants to list patents claiming a drug or method of use "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G). The statute thus expressly contemplates that the patent holder will describe the scope of the patents and relate them to the drug or method of use for which approval is sought. The resulting Orange Book listings are supposed to notify later ANDA applicants which drugs or methods of use are patented so that those applicants can submit appropriate certifications under 21 U.S.C. § 355(j)(2)(A)(vii) and (viii). "Patent information" must be construed broadly in light of that purpose.

Importantly, when Congress adopted the counterclaim provision in 2003, the FDA had already adopted a regulation (the Patent Listing Rule) that broadly construed the scope of "patent information" required under the Hatch-Waxman Act. Under that

regulation, 21 C.F.R. § 314.53, the FDA required patentees to submit not only patent numbers and expiration dates, but also use code narratives and other patent-related information. The FDA's interpretation deserves deference, as courts "have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer[.]" *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1984).

Indeed, Congress was not just constructively aware, but *actually* aware of the FDA's broad reading of "patent information" when it adopted the amendment authorizing counterclaims to correct or delete erroneous "patent information." *See Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 19 (2003) (statement of sponsoring Sen. Schumer: "The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing, but it goes much further."). Such awareness indicates that Congress intended to adopt the FDA's broad view of "patent information."

C. The Federal Circuit's Decision Is Inconsistent with the Careful Balance Struck by the Hatch-Waxman Act

The Hatch-Waxman Act was designed to strike a careful balance between "two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Caraco Pharm. Labs., Ltd. v. Forest Labs.,*

Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008) (quotation marks and citation omitted); *see also* Pet. App. 57a–64a (Gajarsa, J., dissenting from denial of rehearing en banc). The Federal Circuit's decision in this case threatens to upset the careful equilibrium established by the Act and its amendments. The decision below renders section viii largely useless and enables branded manufacturers to misuse Orange Book listings to extend *de facto* patent protection and delay legitimate generic competition.

Section viii allows a generic manufacturer to certify that a patent "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). If approved by the FDA, a section viii application permits the generic manufacturer to proceed to market without litigation. There are tradeoffs, however. Even if the section viii applicant is the first to file an ANDA, it is not entitled to 180 days of generic marketing exclusivity. *See* 21 U.S.C. §§ 505(j)(2)(A)(vii)(IV), 505(j)(5)(B)(iv). Furthermore, section viii allows the applicant to market drugs only for particular uses: uses that are FDA-approved and not patented.

As a practical matter, the Federal Circuit's decision vitiates section viii. Patent holders can unilaterally prevent section viii certifications by submitting overly broad use descriptions to the FDA. The FDA does not scrutinize Orange Book listings because it claims to lack expertise on patent issues. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 885 (D.C. Cir. 2004) (FDA "refuses to determine independently what use a patent covers and instead accepts at face value the use claimed by the patent holder"); 21 C.F.R. § 314.53(f) (FDA "will not change the

patent information in the list" unless the patentee requests). And now the Federal Circuit has held that the courts are powerless to force brand-name manufacturers to acknowledge that their patents cover certain uses but not others.

For example, assume a branded manufacturer's patents on a compound and a method of using it to treat disease 1 have expired, but a patent on using the compound to treat disease 2 remains in force. If the statute worked as Congress intended, a generic drug maker could file a section viii certification and enter the market with a carve-out label limited to treating disease 1. The branded manufacturer, however, can stifle that competition by submitting an overbroad description covering both uses. The FDA will not approve the generic's ANDA because the proposed use falls within the Orange Book description submitted by the patent holder, even though the patent on its face does not cover the use of the drug to treat disease 1. The FDA also will not review the accuracy of the Orange Book description, and the Federal Circuit has now held that the courts are impotent too, even though Congress adopted the counterclaim provision to prevent just this type of chicanery.

To be sure, a generic competitor may still file a "paragraph IV" certification of noninfringement, but that is cold comfort. Even though the generic manufacturer has no desire to promote the patented use of the drug, the statute normally will require it to match the original drug labeling covering both patented and unpatented uses. *See* 21 U.S.C. § 355(j)(2)(A)(v). The patentee will then claim that the generic has induced infringement by selling the

drug with broad labeling that has no carve-out. In most cases, the generic's defenses will be limited to invalidity and inequitable conduct, difficult defenses to establish given the prevailing burdens of proof. Moreover, paragraph IV litigation is expensive, time-consuming, and leads to an automatic 30-month stay of FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii). That expense and delay would not occur if the generic manufacturer could carve out the unpatented use under section viii. Ironically, but inevitably, generic entry would be stalled in the very cases where Congress sought to accelerate it.

This Court has previously considered the careful balance of the Hatch-Waxman amendments in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). In that case, the Court addressed whether the safe harbor of 35 U.S.C. § 271(e)(1) extended to use of inventions to obtain marketing approval of medical devices. In ruling that the exemption from infringement should be broadly construed, the Court noted the structure of the Act as a whole and the aim of the Act to "respond to two unintended distortions … produced by the requirement that certain products must receive premarket regulatory approval." 496 U.S. at 669. On the front end, a patent holder could not reap the benefit of its invention until receiving regulatory approval. *Id.* On the back end, the "combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term" because even after patent protection expired, potential competitors would be delayed until regulatory approval was obtained. *Id.* at 670. The statute "sought to eliminate this distortion from both ends of the patent period," *id.,* thus maintaining the careful balance between

encouraging development of such products and fostering access to less costly alternatives.

This Court concluded that Congress could not have intended the statute to be interpreted in a way that would allow to stand the very distortions the statute was designed to avoid:

> It seems most implausible to us that Congress, being demonstrably aware of … dual distorting effects of regulatory approval requirements … that were roughly offsetting … should choose to address both those distortions only for drug products; and for other products … should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection.

Id. at 672–73. Given the structure of the statute and the acknowledged goal of balancing these distortions, the Court held that "[i]t would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here." *Id.* at 673.

This case raises the same concerns about disrupting the carefully designed balance of the Hatch-Waxman Act. The Federal Circuit's interpretation effectively allows branded manufacturers to extend patent protection through incorrect Orange Book listings because section viii carve-outs become impossible. Viewing the structure of the Hatch-Waxman

Act and amendments as a whole, the idea that Congress intended such result is, as in *Eli Lilly*, "implausible."

D. Affirming the Federal Circuit's Decision Would Have Terrible Practical Effects

If allowed to stand, the decision below will have terrible consequences. In particular, it will allow brand-name drug manufacturers to abuse use codes with impunity, effectively blocking generic competition and providing unwarranted patent protection for drug uses that are not patented. The inevitable result will be restricted supply and higher prices for critical drugs.

With no FDA oversight and no judicial remedy, nothing will stop branded manufacturers from artificially extending the scope of their patent protection. As one commentator recognized even before the Federal Circuit's decision in this case, "[i]nstead of appropriately assigning the use code, pioneers may be motivated to assign an extremely broad use code to its method of use, thereby optimizing patent protection."[2] If the decision below is affirmed, they will be especially motivated—and unimpeded.

That is especially worrisome because, before this case, section viii certifications were quite common and becoming increasingly important. Many patents on the basic chemical composition of blockbuster

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[2] Julie Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 164 (2007).

drugs have expired or soon will. Foreseeing this, branded manufacturers have secured follow-on patents on particular methods of use in an effort to maintain "evergreen" patent protection.[3] Section viii certifications allow entrants to enter the market yet still respect incumbents' limited remaining patent rights. Moreover, section viii applications are especially useful and popular because, unlike paragraph IV certifications, they are not considered technical acts of infringement under 35 U.S.C. § 271(e)(2)(A) and thus do not automatically trigger the 30-month delay of FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii).

As a practical matter, an affirmance of the decision below would severely reduce if not eliminate the availability of section viii applications, and the resulting lengthy delays in generic entry would result in significant, tangible costs to consumers and taxpayers. On average, generic drugs cost 80 to 85% less than brand-name drugs.[4] Thus, where, as here, generic entry is artificially delayed, drug prices will remain artificially high.

Branded drug companies claim they need patent protection as a reward for undertaking research, but that excuse rings hollow where patent protection on the use at issue has expired. In such cases, the

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[3] *See*, *e.g.*, Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH L. & POL'Y 379 (2007) (describing patents procured by pharmaceutical companies to extend the length of patent protection on their products).

[4] *See* Somnath Pal, *Directions in Generic Drugs*, 35 U.S. PHARMACIST 8 (Jun. 17, 2010), *available at* http://www.uspharmacist.com/content/s/127/c/21064.

patentee has already received its just reward. Strategic gamesmanship that improperly broadens and extends patent coverage should not be tolerated.

CONCLUSION

The judgment of the Federal Circuit should be reversed.

Respectfully submitted,

Dan L. Bagatell
Counsel of Record
PERKINS COIE LLP
2901 N. Central Avenue
Suite 2000
Phoenix, Arizona 85012

Shannon M. Bloodworth
PERKINS COIE LLP
700 13th Street, N.W.
Washington, D.C. 20005

David J. Harth
Sarah C. Walkenhorst
PERKINS COIE LLP
1 East Main Street
Madison, Wisconsin 53703

Counsel for *Amicus Curiae*
Mylan Pharmaceuticals Inc.

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