No. 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.,

Defendants-Appellees.

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 *AMICUS CURIAE* GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF DEFENDANTS-APPELLEES' PETITION FOR PANEL REHEARING OR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *Amicus Curiae* Generic Pharmaceutical Association certifies the following:

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

   Generic Pharmaceutical Association.

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 the party or *amicus* represented by us are:

   None.

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

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Dated: June 3, 2010

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INTRODUCTION

The Generic Pharmaceutical Association ("GPhA") supports *en banc* review in this case because it could have ramifications for Hatch-Waxman disputes in which the name-brand drug maker's patent "claims at least one, but not all, approved methods of using [the] drug" at issue. (Majority Op. at 11.) Left undisturbed, the panel's ruling could render largely useless a key provision of the Act – "section viii" – under which generic drug makers may obtain accelerated FDA approval to market generic drugs for uses that everyone agrees do not infringe any patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii). Moreover, the majority's ruling that the Act's reference to "patent information" is limited to "the patent number and the expiration date" (Majority Op. at 13) could effectively render much of FDA's "Submission of Patent Information" regulation invalid. *See* 21 C.F.R. § 314.53.

GPhA agrees with Defendants-Appellees ("Caraco") and the other *amici* that the divided panel's reading of Hatch-Waxman's counterclaim provision is contrary to the Act's text, structure, legislative history, and purpose—as well as *Chevron*. GPhA also agrees with Caraco and the other *amici* that the result here is attributable, not to the FDA's decisions, but to Plaintiffs-Appellants' ("Novo") "unjustified manipulation of the Orange Book." (Dissent at 27.) GPhA files this brief, however, principally to underscore the broad importance of this case to the

generic industry and the consumers that rely on that industry to supply safe and affordable generic medicines.

As GPhA can attest from its members' experience, section viii—and Hatch-Waxman's counterclaim provision, which permits correction of overbroad patent descriptions provided to the FDA by name-brand drug companies—is critically and increasingly important to generic competition. As their patents on the chemical compounds contained in their drugs near expiration, brand companies increasingly seek and obtain follow-on patents on particular *methods* of using those compounds—a process sometimes referred to as "evergreening." If the panel's ruling stands, Novo's manipulative actions will become a playbook for all brands. Whenever brands have just one unexpired method patent, they will attempt to bar competition for *all* uses of the compound at issue, including non-infringing uses, by submitting overbroad patent descriptions to the FDA.

STATEMENT OF INTEREST

A national trade association consisting of more than 140 companies involved in the supply, manufacture, marketing, and distribution of generic pharmaceuticals, GPhA advances its members' interests by advocating laws, regulations, and court decisions that encourage the marketing of safe, effective, and affordable prescription drugs. This benefits not only the association's members and the pharmaceutical industry as a whole, but also the consuming public. Generic

manufacturers invest millions of dollars in innovative research and development to bring to the public non-infringing bioequivalents of brand name drugs. And GPhA members manufacture more than 90% of all affordable prescriptions dispensed in the United States, accounting for nearly three billion prescriptions annually.

To further that mission, GPhA prepares and disseminates reliable information about the pharmaceutical industry; participates in legislative, regulatory, and administrative proceedings; and promotes the correct interpretation by the courts and the FDA of laws that directly affect the manufacture, distribution, sale, or marketing of generic drugs. GPhA has sought permission, and been granted leave, to file multiple briefs before this Court, and files the instant *amicus curiae* brief in accordance with the Court's Order dated June 1, 2010.

GPhA's broad interest in this case arises from the system created by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. Under those amendments, generic competitors seeking FDA approval to market generic versions of brand-name drugs must address patents owned or licensed by brand companies, usually triggering infringement actions. Congress created the Hatch-Waxman infringement suit provision to ensure that patent validity and infringement issues are resolved quickly. This early-resolution mechanism is essential for getting generic drugs into the hands of the American public quickly, consistent with the legitimate patent rights of brand-name drug companies.

RELEVANT BACKGROUND

Hatch-Waxman permits a company seeking approval of generic drugs to file an Abbreviated New Drug Application ("ANDA"), which relies on the safety and efficacy data submitted for the branded version of the drug. An ANDA must either contain a "certification" or a "section viii statement" to any patents that the brand company has submitted to FDA for listing in the Agency's "Orange Book." The timing of FDA's approval depends, *inter alia*, on whether the ANDA applicant submits a certification or a section viii statement, and if a patent certification, on the type of certification the generic drug company provides.

A section viii statement is appropriate when the ANDA application does not seek FDA approval to market the drug for any of the approved uses covered by the branded company's listed patent(s). While a branded drug company may have a patent on one of several approved uses of a drug, this does not prevent generic competition on the other unpatented, approved uses. The section viii process plays a vital – indeed critical – role in speeding the approval and marketing of lower-cost generic drugs for uses not covered (or no longer covered) by patent protection. Without question, the public not only deserves prompt access to such medications, but desperately needs such access as the cost of health care continues to skyrocket.

The dispute here involves Caraco's effort to obtain section viii approval of a generic version of a diabetes drug called repaglinide. Novo markets repaglinide

under the brand name Prandin, which has three approved uses, only one of which currently is patented. When Caraco sought approval through the section viii process to market a generic version of repaglinide for the two *non*-patented uses, Novo sought to delay generic competition by submitting to the FDA a new patent description (which the FDA calls a "use code") suggesting that its patent covered *all* approved uses. Novo's manipulation of the patent listing process triggered FDA's rejection of Caraco's section viii statement because FDA relies solely on patent descriptions provided by the brand company. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347-50 (Fed. Cir. 2003).

The district court granted Caraco's request for an injunction requiring Novo to correct its patent information. But a divided panel of this Court reversed, holding that: (1) Hatch-Waxman's counterclaim provision does not apply to overbroad patent descriptions; and (2) "patent information" includes only patent numbers and expiration dates, but not the patent descriptions (or "use codes").

ARGUMENT

The Court should grant the petition for rehearing *en banc*. First, because brands increasingly seek to obtain new method-of-use patents as their patents on the underlying compound expire, both section viii approvals and the counterclaim provision are of increasing importance. The panel decision, in fact, threatens to undermine the delicate balance that Congress struck between encouraging

innovation and expediting the introduction of affordable generic medicines in a way that fundamentally harms generic companies and patients. Second, in ruling that the term "patent information" is limited to "the patent number and the expiration date," the panel decision could be construed as effectively holding much of FDA's "Submission of Patent Information" regulation invalid under Hatch-Waxman. If so construed, the panel would have done so without so much as seeking the Agency's views on that question. For at least these independent reasons, 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).

I. THE MAJORITY'S DECISION COULD SIGNIFICANTLY DELAY GENERIC COMPETITION.

The problem that Novo's actions have created for Caraco is anything but isolated. As the panel noted, "[o]ften pharmaceutical formulations have multiple uses and applications." (Majority Op. at 4.) And as the experience of GPhA's members' confirms, as patents on the chemical *compounds* that compose drugs expire, name-brand drug companies increasingly apply for and obtain patents on new and different *uses* of their drug compounds to extend their monopolies.

Insofar as a brand's method patents satisfy the requirements of the Patent Act, brands may seek to enforce them within their proper scope. Brand companies may *not*, however, use such method patents to block generics from marketing the compound at issue for *unpatented* uses. Yet, this is precisely what the panel

majority's decision sanctions. Thus, if left to stand, Novo's manipulative actions will be followed by every other brand company in the hopes of impermissibly delaying generic competition.

But Congress created section viii as an *alternative* to "paragraph IV" litigation whenever the generic seeks to market its product only for non-infringing uses. Under the panel's ruling, however, generics could be *required* to litigate under paragraph IV, could be *required* to endure a 30-month stay, and could be *required* to expend years and millions of dollars proving patent invalidity, unenforceability, or non-infringement. All of this not only delays generic market entry, but could deter generic companies from trying to seek FDA approval for some drugs in the first place, thus severely harming consumers. And all of this results not from Hatch-Waxman as enacted by Congress, but as manipulated by brand companies like Novo, here, and apparently sanctioned by the panel decision. Indeed, as Judge Dyk explained in his 28-page dissent, the result authorized by the panel majority "cannot be what Congress intended." (Dissent at 17.) *En banc* review is therefore urgently needed.

II. THE MAJORITY COULD, IN EFFECT, BE VIEWED AS INVALIDATING MUCH OF FDA'S PATENT LISTING REGULATION WITHOUT INVITING, LET ALONE CONSIDERING, THE AGENCY'S VIEWS.

The majority ruling also warrants review because it could prevent FDA from enforcing its Hatch-Waxman implementing regulation, 21 C.F.R. § 314.53

(requiring use code and other information beyond patent numbers and expiration dates), if not effectively invalidating much of the regulation altogether. That regulation, FDA likely believes, is critical to the Agency's ability to administer Hatch-Waxman and to ensure the proper functioning of both section viii statements and paragraph IV certifications. *See, e.g.*, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) ("[W]e believe that it is necessary that an NDA holder submit more specific information on the approved methods of use protected by a submitted patent. Only with this information can we determine what submission is required of the ANDA and 505(b)(2) applicants referencing the approved drug."). The panel, however, gave cursory treatment to the question whether the reading of "patent information" advocated by Caraco was entitled to *Chevron* deference; it was dismissive of the notion that Congress adopted the Agency's longstanding interpretation of an undefined statutory term; and it ignored FDA's own explanation for its adoption of its rules. Thus, for this reason too, the Court should grant *en banc* review or, at a minimum, seek the Agency's views on the issue now.

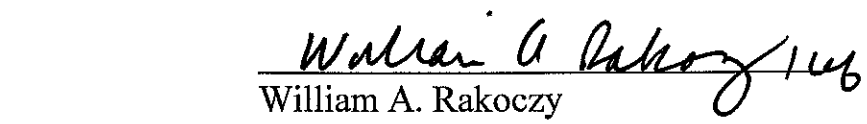
CONCLUSION

In summary, under the majority's ruling, brands that hold compound patents with multiple approved uses could potentially block all generic competition so long as there is at least *one* patent covering *one* approved use, thus rendering section viii largely useless. The decision threatens both wide-ranging abuse of method patents

and even FDA's authority to implement the statute. The Court should grant the petition for rehearing because Congress *already* "remed[ied] the situation." (Concurrence at 3.) At a minimum, this Court should seek the views of the FDA before allowing a ruling to stand that could be construed as invalidating the Agency's regulations under *Chevron*.

Dated: June 3, 2010

Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Lara E. FitzSimmons, hereby certify that on June 3, 2010, I caused an original and 18 copies of the foregoing *Brief of Amicus Curiae Generic Pharmaceutical Association in Support of Defendants-Appellees' Petition for Rehearing or Rehearing En Banc*, to filed with the Clerk of the Court for the Federal Circuit Court of Appeals via FedEx® overnight delivery as follows:

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