2010-1001

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**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

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NOVO NORDISK A/S and NOVO NORDISK, INC,

*Plaintiffs-Appellants*,

v.

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

*Defendants-Appellees.*

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Appeal from the United States District Court for the Eastern District of Michigan
in case no. 05–CV–04158, Senior Judge Avern Cohn

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# BRIEF OF *AMICUS CURIAE* MYLAN PHARMACEUTICALS INC. IN SUPPORT OF DEFENDANTS-APPELLEES' COMBINED PETITION FOR PANEL REHEARING OR REHEARING EN BANC


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May 28, 2010

## CERTIFICATE OF INTEREST

Counsel for the *amicus curiae* listed below certifies the following:

The full name of every party or *amicus curiae* represented by me is:

Mylan Pharmaceuticals Inc.

The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

none

All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

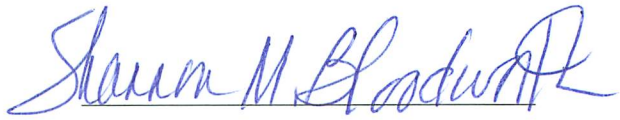
Mylan Inc.

The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this Court are:

PERKINS COIE LLP

Shannon M. Bloodworth

Dated: May 28, 2010



Shannon M. Bloodworth

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## STATEMENT OF INTEREST

Mylan is a generic drug manufacturer that frequently files Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic drugs for particular indications. In doing so, Mylan often relies on "section viii" statements that Mylan's proposed methods of use are not patented. FDA, however, will not grant approval if a proposed use falls within the description of a patented method of use listed in its Orange Book. The accuracy of Orange Book patent information is thus critical.

Regrettably, branded manufacturers often overstate the scope of their patents, and FDA does not police the accuracy of Orange Book information. In *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2002), this Court held that generics had no right to sue to correct Orange Book listings. In response, Congress expressly authorized ANDA applicants to file counterclaims to correct or delete erroneous patent information in the Orange Book. The decision here, however, reads that provision extremely narrowly, holding that correctable "patent information" is limited to patent numbers and expiration dates and that counterclaims are available only in extreme cases when *no* approved uses are patented.

The decision eviscerates the counterclaim provision and enables incumbents to block legitimate section viii applications. Mylan urges rehearing because the

result will be devastating for the generic industry and consumers alike.[1]

## ARGUMENT SUPPORTING PANEL REHEARING OR REHEARING EN BANC

### A. Congress Did Not Limit Counterclaims to Extreme Cases in Which None of the Approved Uses Are Patented

The 2003 amendments authorized ANDA applicants to assert counterclaims to correct or delete patent information "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 listed patent. The majority, however, reads it 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 purpose of the counterclaim provision was to provide a remedy when patent holders submit erroneous information to FDA about patent coverage of drugs or methods of using them. The goal was not simply to correct the Orange Book for the sake of correcting it, but to enable ANDA applicants to enter the market when the ANDA does not infringe. Under the majority's narrow reading, a

[1] Mylan is particularly disturbed because it (like Caraco) has sought FDA approval to sell repaglinide (alone) for use in treating type 2 diabetes. Indeed, Novo Nordisk recently sued Mylan in an effort to block Mylan's introduction of generic repaglinide. Although the district court has dismissed the complaint for lack of jurisdiction, *see Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-02445, 2010 WL 1372437 (D.N.J. Mar. 31, 2010), Novo Nordisk has vowed to sue again,

patentee may misidentify a patent as covering one approved use even though it actually covers a different approved use, yet competitors will have no way to correct the misinformation and file a section viii certification that the uses for which they seek approval are not patented. That is the kind of abuse that Congress abhorred, and the kind of loophole that it intended to close. *See* 149 Cong. Rec. 31121, 31200 (Nov. 24, 2003) ("The 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.").

The majority assumes that Congress merely intended to reverse the result on the particular facts of *Mylan v. Thompson*, but the statute was not tailored to just those facts. *Mylan v. Thompson* was indeed a gross example of the problems with existing law, but it was far from the only abuse shown to Congress. The year before, the Federal Trade Commission ("FTC") had issued a 129-page study describing a wide range of strategies that branded drug manufacturers had used to delay generic entry.[2] Nothing in the legislative history suggests that Congress was limiting itself to the particular facts of *Mylan v. Thompson* in authorizing counterclaims. The solution was general.[3]

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and Mylan may need to file a counterclaim under the statute at issue here.

[2] *See* FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf; *see also* 149 Cong. Rec. 15490, 15514 (Jun. 19, 2003) (Sen. McCain noting abuses).

[3] *See* Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-*

Ultimately, the statutory text belies the majority's conclusion that Congress intended to limit counterclaims to extreme cases in which a listed patent covers no approved uses whatsoever. In such cases, the remedy would be to delete the patent from the Orange Book entirely. But Congress went further and authorized counterclaims to "correct" as well as to "delete" erroneous patent information. 21 U.S.C. § 355(j)(5)(C)(ii)(I). By authorizing correction as well as deletion, Congress intended to cover situations where the listing is partly right and partly wrong.

### B. As FDA Determined, "Patent Information" Includes Information About Patent Scope, Not Just Serial Numbers and Expiration Dates

Congress adopted the counterclaim provision to ensure that generic drug makers have judicial recourse to correct or delete misinformation about patent coverage that branded drug makers have submitted to FDA. In holding that correctable "patent information" is limited to patent numbers and expiration dates and excludes the uses that patents purportedly cover, the majority defies the language of the statute and 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). The statute thus expressly contemplates that the patentee will describe the scope of the patents and relate them to the

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*Waxman Regime on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005) (describing the legislative history).

drug or method of use for which approval is sought. Indeed, the whole point of the resulting Orange Book listings is to notify later ANDA applicants which drugs or methods of use may be patented so that the ANDA applicants can submit appropriate certifications under § 355(j)(2)(A)(vii) and (viii). "Patent information" must be read in light of that purpose, not in a vacuum.

Furthermore, when Congress adopted the counterclaim provision in 2003, FDA had already adopted a regulation (the Patent Listing Rule) that broadly construed the scope of "patent information" required under Hatch-Waxman. Under 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. 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). Moreover, Congress was aware of 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., 1st Sess. 19 (2003) (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."). As Judge Dyk noted in dissent (at 14), such awareness indicates that Congress intended to adopt FDA's broad view of "patent information."

### C. The Panel's Decision Will Have Grave Practical Effects

Rehearing is also necessary because the panel decision will have terrible consequences. If left standing, it would allow brand-name drug manufacturers to abuse use codes with impunity, effectively blocking generic competition and extending patent protection for drug uses that are not patented. The inevitable result will be restricted supply and higher prices for critical drugs.

#### 1. The Decision Will Deter and Delay Legitimate Competition

Congress recognized the critical importance of generic competition both when originally adopting the Hatch-Waxman Act in 1984 and when amending it in 2003 to authorize counterclaims to delete or correct misinformation in the Orange Book. As noted above, even before Congress adopted the counterclaim provision, the FTC had issued a study describing various strategies that branded manufacturers were using to delay generic entry. This decision ratifies yet another strategem: submitting overbroad use descriptions that do not match the underlying patents yet effectively prevent FDA approval of section viii carve-out applications.

Under the panel's decision, a branded manufacturer may submit overly broad use descriptions covering both patented and unpatented methods of use, yet

generic competitors cannot counterclaim to correct those descriptions. Counterclaims are an indispensable remedy because FDA refuses to review the accuracy of Orange Book listings on grounds that it lacks patent expertise. *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 requested by the patentee).

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 this decision, "[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." 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). After the panel's decision, they will be especially motivated—and unimpeded.

For example, assume a branded manufacturer's patents on a compound and using it to treat disease 1 have expired, but a patent on using it to treat disease 2 remains in force. If the statute worked as Congress intended, a generic 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. The FDA will not review the accuracy of the Orange Book description, and this Court has now held that the courts are impotent too, even though Congress adopted the counterclaim provision to prevent such chicanery.

Technically, the generic competitor may still file a paragraph IV certification of noninfringement, but that is cold comfort—as a majority of the panel has recognized (Concurrence at 1, Dissent at 26). Even though the generic 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 would then claim that the generic has induced infringement by selling the drug with broad labeling that has no carve-out. In effect, by overstating the scope of its patent, the patentee aims to induce inducement and create an infringement claim out of whole cloth.

Mylan hopes the courts would find remedies for such abuse, perhaps finding that the generic lacked specific intent to induce infringement or, alternatively, that the patent is unenforceable for misuse. Those defenses, however, would be fraught with danger. In any event, 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 delay would not occur if the generic could carve out the unpatented use under section viii. Ironically, but inevitably, generic entry will be stalled in the very cases where Congress specifically sought to accelerate it.

### 2. Blocking Generic Entry Will Have Broad and Harmful Effects on the Public at Large

Section viii certifications are common and becoming increasingly important. Many patents on the basic chemical composition of blockbuster 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.[4] Section viii certifications allow entrants to enter the market yet still respect incumbents' limited remaining patent rights. Moreover, section viii applications are especially popular because, unlike paragraph IV certifications, they do not automatically infringe under 35 U.S.C. § 271(e)(2)(A) and thus do not trigger the 30-month delay in FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii).

As a practical matter, the panel's decision would severely reduce the availability of section viii applications, and the resulting lengthy delays in generic entry will result in significant, tangible harms to consumers. Generic competition typically lowers drug prices by 30 to 80%. Thus, where, as here, generic entry is

[4] *See, e.g.*, Yoshitani & Cooper, *Pharmaceutical Reformulation and 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).

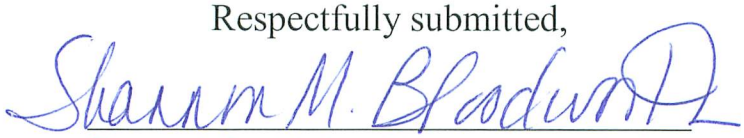
artificially delayed, drug prices will remain artificially high. Of course, branded drug companies contend that they need patent protection to reward them for undertaking the risk of expensive research. But even if that is true, the excuse rings hollow where the use at issue is no longer subject to patent protection. In such cases, the patentee already received its just reward. The Court should not countenance strategic gamesmanship that broadens and extends patent coverage.

## CONCLUSION

The issues here may seem obscure at first blush, but they are critical to proper operation of the Act. Congress overturned *Mylan v. Thompson* and authorized counterclaims because it recognized that its carefully balanced statutory scheme will not work if misinformation in the Orange Book cannot be corrected. The panel's decision not only renders the counterclaim provision largely useless, but allows drug patent holders to nullify section viii and block entry even when a generic seeks approval only for unpatented uses. The decision is bad law and worse public policy, and Mylan urges the Court to grant rehearing and correct it.

Waiting is not an option. Decisions in other areas can "percolate" through later cases, and the Court can then refine them. The decision here, however, rules out counterclaims in a vast heartland of cases. If the decision stands, those counterclaims simply will not be brought. Rehearing needs to be granted now because there will be no next case tomorrow.

Respectfully submitted,



Counsel for Mylan Pharmaceuticals Inc.

## CERTIFICATE OF COMPLIANCE

As principal counsel, I certify that the foregoing *amicus* brief complies with the limitations of Federal Circuit Rules 35(g) and 40(g).

May 28, 2010.

Shannon M. Bloodworth

## PROOF OF SERVICE

I, Rebecca Bentley, certify that I am employed by the law firm of Perkins Coie LLP, whose address is 607 14th Street, N.W., Washington, D.C. 20005.

On May 28, 2010, I caused an original and twelve copies of this brief to be delivered for filing to:

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On the same date, I caused two copies of this brief to be sent by FedEx to counsel of record for the parties at the following addresses:

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: May 28, 2010

Rebecca Bentley