2010-1001

In the United States Court of Appeals for the Federal Circuit

Novo Nordisk A/S and
Novo Nordisk Inc.,

Plaintiffs-Appellants,

V.

Caraco Pharmaceutical Laboratories, Ltd.,
and Sun Pharmaceutical Industries, Ltd.

Defendant-Appellee,

On Appeal from the United States District Court
for the Eastern District of Michigan
in Case No. 2:05-CV-40188, Judge Avern Cohn

Brief of Apotex, Inc. and Impax Laboratories, Inc. as *Amici Curiae* in Support of Caraco et al.'s Petition for Panel Re-Hearing or Re-Hearing En Banc

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May 28, 2010

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *Amicus Curiae* Apotex, Inc. certifies the following:

1. The full name of every party or amicus represented by us is:

   Apotex, Inc.

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

   None.

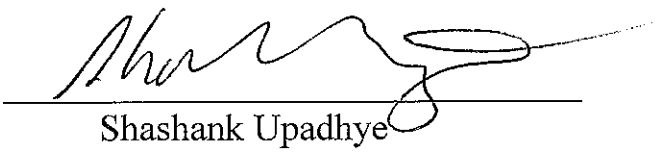
3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party represented by us are:

   None.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or expected to appear in this court are:

   Shashank Upadhye

Dated: May 27, 2010



Shashank Upadhye

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Novo Nordisk A/S and Novo Nordisk Inc. v. Caraco Pharm. Labs., Ltd., & Sun Pharm. Indus., Ltd.

No. 2:05-CV-40168

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Impax Laboratories, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Impax Laboratories, Inc.

2. 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.

3. 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:

None.

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

Michael A. Berta, Wilson Sonsini Goodrich & Rosati

5/27/2010
Date

Signature of counsel

MICHAEL A BERTA
Printed name of counsel

Please Note: All questions must be answered

cc:

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INTEREST OF *AMICI CURIAE*

Amici curiae Apotex, Inc. and Impax Laboratories, Inc. are generic drug companies that frequently file Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market their drugs. Engaged in dozens of patent lawsuits under the Hatch Waxman Act, 21 U.S.C. 355(j) et seq., *amici* file this brief because, without correction, the underlying panel decision will gut the Act's "section viii" approval process, which Congress designed as an *alternative* to litigation.[1]

INTRODUCTION

Apotex and Impax fully support the showing of Defendants-Appellees ("Caraco") that the panel majority's reading of the Hatch-Waxman Act's counterclaim provision is contrary to the Act's text, structure, legislative history, and purpose. *Amici* file this brief to stress other reasons for granting rehearing en banc.

Most importantly, *amici* will address the position of Judge Clevenger—who reasoned that the FDA "gummed up the works" in this case by "creat[ing] a situation where Caraco can no longer assert that its proposed labeling does not infringe the '358 patent," Op. at 2—and that of Judge Rader, who charged that "Caraco's real complaint should lie with the FDA, not with Novo. . . . It was the FDA, not Novo, that tipped the careful balance in the favor of pioneering manufacturers." Op. at 12. As shown below, Judges Clevenger and Rader were mistaken.

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[1] By email of May 26, 2010, counsel for Novo Nordisk consented to this amicus brief—as has Caraco. Thus, no motion for leave to file is required.

In fact, when the FDA had the opportunity, it *rejected* Novo's attempt to game the system. And Novo admitted at oral argument that the FDA did not require Novo to submit the patent description that enabled Novo to block generic approval. Novo changed its description *voluntarily*, immediately after FDA approved Caraco's request to carve-out non-infringing uses of Novo's drug. Thus, the FDA approved Caraco's carve-out. It was *Novo* that thwarted it.

As Judge Dyk noted, in "adopting Novo's disingenuous argument blam[ing] the FDA," the majority overlooks "the manipulative nature of Novo's actions." Dissent at 25. This manipulation—causing the FDA to reject approval of a drug that Novo concedes would have been marketed for only non-infringing uses—is unconscionable. And now that the path for gaming the Act is clear, it will be followed by brand after brand, depriving those who are ill of needed cost-effective drugs. The majority's reasoning effectively deprives the FDA of authority to require patent descriptions, rendering obsolete a long-established regulatory system. The divided panel's ruling presents a question of "exceptional importance," justifying en banc review. Fed. R. App. P. 35; Fed. Cir. R. 35(b).

STATEMENT

Hatch Waxman provides the framework for filing ANDAs and quickly litigating potential patent disputes. Hatch Waxman litigation follows a typical pattern: the ANDA is filed, the so-called Paragraph IV Notice Letter is sent to the

brand, which then has 45-days to sue for patent infringement. A timely filed suit invokes an automatic statutory 30-month stay that bars the FDA from approving the generic's ANDA. The stay provides time for the district court to vet the patent issues before the generic launches, but provides an end-date of that window. But for the 30-month stay (and for another reason not relevant here), the FDA would normally approve the ANDA and the generic company could launch its product.

To avoid patent infringement and to avoid unnecessary delays to generic drug approval via the 30-month stay, Congress enacted the so-called "section viii" provision to allows generic companies to "carve out" parts of a label; the carve-out provision allows a generic company to seek FDA approval for something less than what the brand company has FDA approval to do. The panel decision effectively gutted it because it places the onus on the FDA to take action that the FDA has repeatedly said it will not take because it lacks the necessary expertise and resources.

ARGUMENT

When a branded drug company has a patent on one of several approved uses of a drug, this does not prevent generic competition on the other unpatented, approved uses. In those circumstances, the Act permits generics to file a "section viii" statement indicating that it is not seeking approval to market the drug for any of the approved uses covered by the branded company's method-of-use patents.

See 21 U.S.C. 355(j)(2)(A)(viii).[2] The section viii process plays an important role in speeding the approval and marketing of a lower cost generic drug if there is no enforceable patent covering the drug compound.

For example, assume a brand company has an FDA approved psychiatric drug X to treat: (i) depression; (ii) social agrophobia; (iii) fear of heights; and (iv) controlling anger and rage and indication is patented via a method of using drug X to treat the condition but the original compound/molecule patent claiming the compound per se also contains the method of using the drug X for the treatment of depression. Assume the drug X compound patent expires soon. It is perfectly permissible and the plain statutory authority exists to do so, wherein the generic company files its ANDA seeking only approval for the depression indication, which will be unpatented soon. The generic company files Section viii statements to carve out indications (ii) to (iv) and to explicitly not seek approval for those other still-patented indications. This is the very intention of Section viii.[3]

Because FDA rules require brand companies to file the so-called Use Code descriptions, a proper Use Code states that, "Drug X for the use and treatment of

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[2] See Shashank Upadhye, Generic Pharmaceutical Patent and FDA Law, Section 10:6, 10:7 (Thomson West, 2010)(Westlaw database: GENPHARMA) ("Generic Pharmaceutical") for detailed example of how Section viii statements are used.

[3] *Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) ("A section viii statement indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent.").

depression, social agrophobia, fear of heights, and controlling anger/rage." But if the brand company files a Use Code description that states, "Drug X for the treatment of mental health", then under the panel's decision, the generic has no recourse except to file the so-called Paragraph IV certification and engage in costly litigation and use up scarce judicial resources to prove that the patent is invalid. Recourse to FDA is not available because the FDA and the courts stated *ad nauseum* that FDA's role in Orange Book maintenance is simply ministerial. It does not and will not police Orange Book listings. It lacks the requisite expertise and resources. The brand could thus include a Use Code for Drug X stating, "the use of Drug X for the treatment of any ailment or health issue" which would encompass every malady heretofore known. FDA subjectively would know that the Use Code is ridiculous but would be powerless to do anything. Nor according to the panel, could the affected generic company do anything to force the brand company to change the code back to something more appropriate.

I. THE MAJORITY ERRED IN BLAMING THE FDA FOR NOVO'S ORANGE BOOK TRICK.

Novo's exchanges with FDA. Before changing its use code, Novo asked the FDA to adopt the position that, "[a]s there will only be a single indication for PRANDIN, there is no additional indication or use that can be carved out by a section viii statement." But the FDA said no. Even though the FDA requested "a simplified indication" in the "'INDICATIONS AND USAGE section of the la-

bels," it explained, the "DOSAGE AND ADMINISTRATION section" would "carv[e] out the metformin information," which it noted "will not render the product less safe or effective." A637. In other words, the simplified indication would affect one portion of the repaglinide label; the carve-out would affect another.

It is therefore wrong to say, as did the majority, that the FDA "gummed up the works," "created" Caraco's problem, or "tipped the careful balance in the favor of pioneering manufacturers." Op. at 12. The FDA did no such thing. Instead, FDA *accepted* Caraco's carve-out, and *approved* its section viii statement. As the agency put it, "FDA has concluded when information regarding the combination use of repaglinide with metformin is carved out, generic repaglinide will remain safe and effective for the remaining, nonprotected conditions of use." It doesn't get any clearer than that. Judges Clevenger and Rader ignored this straightforward FDA decision and declared that FDA did the opposite.

Novo's admissions at oral argument. Judge Clevenger was also mistaken in asserting that the FDA "instructed Novo to '[s]ubmit the description of the approved indication *or* method of use that you propose FDA include as the 'Use Code' in the Orange Book," Concurrence at 2 (emphasis added)—as if the FDA somehow "instructed" Novo to switch from its accurate use code to the misleading one. Here again, the FDA did no such thing—which is why "Novo *admitted* that

FDA did not direct or request that Novo changes its use code, nor was this required under FDA regulations." Dissent at 24 (emphasis added).

Indeed, the rest of the form shows that, contrary to Judge Clevenger's suggestion, Novo *violated* the form by changing its use code. On the prior page, the form explains that the "information" to be provided is "*[f]or each approved method of use claimed by the patent.*" A919 (emphasis added); *see also* 21 C.F.R. § 314.53(c)(2)(ii)(P)(2) (requiring Novo to identify "the specific section of the approved labeling for the drug product *that corresponds to the method of use claimed by the patent submitted.*") (emphasis added). When Novo changed its use code, it violated this instruction because Novo's new code covers uses *not* claimed by the patent. Dissent at 24. The majority erred in blaming FDA for "gumm[ing] up the works." Concurrence at 2.

II. LEFT UNCORRECTED, THE MAJORITY OPINION WILL DELAY GENERIC DRUG APPROVALS.

Though the majority erred in blaming FDA, they correctly perceived that the result here tips the Hatch-Waxman balance in favor of brands—in situations where the generic concededly does not infringe. This is indeed an "extraordinary result" (Pet. 1), which, as Judges Clevenger and Dyk recognized, cannot adequately be addressed by paragraph IV litigation. *See* Concurrence at 1; Dissent at 26; *see also* Pet. at 13-15. To the contrary, the decision will open the floodgates to brand abuse of method patents and even threaten FDA's authority to implement the statute.

Brand abuse. Congress enacted the counterclaim provision precisely "to prevent manipulative practices by patent holders with respect to Orange Book listings," which "were designed to *delay* the onset of competition from generic drug manufacturers." Dissent at 1 (emphasis added). But now, under the majority's ruling, any time a brand holds a compound patent with multiple approved uses, it can block all generic competition so long as it has a patent covering a *single* approved use. The only question left by the majority's decision is, who will suffer next?

As noted by Judge Dyk, "[t]he manipulative nature of Novo's actions is confirmed not only by the lack of justification for the change, but also by the timing of the change (two years after the labeling change was initiated by the FDA and immediately after the FDA approved Caraco's section viii carve-out), and by its own admission that preventing approval of Caraco's ANDA was part of the motivation for changing the use code." Dissent. at 25. To this, we must add Novo's admission that "FDA did not direct or request that Novo change its use code, nor was this required under FDA regulations." Dissent at 24.[4]

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[4] Many drugs are also combined with other drugs to form combination drugs, eg., cough + sinus combination product. A patent expiring on the "cough" medicine ought to allow generic companies to make and sell a generic cough medicine. But if the brand company has a combination patent (to the cough + sinus combination) and submits a Use Code that states, "use of cough medicine to treat cold and flu symptoms" then in effect, the expiring cough medicine patent cannot be practiced because the generic company would be forced to include the full Use Code description, which could colorably include the use in combination with sinus medicine, and hence possibly infringing the combination patent. Thus, one cannot ever

It is no answer to say that FDA should not take use code descriptors at face value. Concurrence at 3. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) ("FDA . . . does not evaluate patent information"; it simply "publishes information it receives"). "[I]ssues of patent claim and infringement are matters of patent law, and FDA does not have the authority . . . to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug." Testimony of Lester M. Crawford, Dep. Comm'r of Food & Drugs, House Committee on Energy & Commerce, Oct. 9, 2002. After all, the Hatch-Waxman Act requires the FDA to "*publish*" patent information—not to evaluate it. 21 U.S.C. § 355(c)(2) (emphasis added). FDA simply does not possess the expertise to evaluate patents.[5] Nor does FDA have the resources to do so.

FDA deprived of authority to require use codes. The majority opinion may also extinguish FDA's authority to require use codes. "According to the majority, method of use information is not 'patent information.' The majority construes the term as limited to the patent number and expiration date: '[T]he Act defined the

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practice the so-called monotherapy using cough medicine alone even though the relevant patent is now expired.

[5] *Watson Pharmaceuticals, Inc. v. Henney*, 194 F.Supp.2d 442, 445-446 (D. Md. 2001) ("In this case, it is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise-much less any statutory franchise to determine matters of substantive patent law.").

term 'patent information' as 'the patent number and expiration date.'" Dissent at 5 (quoting Op. at 13). FDA's settled reading of the term (and congressional adoption too) require patent descriptions. But it also means the FDA has no authority to require use codes in the first place, which leaves FDA without its well-established tool to implement section viii. Congress could not have intended this result.

Finally the panel decision emphasized certain parts of the statute, but judicially eviscerated other parts of the same statute. The panel emphasized the portions relating to "patent" and "expiration":

> If *the patent information described in subsection (b)* of this section could not be filed with the submission of an application under subsection (b) of this section ..., the holder of an approved application shall file with the Secretary *the patent number* and *the expiration date* of any patent which claims the drug for which the application was submitted 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. [601 F.3d at 1361]

But the panel ignored the rest, rendering the following language superfluous:

> If *the patent information described in subsection (b)* of this section could not be filed with the submission of an application under subsection (b) of this section ..., the holder of an approved application shall file with the Secretary *the patent number* and *the expiration date* of any patent ~~which claims the drug for which the application was submitted 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.~~

CONCLUSION

The Court should grant the petition for rehearing for the above reasons.

Dated: May 28, 2010

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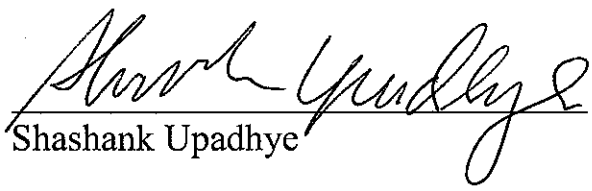

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